

Regular Session, 2008

SENATE BILL NO. 571

BY SENATOR MICHOT AND REPRESENTATIVE MILLS

HEALTH/HOSPITALS DEPT. Provides for changes to the Louisiana Wholesale Drug Distributors Act. (8/15/08)

1 AN ACT
2 To amend and reenact R.S. 37:3461, 3462(2) through (5), 3463(C), 3467(A)(2) and (3),
3 3469, 3470, 3472, 3473, 3474.1(A)(1), (2), (5), and (6) and (B), 3478(C), 3479(A),
4 and 3480 and to enact R.S. 37:3462(6) through (16), 3467(B)(5), 3474.1(A)(7) and
5 (8), (C), (D), (E), and (F), 3474.2, 3474.3, 3474.4, and 3477, relative to the Louisiana
6 Wholesale Drug Distributors Act; to provide for a short title; to provide for
7 definitions; to set the terms of board members; to provide for the powers and duties
8 of the board; to provide for qualifications and requirements for licensure; to provide
9 for inspections; to provide for applicants from other states; to provide for the denial,
10 revocation, or suspension of a license; to provide for enforcement proceedings; to
11 provide for injunction proceedings; to provide for quarantine of a legend drug or
12 device; to authorize the board to obtain criminal history record information; to
13 provide for penalties; to provide for fees; to provide for unauthorized sales; and to
14 provide for related matters.

15 Be it enacted by the Legislature of Louisiana:

16 Section 1. R.S. 37:3461, 3462(2) through (5), 3463(C), 3467(A)(2) and (3), 3469,
17 3470, 3472, 3473, 3474.1(A)(1), (2), (5), and (6) and (B), 3478(C), 3479(A), and 3480 are

1 hereby amended and reenacted and R.S. 37:3462(6) through (16), 3467(B)(5), 3474.1(A)(7)
2 and (8), (C), (D), (E), and (F), 3474.2, 3474.3, 3474.4, and 3477 are hereby enacted to read
3 as follows:

4 §3461. General provisions **and short title**

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

7 **B.** In order to safeguard life and health and to promote the public welfare,
8 any person engaged in the wholesale distribution **or sale** of **legend** drugs **or legend**
9 **devices** as defined in this Chapter shall be required to submit evidence ~~that he is~~
10 **qualified of qualification** to be engaged in the wholesale drug distribution business
11 and shall be licensed as hereinafter provided.

12 §3462. Definitions

13 As used in this Chapter:

14 * * *

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

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

25 (4) "Legend drug" means any drug intended for use by humans that carries
26 on its label **any of** the **following** statement: ~~"Warning=~~ **Caution:** Federal law
27 prohibits dispensing without a prescription", **"Rx," or "Rx Only"**.

28 (5) ~~"Manufacturer" means a person who manufactures legend drugs and~~
29 ~~includes a labeler, primary distributor, or person who prepares legend drugs in~~

1 dosage form, by mixing, compounding, encapsulating, entableting, or by other
2 process: "Manufacturer" means any of the following:

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

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

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

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

11 (7) "Bureau" means the Louisiana Bureau of Criminal Identification
12 and Information of the office of state police, Department of Public Safety and
13 Corrections.

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

22 (9) "FBI" means the Federal Bureau of Investigation of the United
23 States Department of Justice.

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

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

1 A. The board shall:

2 * * *

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

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

8 * * *

9 B. The board may:

10 * * *

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

12 * * *

13 §3469. Qualifications and requirements of applicant **for licensure**

14 A. Every applicant ~~or responsible party~~ for licensure as a wholesale drug
15 distributor shall **submit to the board the names of the designated responsible**
16 **party and any owners who shall** be at least twenty-one years of age and of good
17 moral character and temperate habits. Conviction of a felony violation of federal or
18 state law **by the applicant, responsible party, or owner** may be grounds for denial
19 of a license.

20 B. The application for licensure shall be made on a form provided by the
21 board. Each application shall be accompanied with the reasonable licensure fee
22 prescribed by the board. Each application form shall contain language that
23 authorizes the board to ~~conduct a background check~~ **obtain a criminal history**
24 **record** on ~~the applicant~~ **the applicant, responsible party, and any owners** to
25 determine if ~~he has~~ **the applicant, responsible party or owners have** ever been
26 convicted of a felony violation of federal or state law.

