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LOUISIANA LICENSING LAW FOR WHOLESALE DRUG DISTRIBUTORS

Louisiana Revised Statutes

TITLE 37

CHAPTER 54. WHOLESALE DRUG DISTRIBUTORS

§3461. General provisions and short title

A. This Chapter shall be known and may be cited as the "Louisiana Wholesale Drug Distributors Act".

B. In order to safeguard life and health and to promote the public welfare, any person engaged in the wholesale distribution or sale of legend drugs or legend devices as defined in this Chapter shall be required to submit evidence of qualification to be engaged in the wholesale drug distribution business and shall be licensed as hereinafter provided.

Acts 1988, No. 852, §1; Acts 1995, No. 1152, §1, eff. June 29, 1995; Acts 2008, No. 597, §1.

§3462. Definitions

As used in this Chapter:

(1) "Applicant" means a person who applies for licensure as a wholesale drug distributor.

(2) "Board" means the Louisiana Board of Wholesale Drug Distributors.

(3) "Bureau" means the Louisiana Bureau of Criminal Identification and Information of the office of state police within the Department of Public Safety and Corrections.

(4) "Criminal history record information" means information collected by state and federal criminal justice agencies on persons consisting of identifiable descriptions and notations of arrests, detentions, indictments, bills of information, or any formal criminal charges, and any disposition arising therefrom, including sentencing, criminal correctional supervision, and release, but does not include intelligence for investigatory purposes, nor does it include any identification information which does not indicate involvement of the person in the criminal justice system.

(5) "FBI" means the Federal Bureau of Investigation of the United States Department of Justice.

(6) "Legend device" means any device intended for use by humans that carries on its label "Rx", "Rx only", a designation for physician use only, or a statement that federal law restricts the device to sale by or on the order of a licensed health care practitioner.

(7) "Legend drug" means any drug intended for use by humans that carries on its label any of the following: "Caution: Federal law prohibits dispensing without a prescription", "Rx", or "Rx Only".

(8) "Legend drug pedigree" means a written document or electronic file recording each wholesale distribution of a legend drug.

(9) "Licensure" means any license that the board is authorized by law to issue.

(10) "Manufacturer" means any of the following:

(a) A person who manufactures legend drugs and includes a labeler or primary distributor.

(b) A person who prepares legend drugs in dosage form by mixing, compounding, encapsulating, entableting, or by other processes.

(c) A person who manufactures, assembles, processes, or modifies legend devices.

(11) "Owner" means a natural person who owns greater than a ten percent interest in the wholesale drug distributor.

(12) "Person" means a natural or juridical person, including a proprietorship, partnership, corporation, limited liability company, trust, business firm, association, franchise arrangement, combination of any of these entities, or any other legal entity.

(13) "Responsible party" means a natural person designated by the applicant or licensee as responsible for facility operations of the applicant or licensee.

(14) "Third-party logistics provider" means a person that contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of the manufacturer, but does not take title to the legend drug or legend device or have responsibility to direct the sale or disposition of the legend drug or legend device.

(15) "Wholesale drug distribution" means the distribution or sale of legend drugs or legend devices to other than the consumer or patient, including but not limited to distribution by manufacturers, repackagers, own label distributors, jobbers, third-party logistics providers, retail pharmacy warehouses, pharmacies, brokers, agents, and wholesale drug distributors.

(16) "Wholesale drug distributor" means any person who sells or distributes legend drugs or legend devices to other than the consumer or patient, including but not limited to manufacturers, repackagers, own label distributors, jobbers, third-party logistics providers, retail pharmacy warehouses, brokers, agents, and pharmacies.

Acts 1988, No. 852, §1; Acts 2008, No. 597, §1.

§3463. Board; appointments; terms; removal; compensation; officers

A. The Louisiana Board of Wholesale Drug Distributors is hereby created within the Department of Health and Hospitals and is subject to the provisions of R.S. 36:803.

