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## Title 46 PROFESSIONAL AND OCCUPATIONAL STANDARDS

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**Title 46**  
**PROFESSIONAL AND OCCUPATIONAL STANDARDS**  
**Part XCI. Wholesale Drug Distributors**

**Chapter 1. General Provisions**

**§101. Authority**

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

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

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

**§103. Definition**

A. As used in this regulation, unless the context otherwise requires:

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

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

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

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

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

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

ii. it is a color additive, the intended use of which is for the purpose of coloring only, and is unsafe within the meaning of federal or Louisiana law or rule; or

e. it purports to be or is represented as a drug or device the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in the compendium. Such a determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set

forth in the compendium, or in the absence of or inadequacy of these tests or methods of assay, those prescribed under the authority of federal or state law or rule. No drug or device defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefore set forth in the compendium, if its difference in strength, quality, or purity from the standard is plainly stated on its label;

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

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

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

ii. substituted wholly or in part thereof; or

h. it is a device, all consideration as noted in the federal Food, Drug, and Cosmetic Act.

*Agent or Representative*—a person authorized by another person called the principal to act for him or on his behalf in wholesale drug distribution and who may or may not take physical possession such that the drug or device is sold to the agent or representative and may be shipped to a third party.

*Applicant or Responsible Party*—an individual designated by the applying or licensed entity as the person responsible for facility operations and/or licensing for the applying or licensed facility location.

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

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

*Board*—the Louisiana Board of Wholesale Drug Distributors.

*Broker*—a person participating in the wholesale distribution of a drug or device that buys or sells the drug or device, but does not take physical possession such that it is sold to the broker and shipped to a third party.

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

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

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

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

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

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

*Distributor*—any person who is lawfully engaged in wholesale drug or device distribution.

*Drug or Device*—any legend drug or legend device intended for use by humans which can be dispensed by prescription or order of a licensed practitioner and whose labeling contains the legend "Caution: Federal law prohibits dispensing without a prescription." or "Caution: Federal law restricts this device to sale by or on the order of a (*licensed healthcare practitioner*)." or "Rx only."

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

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

*Freight Forwarder*—a person participating in the wholesale distribution of a drug or device that acts as the agent for the distribution of a drug or device, and does or does not take physical possession such that it is sold to the broker and shipped to a third party.

*Jobber*—a person who purchases drugs or devices, usually in bulk, to sell to another person in the wholesale drug distribution industry.

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

*Legend Drug*—

a. a drug limited by Section 503(b)(1) of the federal Food, Drug, and Cosmetic Act to being dispensed by or upon a licensed practitioner's prescription because the drug is:

- i. habit-forming;
- ii. toxic or having potential for harm;
- iii. limited in its use to use under a practitioner's supervision by the new drug application for the drug.

b. The product label of a legend drug is required to contain the statement "Rx Only" or "CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT A PRESCRIPTION".

c. a legend drug includes prescription drugs subject to the requirement of Section 503(b)(1) of the federal Food, Drug, and Cosmetic Act, which shall be exempt from Section 502(F)(1) if certain specified conditions are met.

*Licensed Practitioner or Appropriate Licensed Practitioner*—a person who is duly licensed, registered, or otherwise authorized by law to administer, prescribe, or dispense, as appropriate, a drug or device for medical purposes in the course of professional practice.

*Manufacture or Manufacturing*—the act of preparing a drug or device in dosage form, by mixing, propagating, compounding, processing, encapsulating, entableting, or other process, including packaging, repackaging, or labeling.

*Manufacturer*—a person engaged in manufacturing a drug or device and includes a labeler, primary distributor, or person who is engaged in preparing drugs or devices in dosage form, by mixing, propagating, compounding, conversion, processing, encapsulating, entableting, or other process, including packaging, repackaging, or labeling.

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

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

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

*Own Label Distributor*—a person that packages and/or manufactures and packages a drug or device that bears the name of the distributor along with the distributor's national drug code number and lot number.

*Person*—individual, partnership, corporation, limited liability company, trust, business firm, association, franchise arrangement, combination of any of these entities, or any other legal entity, including government.

*Pharmacy*—any pharmacy licensed by the appropriate regulatory board or agency of the state in which the pharmacy facility is located.