27 §3470. Inspections

28 The board, or a representative of the board, may conduct inspections of ~~in-~~
29 ~~state~~ facilities during normal business hours upon receipt of an application for

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

9 * * *

10 §3472. Reinspection

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

17 §3473. Applicants from other states; waiver of inspection

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

23 §3474.1. Denial, revocation, or suspension of license

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

27 (1) Conviction of a felony ~~violation of federal or state laws or regulations of~~
 28 **the licensee, responsible party, or owner.** The record of such conviction, or
 29 certified copy thereof from the clerk of court where such conviction occurred or by

1 the judge of such court, shall be sufficient evidence to warrant revocation or
2 suspension.

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

8 * * *

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

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

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

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

17 B. Proceedings for any disciplinary actions or for the denial, revocation, or
18 suspension of a license shall be conducted in accordance with rules and regulations
19 adopted by the board pursuant to the Administrative Procedure Act. ~~The board may~~
20 ~~require a person against whom disciplinary action has been taken to pay not more~~
21 ~~than one thousand dollars per violation with the maximum aggregate penalty not to~~
22 ~~exceed fifty times the maximum penalty per individual violation. No license shall~~
23 ~~be issued, reinstated, or renewed until such penalty has been paid in full.~~

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

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

29 **E. In addition to the fine, the board may assess all costs incurred in**

1 connection with the proceedings to a person who is subject to the authority of
2 the board, including but not limited to investigator, stenographer, and attorney
3 fees.

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

6 §3474.2. Enforcement action against other persons; penalties

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

10 (1) Participating or engaging in wholesale drug distribution.

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

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

16 B. For the purpose of this Section, the term "enforcement action" shall
17 include but not be limited to the assessment of a fine in an amount not to exceed
18 one thousand dollars per violation. Each day on which a violation occurs shall
19 constitute a separate violation.

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

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

26 §3474.3. Injunction proceedings; penalties

27 A. The board may seek in any court of competent jurisdiction a writ of
28 injunction enjoining any person from participating in wholesale drug
29 distribution until such person obtains the necessary license under the provisions

1 of this Chapter. This injunction shall not be subject to being released upon
2 bond.

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

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

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

11 §3474.4. Order to quarantine a legend drug or legend device

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

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

21 * * *

22 §3477. Authorization to obtain criminal history record information

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

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

1 **information.**

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

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

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

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

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

1 **jurisdiction, be released or otherwise disclosed by the board to any other person**
2 **or agency.**

3 §3478. Unlawful participation; penalty

4 * * *

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

8 §3479. Fees

9 A. To defray the cost of administering the provisions of this Chapter, the
10 board shall fix ~~reasonable fees to be assessed under this Chapter.~~ **not to exceed the**
11 **following:**

- 12 **(1) Initial license fee** **\$600**
- 13 **(2) License renewal fee** **\$600**
- 14 **(3) Initial inspection fee** **\$300**
- 15 **(4) Duplicate license fee** **\$100**
- 16 **(5) Reinstatement fee for licenses suspended, revoked, or expired** **\$600**
- 17 **(6) License verification fee** **\$100**

18 * * *

19 §3480. Unauthorized sales

20 Wholesale drug distributors shall sell or distribute **legend** drugs or **legend**
21 devices only to ~~an individual, corporation, or entity~~ **a person** who is authorized, by
22 law or regulation, to procure or possess ~~such~~ **legend** drugs or **legend** devices.

The original instrument and the following digest, which constitutes no part of the legislative instrument, were prepared by Greg Waddell.

DIGEST

Present law requires a person to submit evidence of qualification and licensure in order to engage in the wholesale distribution of drugs.

Proposed law changes present law by requiring that a person must submit evidence of qualification and licensure in order to distribute or sell legend drugs or legend devices.

Present law defines board, wholesale drug distribution, wholesale drug distributor, legend drug, and manufacturer.

