2015 Regular Session **ENROLLED**

SENATE BILL NO. 39

BY SENATOR MILLS

Prefiled pursuant to Article III, Section 2(A)(4)(b)(i) of the Constitution of Louisiana.

AN ACT

To amend and reenact the Chapter heading of Chapter 54 of Title 37 of the Louisiana Revised Statutes of 1950, R.S. 37:3461, 3462, 3463(A), 3464, 3467, 3469, 3470, 3471(A), 3472, 3473, the introductory paragraph of 3474.1(A), 3474.1(A)(1), (2), and (5) and (B), 3474.2(A)(1) and (2), 3474.3(A), 3474.4, 3475, 3477(A), (D), and (E), 3478(A) and (B), 3480, 3481, and 3482 and to repeal R.S. 37:3474, relative to the Louisiana Board of Drug and Device Distributors; to provide definitions; to change the name of the board; to provide for the qualifications of board members; to provide duties and powers of the board; to provide for licensure requirements; to provide for inspections by the board; to provide for reinspection of distribution and sales facilities; to provide authority for the board to waive inspection; to provide authority for the board to discipline; to provide the board authority to take enforcement actions against non-licensees; to provide for injunction proceedings; to provide for a board order to quarantine a legend drug or legend device; to provide for annual renewal of a license; to provide for authorization for the board to obtain criminal history record information; to provide for unlawful participation; to provide for unauthorized sales; to provide for mandatory reporting; to provide for applicability of the practice act; to repeal provisions related to manufacturer distribution of legend drugs and legend devices; to provide for an effective date; and to provide for related matters.

Be it enacted by the Legislature of Louisiana:

Section 1. The Chapter heading of Chapter 54 of Title 37 of the Louisiana Revised Statutes of 1950, R.S. 37:3461, 3462, 3463(A), 3464, 3467, 3469, 3470, 3471(A), 3472, 3473, the introductory paragraph of 3474.1(A), 3474.1(A)(1), (2), and (5) and (B), 3474.2(A)(1) and (2), 3474.3(A), 3474.4, 3475, 3477(A), (D), and (E), 3478(A) and (B), 3480, 3481, and 3482 are hereby amended and reenacted to read as follows:

CHAPTER 54. ~~WHOLESALE~~ DRUG **AND DEVICE** DISTRIBUTORS

§3461. General provisions and short title

A. This Chapter shall be known and may be cited as the "Louisiana ~~Wholesale~~ Drug **and Device** 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~~ **legend** drug **or legend device** distribution business and shall be licensed as hereinafter provided.

§3462. Definitions

As used in this Chapter:

(1) "Applicant" means a person who applies for licensure as a ~~wholesale~~ **legend** drug **or legend device** distributor.

(2) "Board" means the Louisiana Board of ~~Wholesale~~ Drug **and Device** 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) **"Designated responsible party" means a natural person designated by the applicant or licensee as responsible for facility operations of the applicant or licensee facility.**

(6) "Distribution" means the sale or facilitation of delivery of legend drugs or legend devices to a person 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 distributors.

(7) "Distributor" means any person engaged in distribution, including but not limited to manufacturers, repackagers, own-label distributors, jobbers, third-party logistics providers, retail pharmacy warehouses, pharmacies, brokers, agents, and wholesale distributors.

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

~~(6)~~ **(9)** "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)~~ **(10)** "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)~~ **(11)** "Licensure" means any license**, permit, or registration** that the board is authorized by law to issue.

~~(10)~~ **(12)** "Manufacturer" means any of the following:

(a) A person who manufactures legend drugs **or legend devices** 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.

(d) An affiliate of a person described in Subparagraph (a), (b), (c), or (f) of this Paragraph that receives the legend drugs or legend devices directly from a person described in this Subparagraph or Subparagraph (a), (b),(c), or (f) of

this Paragraph.

(e) A co-licensed partner of the person described in Subparagraph (a), (b), (c), or (f) of this Paragraph that obtains the legend drugs or legend devices directly from a person described in this Subparagraph or Subparagraph (a), (b), (c), or (f) of this Paragraph.

(f) A person who holds an approved new drug application under the United States Food and Drug Administration or holds a biologics license issued by the United States Food and Drug Administration for such product; or, if such product is not the subject of an approved application or license, the person who manufactured the product.

~~(11)~~ **(13)** "Owner" means a natural person who owns greater than a ten percent interest in the ~~wholesale drug~~ distributor.