**Prescription Drug**—any drug required by federal or state law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to Section 503(b) of the Federal Food, Drug, and Cosmetic Act.

**Private Label Distributor**—a person that packages and/or manufactures and packages a drug or device that bears the name of the distributor along with the distributor's national drug code number and lot number.

**Repackage or Repackaging**—changing or altering the container, wrapper, or label of a drug or device to further its distribution.

**Repackager**—a person who repackages or engages in repackaging.

**Rx Only**—any human drug or device required by federal or state law or regulation to be dispensed by prescription only.

**Sale, Selling, or To Sell**—any transfer of ownership, or percentage thereof, of a drug or device whereby a risk of loss is assumed by the person acquiring the ownership including distribution, barter, exchange, or gift.

**Warehouse or Warehouseman**—a person engaged in the business of receiving, storing, and/or distributing a drug or device whether it is owned by this person or another person.

**Wholesale Drug or Device Distribution and Wholesale Distributions**—the distribution of drugs or devices to persons other than consumers or patients including distribution by manufacturers, repackagers, own label distributors, jobbers, and wholesale drug or device distributors, but does not include:

a. sale or transfer between any division, subsidiary, parent and/or affiliated or related company under common ownership and control, or a sale to a customer to cover a particular unforeseen need or from such a common ownership facility as certified by a licensed facility;

b. the purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization from the group purchasing organization or from other hospitals or health care entities that are members of such organization;

c. the sale, purchase or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in Section 501(c)(3) of the federal Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

d. the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control; for the purposes of this regulation *common control* means the power to direct or cause the direction of the management and policies of a person or an organization whether by ownership of stock, voting rights, by contract or otherwise;

e. the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical

reasons; for purposes of this regulation, *emergency medical reasons* include transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage that arises from delays in or interruptions of regular distribution schedules;

f. the sale, purchase, or trade of a drug; an offer to sell, purchase, or trade a drug; or the dispensing of a drug pursuant to a prescription;

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

h. the sale, purchase or trade of blood and blood components intended for transfusion.

**Wholesale Drug or Device Distributor**—any person engaged in wholesale distribution of drugs or devices, including but not limited to:

a. manufacturers;

b. repackers' own-label distributors;

c. private label distributors;

d. jobbers;

e. brokers;

f. warehouses;

g. including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses;

h. independent wholesale drug traders;

i. retail pharmacies that conduct wholesale distributions; and

j. freight forwarders.

**Wholesale Drug Trader**—a person in the wholesale drug distribution industry who sells or distributes a drug or device which is substantially in the same form it is purchased by a person other than a consumer or patient.

**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).

## Chapter 3. Wholesale Drug or Device Distributors

### §301. Licensing, Renewal and Reinstatement Requirements

A. Every wholesale drug or device distributor who engages in the wholesale distribution of drugs or devices, to include without limitation, manufacturing in this state, shipping in or into this state or selling or offering to sell in or into this state, shall register annually with the board by application for a license on a form furnished by the board and accompanied by the license fee.

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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.

B. A license shall be renewed annually by timely and properly submitting application and other pertinent information which may be requested as well as the payment of a renewal fee of \$200, to the board prior to December 31 each calendar year.

C. All licenses issued by the board and not otherwise timely and properly renewed, shall expire on December 31 for the calendar year issued.

D. Each application for the renewal of the license must be made on or before December 31 of each year.

1. If a license is not timely and properly renewed on or before the December 31 expiration date, a person may apply for reinstatement of the expired license within one year, or by the next December 31 after expiration of the license, upon timely and properly submitting an application to the board, and other pertinent information which may be requested, as well as payment of the renewal fee and the reinstatement fee.

2. During the period the license is expired until reinstatement of the expired license, the person may not lawfully operate as a wholesale drug or device distributor in Louisiana.

3. If a license is expired beyond one year, a person may apply for reinstatement of the expired license by submitting an application to the board, along with any pertinent information and documents which may be required, as well as payment of the application fee and the reinstatement fee.

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

F. Out-of-state wholesale 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 wholesale 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.

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 wholesale 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 wholesale 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 regulatory board or agency must be submitted to the board confirming such fact.