The board shall administer the provisions of this Chapter. It shall be composed of seven members, five of whom shall be licensed wholesale drug distributors and two of whom shall be actively engaged in the pharmaceutical manufacturing industry.

B. The governor shall appoint, subject to Senate confirmation, members to the board from a list containing the names of five persons, submitted by the Louisiana Association of Wholesale Drug Distributors and from a list containing the names of two persons, submitted by the Pharmaceutical Research and Manufacturers of America. In the event of the death or resignation of any member of the board, the governor shall appoint his successor in the manner of the original appointment for the remainder of the unexpired term.

C. Each member appointed to the board shall serve a term of five years.

D. Each member shall serve until his successor has been appointed and qualified.

E. The presidents of the Pharmaceutical Research and Manufacturers of America and the Louisiana Association of Wholesale Drug Distributors shall submit the nominations within sixty days after receipt of notice of death, resignation, or removal of a member of the board and at least thirty days prior to the expiration of the term of a member of the board.

F.(1) Any member of the board may be removed by the governor, or a majority vote of the board, after notice and a hearing by the board wherein grounds for removal have been established. Grounds for removal shall include but not be limited to incompetence, neglect of duty, unprofessional or dishonorable conduct, or a violation of this Chapter.

(2) A board member's seat shall be considered vacant after two consecutive absences by that member from official board meetings without a reason acceptable by the board.

G. Each member of the board shall receive seventy-five dollars a day and reimbursement for actual expenses and mileage at the same rate set by the division of administration for state employees under the provisions of R.S. 39:231 for each day while engaged in the discharge of their duties.

H. The board shall elect a chairman, vice chairman, secretary-treasurer, and such other officers as it considers necessary to carry out the duties or functions of the board.

Acts 1988, No. 852, §1; Acts 1995, No. 1152, §1, eff. June 29, 1995; Acts 2008, No. 597, §1.

§3464. Qualifications of board members

Each member of the board shall be at least twenty-one years of age, of good moral character and temperate habits, and a resident of this state and shall have engaged in the pharmaceutical manufacturing business or the wholesale drug distribution business for at least three years.

Acts 1988, No. 852, §1; Acts 1995, No. 1152, §1, eff. June 29, 1995.

§3465. Organization meetings

The board shall hold at least two regular meetings each year. Special meetings may be held at such time and place as specified by a call of the chairman or secretary.

Reasonable notice of all meetings shall be given in writing to each member of the board. A quorum of the board shall be a majority of its members.

Acts 1988, No. 852, §1; Acts 1995, No. 1152, §1, eff. June 29, 1995.

§3466. Domicile of the board

The domicile of the board shall be East Baton Rouge Parish, Louisiana.

Acts 1988, No. 852, §1.

§3467. Duties and powers of the board

A. The board shall:

(1) Approve, deny, revoke, or suspend licenses of qualified applicants for licensure as wholesale drug distributors and renew licenses.

(2) Regulate the distribution of legend drugs or legend devices by wholesale drug distributors.

(3) Monitor compliance with all federal and state laws and regulations regarding the distribution of wholesale legend drugs or legend devices by wholesale drug distributors and promulgate rules and regulations relative thereto.

(4) Conduct inspections of wholesale drug facilities.

(5) Conduct hearings on charges relative to the violation of any provision of this Chapter.

(6) Exercise all other powers necessary and proper to perform its duties within the scope of this Chapter.

B. The board may:

(1) Issue subpoenas and administer oaths to persons giving testimony at hearings.

(2) Employ and fix compensation of persons necessary to carry on the work of the board.

(3) Appoint an attorney to represent the board in all matters pertaining to the administration of this Chapter, define his duties, and fix his compensation.

(4) Adopt all rules and regulations necessary to implement the provisions of this Chapter.

(5) Require licensees to provide a legend drug pedigree.