Proposed law retains the definition of board as the Louisiana Board of Wholesale Drug Distributors, but changes the definitions of wholesale drug distribution, wholesale drug distributor, legend drug, and manufacturer.

Proposed law further adds definitions for applicant, bureau, criminal history record information, FBI, legend device, legend drug pedigree, licensure, owner, person, responsible party, and third party logistics provider.

Present law provides for board members to serve staggered terms, whereby two members serve for a term of one year, one member serves for a term of two years, one member serves for a term of three years, two members serve for a term of four years, and one member serves for a term of five years. Present law further provides that after these initial terms, each member appointed to the board serves a term of five years.

Proposed law repeals present law and provides that each member of the board serve a term of five years.

Present law sets the powers and duties of the board. Authorizes the board to regulate the distribution of drugs by wholesale drug distributors and monitor compliance with all federal and state laws and regulations regarding the distribution of wholesale drugs by wholesale drug distributors.

Proposed law changes present law by authorizing the board to regulate the distribution of legend drugs and legend devices, as well as monitor compliance with all federal laws regarding the distribution of legend drugs and legend devices.

Proposed law allows the board to require licensees to provide a legend drug pedigree.

Present law requires that each applicant for licensure as a wholesale drug distributor be at least twenty-one years of age and of good moral character. Proposed law changes present law by requiring each applicant for licensure to submit to the board the names of the designated responsible party and any owners, who also must be at least 21 years of age and of good moral character.

Present law stipulates that conviction of a felony of federal or state law by the applicant may be grounds for denial of a license.

Proposed law adds that responsible parties and owners convicted of a felony of federal or state law may also constitute grounds for the denial of a license.

Present law authorizes the board to conduct a background check on applicants for licensure.

Proposed law changes present law by authorizing the board instead to obtain a criminal history record on applicants, responsible parties, and owners.

Present law authorizes the board to conduct inspections of in-state facilities during normal business hours upon receipt of an application for licensure.

Proposed law retains present law but deletes the description of facilities as "in-state".

Proposed law further authorizes the board to conduct inspections during normal business hours of facilities which appear to be used by a wholesale drug distributor.

Present law allows the board to conduct reinspections of in-state facilities. Proposed law deletes the description of facilities as "in-state."

Present law provides for the revocation or suspension of the license of a wholesale drug distributor due to a conviction of a felony. Proposed law retains present law and adds that

the license of a wholesale drug distributor can be revoked or suspended if a responsible party or owner is convicted of a felony.

Present law provides for the revocation or suspension of the license of a wholesale drug distributor due to revocation or suspension of a license by another state to distribute wholesale drugs. Proposed law retains present law but adds that any disciplinary action taken by another state on a license to distribute wholesale legend drugs or legend devices constitutes grounds for the revocation or suspension of a license.

Present law provides for the revocation or suspension of the license of a wholesale drug distributor for refusal to comply with inspection during normal business hours. Proposed law retains present law and adds that refusal to permit entry to any licensed facility is also grounds for the revocation or suspension of a license.

Present law provides for the revocation or suspension of the license of a wholesale drug distributor for violating any provisions of law. Proposed law retains present law and adds that a license may also be revoked or suspended for violating any rules or regulations adopted by the board.

Proposed law adds that selling, distributing, or offering to sell or distribute any adulterated, counterfeited, or misbranded legend drug or legend device, or altering, mutilating, destroying, obliterating, or removing any part of the label of a legend drug or legend device is grounds for the revocation or suspension of a license.

Present law provides for a penalty violation in the amount of \$1,000 per violation against any person who disciplinary action has been taken, with the maximum aggregate penalty not to exceed 50 times the maximum penalty per individual violation.

Proposed law maintains the penalty violation amount of \$1,000 per violation, but instead stipulates that each day a violation occurs counts as a separate violation. Proposed law further authorizes the board to assess all costs incurred in connection with proceedings.

Present law provides that a license not be issued, reinstated, or renewed until a penalty is paid in full. Proposed law retains present law.

Proposed law provides for enforcement action against persons not licensed by the board who participate or engage in wholesale drug distribution, falsely use the term "wholesale drug distributor," or violate state provisions and rules and regulations relative to wholesale drug distributors.