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 another facility for the warehousing and/or 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 regulatory board or agency confirming this fact and a current copy of the valid registration or license from the state in which the contracted facility is located must be submitted to the board.

G. Wholesale drug or device distributor applicants and licensees physically located and conducting operations in Louisiana shall provide a list of their wholesale drug or device distributors from whom they purchased and/or received a legend drug or device within the 12 months prior to application or renewal application; the list shall include, but not be limited to:

1. name of each wholesale drug or device distributor;
2. each wholesale drug or device distributor's business address and telephone number; and
3. each wholesale drug or device distributor's distribution address(es) from which the legend drug or device was shipped.

H. 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.

I. 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.

J. If a licensed in-state wholesale drug or device distributor has an additional off-site storage facility, the off-site storage facility may operate under the current wholesale drug or device distribution license held by the licensee as long as the off-site storage facility is in compliance with §309A.1 of these regulations 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.

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

**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).

### §303. Required Information

A. The board requires the following from each person applying for a license to be a wholesale drug or device distributor as part of the initial licensing procedure and as part of any renewal or reinstatement of such license:

1. the name, full business address, and telephone number of the person applying for a license, renewal or reinstatement;
2. all trade or business names used by the person applying for a license, renewal or reinstatement;
3. addresses, telephone numbers, and the names of contact persons for the facility or physical location used by the person applying for a license, renewal or reinstatement in wholesale drug or device distribution;
4. the type of ownership or form of business operation used by the person applying for a license, renewal or reinstatement (i.e., partnership, corporation, or sole proprietorship);
5. the name(s) addresses, and telephone numbers of the owners, partners, directors, officers, and/or managers, as applicable, of the person applying for a license, renewal, or reinstatement, including the name of the state where incorporated or otherwise authorized to conduct business;
6. a list of every state, territory, or district, other than Louisiana, where the facility applying for a license, renewal, or reinstatement holds a current license as a wholesale drug or device distributor;
7. any other information which the board may require to determine qualification for obtaining, renewing, or reinstating a license.

B. Where operations are conducted at more than one facility or physical location by a single wholesale drug or

device distributor, each such facility or physical location shall be licensed by the board.

C. Changes in any information required in this regulation 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.

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

E. Wholesale drug or device distributors with a place of business physically located in Louisiana must notify the board, in writing, within three business days of discovering, or being in a position to have acquired such knowledge of, any theft or diversion of drugs or devices.

F. Wholesale 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.

G. A wholesale drug or device distributor physically located in Louisiana shall report to the appropriate governing authority within 72 hours of discovering, or being in the position to have acquired such knowledge of, any suspected violation of applicable federal, state, or local laws in Louisiana and regulations with regards to wholesale drug or device distribution.

**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).

### §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 wholesale distribution of drugs and devices:

1. any convictions of the applicant under any federal, state, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;
2. any felony convictions of the applicant under federal, state, or local laws;
3. the applicant's past experience in the manufacture or distribution of prescription drugs or devices, including controlled substances;
4. the furnishing by the applicant of false or fraudulent information to the board;

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5. suspension or revocation by federal, state, or local government of any license currently or previously held by the applicant, including a license to distribute or manufacture any drug or device, including controlled substances;

6. compliance with the licensing requirements under any previously granted licenses;

7. compliance with the requirements to maintain and/or make available to the state licensing authorities or to federal, state, or local law enforcement officials those records required to be maintained by wholesale drug or device distributors;

8. any other factors that the board considers relevant to and consistent with its function to protect public health and safety;

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

B. An applicant must be at least 21 years of age and of good moral character and temperate habits.

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

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).

### §307. Personnel

A. Personnel employed in wholesale drug distribution shall have appropriate education and/or experience to assume responsibility for positions related to compliance with state licensing requirements.

B. A wholesale 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 wholesale drug 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).

### §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 wholesale drug or device distributors and their officers, agents, representatives, and employees.

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

a. be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

b. have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

c. have a designed and clearly identified quarantine area for storage of drugs or devices that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;

d. be maintained in a clean and orderly condition; and

e. be free from infestation by insects, rodents, birds, or vermin of any kind.

#### 2. Security

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

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

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

iii. Entry into areas where drugs or devices are held shall be limited to authorized personnel.