C. The board shall make rules and regulations, not inconsistent with law, and shall take such other action as may be necessary to comply with the requirements set forth in the Federal Food, Drug, and Cosmetic Act, as it pertains to wholesale drug distribution, and with the rules and regulations promulgated pursuant thereto, and other pertinent federal authority.

Acts 1988, No. 852, §1; Acts 1991, No. 528, §1; Acts 1995, No. 1152, §1, eff. June 29, 1995; Acts 2008, No. 597, §1.

§3468. Records, prima facie evidence

The books, registers, and records of the board shall be prima facie evidence of the matter therein recorded in any court of law. The board shall keep a full record of all acts and proceedings of the board.

Acts 1988, No. 852, §1.

§3469. Qualifications and requirements for licensure

A. Every applicant for licensure as a wholesale drug distributor shall submit to the board the names of the designated responsible party and any owners who shall be at least twenty-one years of age and of good moral character and temperate habits.

Conviction of a felony violation of federal or state law by the applicant, responsible party, or owner may be grounds for denial of a license.

B. The application for licensure shall be made on a form provided by the board. Each application shall be accompanied with the reasonable licensure fee prescribed by the board. Each application form shall contain language that authorizes the board to obtain a criminal history record on the applicant, responsible party, and any owners to determine if the applicant, responsible party, or owners have ever been convicted of a felony violation of federal or state law.

Acts 1988, No. 852, §1; Acts 1992, No. 802, §1; Acts 1995, No. 1152, §1, eff. June 29, 1995; Acts 2008, No. 597, §1.

§3470. Inspections

The board, or a representative of the board, may conduct inspections of facilities during normal business hours upon receipt of an application for licensure. The board may conduct inspections during normal business hours of facilities that appear to be used by a wholesale drug distributor. The board may also conduct unannounced inspections of current licensees at sufficient intervals to determine compliance with state and federal requirements or when it considers it necessary. Upon inspection, a written report shall be submitted to the board by the inspector. Applicants for licensure and licensees shall be notified in writing by certified mail if any discrepancies are found, and a deadline shall be set in which such discrepancies must be corrected.

Acts 1988, No. 852, §1; Acts 1995, No. 1152, §1, eff. June 29, 1995; Acts 2008, No. 597, §1.

§3471. License; registering; evidence

A. Each applicant who meets the provisions of R.S. 37:3469 and successfully passes the inspection provided in R.S. 37:3470 shall receive a license from the board authorizing him to act as a wholesale drug distributor in this state. The license or a renewal thereof shall be the only evidence of the right of a person to act as a wholesale drug distributor.

B. The license shall be registered in a record book to be kept by the board for that purpose. A copy of the license certified by the secretary of the board shall be received as evidence in all courts of this state.

Acts 1988, No. 852, §1; Acts 1995, No. 1152, §1, eff. June 29, 1995.

§3472. Reinspection

Reinspections of facilities may be conducted as follow-ups to the regular inspections or to guarantee that the applicant or licensee has corrected any discrepancy found by the board. Failure to comply with state and federal laws or the board's regulations shall be prima facie evidence of a violation of this Chapter and shall subject the applicant or licensee either to disciplinary action by the board or forfeiture of the license.

Acts 1988, No. 852, §1; Acts 1995, No. 1152, §1, eff. June 29, 1995; Acts 2008, No. 597, §1.

§3473. Applicants from other states; waiver of inspection

The board may waive the inspection provided in R.S. 37:3470, if the applicant presents to the board a satisfactory certificate of registration or license from an entity which licenses wholesale drug distributors in another state, and if the standards adopted and enforced by such entity are comparable to those provided in this Chapter.

Acts 1988, No. 852, §1; Acts 1995, No. 1152, §1, eff. June 29, 1995; Acts 2008, No. 597, §1.

§3474. Manufacturer distribution of legend drugs and legend devices

A. For the purposes of this Section, the following terms shall have the following meanings:

(1) "Co-licensed partner" means a person in a relationship in which two or more persons have the right to engage in the manufacturing or marketing of a legend drug or legend device.