Proposed law defines "enforcement action" as including but not limited to the assessment of a fine of \$1,000 per violation. Further provides that each day of violation constitutes a separate violation. Further allows the board to assess all costs incurred in connection with an enforcement action and for such action to be conducted in accordance with rules and regulations promulgated in accordance with the Administrative Procedure Act.

Proposed law prohibits an individual from participating in wholesale drug distribution unless properly licensed as a wholesale drug distributor. Allows the board to seek an injunction to prohibit such action and provides that the injunction is not subject to being released upon bond.

Proposed law allows the board to collect not more than \$5,000, attorneys' fees, and court costs from a defendant in a suit for an injunction. Further provides that such costs may be rendered in the same judgment in which the injunction is made absolute.

Proposed law provides that an injunction proceeding is summary and by a judge, without a jury.

Proposed law provides that an injunction proceeding does not prohibit criminal prosecution for any violations of state provisions relative to wholesale drug distributors.

Proposed law allows the board to issue an order to quarantine an adulterated, misbranded, counterfeited, or recalled legend drug or device possessed by a wholesale drug distributor. Provides for a hearing within 30 days of the order. Allows the board to vacate the order if the board determines that inadequate grounds exist to support the order.

Proposed law authorizes the board to require that an applicant, responsible party, or owner provide written consent to obtain state and national criminal history record information as a condition for consideration of the application for licensure. Further provides that the board may charge the applicant for the cost incurred by the board in obtaining criminal history record information.

Proposed law provides that the board give each applicant a copy of the written standards specifying requirements for an applicant for licensure and the grounds which constitute revocation or denial of a license.

Proposed law allows the board to obtain criminal history record information from the La. Bureau of Criminal Identification and Information of the office of state police with the Dept. of Public Safety and Corrections (bureau), as well as from the FBI, of an applicant, responsible party, or owner to determine the eligibility of an applicant for licensure.

Proposed law allows the bureau to conduct a search of its criminal history record information relative to a specific applicant, responsible party, or owner and report its findings to the board within 60 days of the request for information. Allows the bureau to charge the board a processing fee for its search.

Proposed law allows the board to forward fingerprints and other identifying information to the FBI for a search of criminal history record information if the report from the bureau does not constitute grounds for the disqualification of the applicant for licensure.

Proposed law provides that all state and national criminal history record information obtained by the board which is not already public record is private information. Provides that the information is restricted to use by the board, its members, officers, investigators, agents, and attorneys in evaluating the applicant's eligibility for licensure. Further provides that the information remains private unless the applicant consents to its release or a court of competent jurisdiction orders the information be released.

Present law sets penalties for violations, including participating in the wholesale drug distribution business without a license and falsely using the term "wholesale drug distributor," at not less than \$100 nor more than \$300, or imprisonment for not less than 10 days nor more than 30 days, or both.

Proposed law retains present law but sets fines at not less than \$1,000 nor more than \$50,000.

Present law authorizes the board to fix a reasonable fee schedule.

Proposed law retains present law but sets fee schedule categories not to exceed the following amounts:

- (1) Initial license fee of \$600.
- (2) License renewal fee of \$600.
- (3) Initial inspection fee of \$300.

(4) Duplicate license fee of \$100.

(5) Reinstatement fee for licenses suspended, revoked, or expired of \$600.

(6) License verification fee of \$100.

Present law allows the sale or distribution of drugs or devices only to any individual, corporation, or entity who is authorized to procure or possess the drugs or devices.

Proposed law clarifies that the drugs and devices are legend drugs and legend devices.

Proposed law also changes reference to an individual, corporation, or entity to a person.

Effective August 15, 2008.

(Amends R.S. 37:3461, 3462(2) through (5), 3463(C), 3467(A)(2) and (3), 3469, 3470, 3472, 3473, 3474.1(A)(1), (2), (5), and (6) and (B), 3478(C), 3479(A), and 3480; adds R.S. 37:3462(6) through (16), 3467(B)(5), 3474.1(A)(7) and (8), (C), (D), (E), and (F), 3474.2, 3474.3, 3474.4, and 3477)