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

c. A wholesale drug or device 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 wholesale drug or device distributors that distributes medical gases only who stores the medical gas on an open dock shall be equipped with a monitored alarm system to detect entry after hours.

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

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

a. If no storage requirements are established for a drug or device, the drug or device may be held at room temperature, as defined in an official compendium, to help

ensure that its identity, strength, quality, and purity are not adversely affected.

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

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

#### 4. Examination of Materials

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

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

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

d. Brokers, freight forwarders, agents, or representatives of a principal that receives at their place of business licensed by the board shipments of drugs or devices that are to be forwarded to their clients may not open the shipment packages. These packages are to be unopened and free of tampering when forwarded by carrier to the client.

#### 5. Returned, Damaged, and Outdated Drugs or Devices

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

b. Any drugs or devices whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated in a clearly identified area from other drugs or devices until they are either destroyed or returned to the supplier.

c. If the conditions under which a drug or device has been returned cast doubt on the drug or device's safety, identity, strength, quality, or purity, then the drug or device shall be destroyed or returned to the supplier, unless examination, testing or other investigation proves that the drug or device meets appropriate standards for safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug or device has been

returned cast doubt on the drug or device's safety, identity, strength, quality, or purity, the wholesale drug or device distributor shall consider, among other things, the conditions under which the drug or device has been held, stored, or shipped before or during its return and the condition of the drug or device and its container, carton, or labeling, as a result of storage or shipping.

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

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

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

### §311. Drug or Device Distribution Recordkeeping

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

1. source of the drugs or devices, the name and principal address of the seller or transferor, and the address of the facility or physical location from which the drugs or devices were shipped;
2. the identity and quantity of the drugs or devices received and distributed or disposed of; and
3. the dates of receipt and distribution of the drugs or devices.

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

C. Records described in this regulation that are kept at the inspection site facility or licensed physical location or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site facility or licensed physical location and not electronically retrievable shall be made available for inspection within two working days of a request by any official authorized by the board.

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

E. Wholesale drug or device 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.

F. Wholesale drug or device distributors physically located and conducting operations in Louisiana shall verify prior to purchasing or receiving product that their suppliers of drugs or devices are licensed by the board to ship or sell in or into Louisiana; and are responsible for notifying the board of any unlicensed wholesalers.

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).

**§313. Policy and Procedures**

A. Wholesale 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. Wholesale drug or device distributors shall include in their written policies and procedures the following:

1. a procedure whereby the oldest approved stock of a drug or device is distributed first. The procedure may permit deviation from this requirement if such deviation is temporary and appropriate;

2. a procedure to be followed for handling recalls and withdrawals of drugs or devices. Such procedure shall be adequate to deal with recalls and withdrawals due to:

a. an action initiated at the request of the Food and Drug Administration or other federal, state, or local law enforcement or other government agency, including the board;

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

c. any action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design;

3. a procedure to ensure that wholesale drug or device distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency;

4. a procedure to ensure that any outdated drugs or devices shall be segregated from other drugs or devices and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated drugs or devices. This documentation shall be maintained for three years after disposition of the outdated drugs;

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

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

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

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

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

**§315. Responsible Persons**

A. Wholesale drug or device distributors shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale drug or device distribution, storage, and handling, including a description of their duties and a summary of their qualifications. The list shall be provided to the board at the time of annual renewal of license, and any change in the list during the interim shall be provided to the board, in writing, within 60 calendar days of such change.

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).

**§317. Federal, State and Local Law Compliance**

A. Wholesale drug distributors shall operate in compliance with applicable federal, state, and local laws and regulations.

1. Wholesale drug or device distributors shall permit the state licensing authority and authorized federal, state and local law enforcement officials upon having shown appropriate identification to enter and inspect their facility or physical location and delivery vehicles, and to audit their records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.

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

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).

**§319. Salvaging and Reprocessing**

A. Wholesale drug or device distributors shall be subject to the provisions of any applicable federal, state, or local laws or regulations that relate to drug or device product salvaging or reprocessing, including Chapter 21, Parts 207, 210d, 211 or the Code of Federal 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 18:384 (April 1992), amended LR 32:401 (March 2006).