(2) "Pre-market notification 510(k)" or "510(k)" means the process by which a legend device manufacturer seeks regulatory clearance for any new or substantially changed device prior to marketing.

B. Legend drug manufacturers and co-licensed partners of legend drug manufacturers who meet the following criteria shall satisfy the requirements of R.S. 37:3469(A), 3470, and 3473:

(1) Have an approved new drug application from the United States Food and Drug Administration (FDA).

(2) Have an establishment registration issued by the FDA pursuant to 21 CFR Part 207 and meet the requirements of 21 CFR Part 205.

(3) Distribute only FDA-approved legend drugs for which the legend drug manufacturer holds an approved new drug application or use a contracted third-party logistics provider to distribute only FDA-approved legend drugs for which the legend drug manufacturer holds an approved new drug application.

C. Legend device manufacturers and co-licensed partners of legend device manufacturers who meet the following criteria shall satisfy the requirements of R.S. 37:3469(A), 3470, and 3473:

(1) Have a 510(k) approved by the FDA.

(2) Have an establishment registration issued by the FDA pursuant to 21 CFR Part 807 and meet the requirements of 21 CFR Part 801.

(3) Distribute only FDA-approved 510(k) legend devices for which the legend device manufacturer holds an approved 510(k) or use a contracted third-party logistics provider to distribute only FDA-approved 510(k) legend devices for which the legend device manufacturer holds an approved 510(k).

Acts 2008, No. 597, §1.

§3474.1. Denial, revocation, or suspension of license

A. Any person licensed as a wholesale drug distributor under this Chapter may have his license revoked or suspended for a fixed period to be determined by the board for any of the following causes:

(1) Conviction of a felony of the licensee, responsible party, or owner. The record of such conviction, or certified copy thereof from the clerk of court where such conviction occurred or by the judge of such court, shall be sufficient evidence to warrant revocation or suspension.

(2) Suspension, revocation, or other disciplinary action taken by any state or federal agency of a license to distribute wholesale legend drugs or legend devices. A certified copy of the record of suspension or revocation by the state where such suspension or revocation occurred shall be conclusive evidence thereof.

(3) Making any fraudulent or untrue statement to the board.

(4) Refusing to respond or otherwise comply with any request from the board.

(5) Refusing to permit entry to the licensed facility to comply with any inspection during normal business hours.

(6) Selling, distributing, or offering to sell or distribute any adulterated, counterfeited, or misbranded legend drug or legend device.

(7) Altering, mutilating, destroying, obliterating, or removing any part of the label of a legend drug or legend device.

(8) Violating any of the provisions of this Chapter or rules and regulations adopted by the board.

B. Proceedings for any disciplinary actions or for the denial, revocation, or suspension of a license shall be conducted in accordance with rules and regulations adopted by the board pursuant to the Administrative Procedure Act.

C. The board may require a person who is subject to the authority of the board and against whom disciplinary action has been taken to pay a fine of not more than one thousand dollars per violation.

D. Each day on which a violation occurs shall constitute a separate violation.

E. In addition to the fine, the board may assess all costs incurred in connection with the proceedings to a person who is subject to the authority of the board, including but not limited to investigator, stenographer, and attorney fees.

F. No license shall be issued, reinstated, or renewed until the monetary penalties pursuant to this Section have been paid in full.

Acts 1991, No. 528, §1; Acts 1995, No. 1152, §1, eff. June 29, 1995; Acts 2008, No. 597, §1.

§3474.2. Enforcement action against other persons; penalties

A. The board shall have the authority to take enforcement action against any non-licensee found by the board to be guilty of any of the following acts or offenses:

(1) Participating or engaging in wholesale drug distribution.

(2) Using the term "wholesale drug distributor" or otherwise assuming or using such term or advertising in any manner intended to convey the impression that he is a licensed wholesale drug distributor.

(3) Violating any of the provisions of this Chapter or any rules or regulations adopted by the board.

B. For the purposes of this Section, the term "enforcement action" shall include but not be limited to the assessment of a fine in an amount not to exceed one thousand

dollars per violation. Each day on which a violation occurs shall constitute a separate violation.

C. In addition to any other action, the board may assess to a person all reasonable costs incurred in connection with an enforcement action, including investigator, stenographer, and attorney fees.

D. Proceedings for an enforcement action shall be conducted through the promulgation of rules and regulations in accordance with the Administrative Procedure Act.

Acts 2008, No. 597, §1.

§3474.3. Injunction proceedings; penalties

A. The board may seek in any court of competent jurisdiction a writ of injunction enjoining any person from participating in wholesale drug distribution until such person obtains the necessary license under the provisions of this Chapter. This injunction shall not be subject to being released upon bond.

B. In the suit for an injunction, the board may demand of the defendant a penalty of not more than five thousand dollars, reasonable attorney fees, and court costs. This judgment for penalty, attorney fees, and court costs may be rendered in the same judgment in which the injunction is made absolute.

C. The trial of the proceeding by injunction shall be summary and by the judge, without a jury.

D. This Section shall not be construed as barring criminal prosecution for violations of this Chapter.

Acts 2008, No. 597, §1.

§3474.4. Order to quarantine a legend drug or legend device

A. If the board finds a reasonable probability that a wholesale drug distributor possesses an adulterated, misbranded, counterfeited, or recalled legend drug or legend device, the board may issue an order to quarantine the legend drug or legend device.

B. Any order issued pursuant to this Section shall subject the wholesale drug distributor to the order with an opportunity for hearing to be held no later than thirty days after issuance of the order on the actions required by the order. If, after the hearing, the board determines that inadequate grounds exist to support the order, the board shall vacate the order.

Acts 2008, No. 597, §1.

§3475. Annual renewal of license

All licensed wholesale drug distributors shall pay to the board a renewal fee as shall be determined by the board.

Acts 1988, No. 852, §1; Acts 1995, No. 1152, §1, eff. June 29, 1995.

§3476. Failure to renew license; penalties

The failure to pay the renewal fee required by R.S. 37:3475 shall result in an automatic revocation of the license. In such cases, the person shall be reinstated if he files an application for reinstatement with the board within one year after the revocation and pays a reinstatement fee and all delinquent charges as provided by the board.

Acts 1988, No. 852, §1; Acts 1995, No. 1152, §1, eff. June 29, 1995.

§3477. Authorization to obtain criminal history record information

A. The board may require that the applicant, responsible party, and any owners provide written consent to the board to request and obtain state and national criminal history record information as a condition for consideration of the licensure application.

B. The board may charge and collect from the applicant, in addition to all other applicable fees and costs, such amount as may be incurred by the board in requesting and obtaining state and national criminal history record information.

C. The board shall provide each applicant with a copy of the written standards specifying the requirements that shall be met by an applicant and the grounds on which a license may be denied or revoked.

D. Pursuant to this Section, or any other law or board rules or regulations promulgated and adopted by the board, the board may request and obtain state and national criminal history record information from the bureau and the FBI relative to any applicant, responsible party, or owner whose fingerprints the board has obtained for the purpose of determining an applicant's suitability and eligibility for licensure.

E. Upon request by the board and upon the board's submission of fingerprints and other identifying information as may be required, the bureau shall conduct a search of its criminal history record information relative to the applicant, responsible party, or owner and report the results of its search to the board within sixty days from receipt of any such request. The bureau may charge the board a processing fee pursuant to R.S. 15:587 for conducting and reporting on any such search.

F. If the criminal history record information reported by the bureau to the board does not provide grounds for disqualification of the applicant for licensure, the board shall have the authority to forward the fingerprints and other identifying information as may be required to the FBI with a request for a search of national criminal history record information.