**§321. Facility or Physical Location Inspections and Records Inspections**

A. The board may conduct inspections, and reinspections, upon all facilities and physical locations, including delivery vehicles, purporting or appearing to be used by a person licensed by the board, or applying for a renewal or a new license to the board. The board, in its discretion, may accept a satisfactory inspection by the United States Food and Drug Administration (USFDA) or a state agency which the board determines to be comparable to that made by USFDA or the board.

B. The board may waive the initial inspection if an applicant whose applying facility is not located within Louisiana presents to the board a satisfactory license or certificate of registration for wholesale drug or device distribution as issued by the appropriate regulatory board or agency of the state in which the applying facility is located.

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

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

**Chapter 5. Powers and Functions of the Board****§501. Injunctive Powers**

A. The board may, in its discretion, and in addition to various remedies provided by law and its regulations, petition a court having competent jurisdiction over the parties and subject matter for injunctive relief to enjoin violations of the Louisiana statutes for wholesale drug distributors and/or the board's regulations, or of any conduct which constitutes a clear and present danger to the public health and safety.

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

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

**§503. Board Domicile; Meetings**

A. The board shall be domiciled in Baton Rouge, Louisiana. The regular meetings of the board shall be held at least two times a year in accordance with applicable law and at any other time the board deems necessary, at a time and place designed by the chairman.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:385 (April 1992), amended LR 29:1481 (August 2003), LR 32:401 (March 2006).

**§505. Rules of Order**

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

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

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

**§507. Rule Promulgation**

A. The board shall have the authority to adopt, amend or repeal any rule necessary to implement and enforce the Louisiana statutes for wholesale drug distributors, in keeping with its function, in strict accordance with the Louisiana Administrative Procedure Act.

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

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

**§509. Inspection Contracts**

A. The board may contract with any person or agency it deems qualified to conduct any inspections or reinspections required by state or federal law.

B. The board shall retain exclusive jurisdiction to adjudicate all complaints, allegations of misconduct, or noncompliance by any licensee or applicant for license, renewal, or reinstatement of a license and to impose appropriate sanctions.

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

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

**Chapter 7. Disciplinary Procedures****§701. Complaint Initiations**

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

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

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

**§703. Complaint Investigations**

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

## PROFESSIONAL AND OCCUPATIONAL STANDARDS

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

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

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

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

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

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

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

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

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

### **§705. Complaint Withdrawals**

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

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

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

### **§707. Hearings**

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

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

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

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

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

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

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

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

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

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

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

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

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

J. Judicial Review of Decision. A person who is aggrieved by a final decision or order of the board is entitled to Judicial Review in accordance with the Louisiana

Administrative Procedure Act. Proceedings for Judicial Review may be instituted in the district court of the parish in which the board is located within 30 days after receipt of the notice of the final decision by the board or if a rehearing or reconsideration occurs within 30 days after the decision thereon.

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

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

### **§709. Emergency Action**

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

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

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

### **§711. Sanctions**

A. After notice and hearing, the board may deny, revoke or suspend a license or otherwise sanction a licensee, for any of the following:

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

B. In addition to the above sanctions, the board may impose a monetary penalty not to exceed \$1,000 per violation. The maximum aggregate monetary penalty shall not exceed 50 times the maximum penalty per individual violation.

C. Each instance where a federal, state, or local law or regulation is violated shall constitute a separate violation.

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

the imposition of a monetary penalty preclude the board from imposing other sanctions.

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

**HISTORICAL NOTE:** Promulgated by the Department of Health and Hospitals, Board of Wholesale Drug Distributors, LR 18:384 (April 1992), amended LR 32:403 (March 2006).

### **§713. Declaratory Statements**

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

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

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

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

## **Chapter 8. Fees**

### **§801. Fees**

A. The board may collect the following fees.

1. Application—\$200
2. Renewal—\$200
3. Reinstatement—\$200

B. An annual renewal fee and renewal application shall be received at the board office with a postmarked date on or before December 31 each calendar year.

C. All licenses, not properly and timely renewed, shall be expired becoming void on midnight December 31.

D. Any license not properly and timely renewed shall be allowed to be reinstated within one year of expiration provided the former licensee submits a renewal application and payment of all applicable fees including the renewal fee and reinstatement fee.

**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).