G. Any and all state or national criminal history record information obtained by the board from the bureau or FBI which is not already a matter of public record shall be deemed nonpublic and confidential information restricted to the exclusive use of the board, its members, officers, investigators, agents, and attorneys in evaluating the applicant's eligibility or disqualification for licensure. No such information or records related thereto shall, except with the written consent of the individual or by order of a court of competent jurisdiction, be released or otherwise disclosed by the board to any other person or agency.

Acts 2008, No. 597, §1.

§3478. Unlawful participation; penalty

A. No person shall participate or engage in the wholesale drug distribution business without a license issued therefor and compliance with other requirements as provided for in this Chapter.

B. No person shall use in connection with his name the term "wholesale drug distributor", or otherwise assume or use such term or advertise in any manner intending to convey the impression that he is a wholesale drug distributor, unless such person has been duly licensed under the provisions of this Chapter.

C. Whoever violates the provisions of this Section shall be fined not less than one thousand dollars nor more than fifty thousand dollars or imprisoned for not less than ten days nor more than thirty days, or both.

Acts 1988, No. 852, §1; Acts 1995, No. 1152, §1, eff. June 29, 1995; Acts 2008, No. 597, §1.

§3479. Fees

A. To defray the cost of administering the provisions of this Chapter, the board shall fix fees not to exceed the following:

- | | |
|---|-------|
| (1) Initial license fee | \$600 |
| (2) License renewal fee | \$600 |
| (3) Initial inspection fee | \$300 |
| (4) Duplicate license fee | \$100 |
| (5) Reinstatement fee for licenses suspended, revoked, or expired | \$600 |
| (6) License verification fee | \$100 |

B. Any fees fixed by the board shall be subject to legislative oversight review pursuant to the provisions of the Administrative Procedure Act, R.S. 49:950 et seq.

C. All monies collected under this Chapter shall be paid into the treasury of the board and may be expended by the board without appropriation for costs of administration, including salary of employees, travel allowances, and other necessary expenses. Any funds remaining unexpended and unencumbered at the end of each fiscal year shall be retained by the board for expenditure in succeeding years and no part thereof shall revert to the General Fund of the state of Louisiana.

D. This board shall be financially self-sufficient. It shall receive no state funds through appropriation or otherwise and shall not expend any such state funds. No state funds shall be expended or committed to expenditure for the group benefits program or any other health insurance or employee benefit program, for any retirement system, for any salary, per diem payment, travel or expenses, office supplies and materials, rent, purchase of any product or service, or for any other purpose.

Acts 1988, No. 852, §1; Acts 2008, No. 597, §1.

§3480. Unauthorized sales

Wholesale drug distributors shall sell or distribute legend drugs or legend devices only to a person who is authorized, by law or regulation, to procure or possess legend drugs or legend devices.

Acts 1988, No. 852, §1; Acts 2008, No. 597, §1.

§3481. Mandatory reporting

Wholesale drug distributors shall provide copies of the United States Enforcement Accounting Records Controlled Order Substance Reports (ARCOS) of the preceding month to the Louisiana Board of Pharmacy by the fifteenth day of each month, and copies of their controlled substance sales register for a specific controlled substance registrant in Louisiana and excessive controlled substance purchase reports for all controlled substance registrants in Louisiana required by 21 CFR 1301.74(b) as requested by the Louisiana Board of Pharmacy. Notwithstanding any other law to the contrary, these reports shall be confidential and shall be destroyed when they have served their purpose.

Acts 1988, No. 852, §1; Acts 1995, No. 1152, §1, eff. June 29, 1995.

§3482. Applicability; conflicts

Nothing in this Chapter shall be construed to authorize the Louisiana Board of Wholesale Drug Distributors to regulate the practice of pharmacy as provided in Chapter 14 of Title 37 of the Louisiana Revised Statutes of 1950. If any provision of this Chapter conflicts with the provisions of Chapter 14 of Title 37 of the Louisiana Revised Statutes of 1950, the provisions of Chapter 14 of Title 37 of the Louisiana Revised Statutes of 1950 shall prevail.

Acts 1988, No. 852, §1.