~~(12)~~ **(14)** "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.~~

(15) "Prescription drug" means a drug for human use which, because of its toxicity or other potentiality for harmful effects, the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or a drug which is limited by a United States Food and Drug Administration new drug application to use under the professional supervision of a practitioner licensed by law to administer such drug.

(16) "Product" means a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing (such as capsules, tablets, and lyophilized products before reconstitution); however, "product", as used in this Chapter, does not include any of the following:

(a) Blood or blood components intended for transfusion.

(b) A radioactive drug or radioactive biological product regulated by the Nuclear Regulatory Commission or by a state pursuant to an agreement with the Nuclear Regulatory Commission.

(c) An imaging drug.

(d) An intravenous product that, by its formulation, is intended for replenishment of fluids and electrolytes or calories, for use to maintain the equilibrium of water and minerals in the body, or for irrigation or sterile water whether for such purpose or injection.

(e) Any medical gas.

(f) A homeopathic drug marketed in accordance with applicable guidance under the federal Drug Supply Chain Security Act.

(g) A drug compounded in compliance with the federal Food, Drug, and Cosmetic Act.

(17) "Repackager" means a person who owns or operates an establishment that repacks and relabels a legend drug, legend device, or package thereof for one of the following purposes:

(a) Further sale.

(b) Distribution without a further transaction.

~~(14)~~ **(18)** "Third-party logistics provider" means a person that ~~contracts with a manufacturer to provide~~ **provides** or ~~coordinate~~ **coordinates** warehousing, ~~distribution~~ **facilitation of delivery**, or other **logistic** services **for a legend drug or legend device in interstate and intrastate commerce** on behalf of ~~the~~ **a** manufacturer, **distributor, or dispenser of a legend drug or legend device** but does not take ~~title to~~ **ownership of** the legend drug or legend device ~~or~~ **nor** have responsibility to direct the sale or disposition of the legend drug or legend device.

(19) "Transaction" means the transfer of a product between persons in which a change of ownership occurs, but does not include a transaction that is exempted from the definition by rules of the board or federal law.

(20) "Transaction history" means a statement, in paper or electronic form, that includes the transaction information for each prior transaction going

back to the manufacturer of the product.

(21) "Transaction information" means:

(a) The proprietary or established name or names of the product.

(b) The strength and dosage form of the product.

(c) The National Drug Code number of the product.

(d) The container size.

(e) The number of containers.

(f) The lot number of the product.

(g) The date of the transaction.

(h) The date of the shipment, if more than twenty-four hours after the date of the transaction.

(i) The business name and address of the person from whom ownership is being transferred.

(j) The business name and address of the person to whom ownership is being transferred.

(22) "Transaction statement" means a statement, in paper or electronic form, that the entity transferring ownership in a transaction meets all of the following conditions:

(a) Is authorized as required under the federal Drug Supply Chain Security Act.

(b) Received the product from a person that is authorized as required under the federal Drug Supply Chain Security Act.

(c) Received transaction information and a transaction statement from the prior owner of the product.

(d) Did not knowingly ship a suspect or illegitimate product.

(e) Had systems and processes in place to comply with verification requirements under the federal Drug Supply Chain Security Act.

(f) Did not knowingly provide false transaction information.

(g) Did not knowingly provide false transaction history.

~~(15)~~ **(23)** "Wholesale ~~drug~~ distribution" means the distribution ~~or sale~~ of

legend drugs or legend devices to **a person** 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~~ **except as exempted in the standards of the federal Drug Supply Chain Security Act as the act pertains to wholesale distribution**.

~~(16)~~ **(24)** "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~~ **engaged in wholesale distribution**.

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

A. The Louisiana Board of ~~Wholesale~~ Drug **and Device** 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~~ **eight** members, five of whom shall be licensed ~~wholesale drug~~ distributors ~~and,~~ two of whom shall be actively engaged in the pharmaceutical manufacturing industry**, and one of whom shall be actively engaged in the medical device industry** .

* * *

§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~~ **as defined by this Chapter**.

* * *

§3467. Duties and powers of the board

A. The board ~~shall~~ **may perform all of the following functions**:

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

(2) **Impose fines, assess costs, or otherwise discipline a licensee.**

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

~~(3)~~ **(4)** 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)~~ **(5)** Conduct inspections of wholesale ~~drug~~ **distribution** facilities.

~~(5)~~ **(6)** 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)~~ **(7)** Issue subpoenas and administer oaths to persons giving testimony at hearings.

~~(2)~~ **(8)** Employ and fix compensation of persons necessary to carry on the work of the board.

~~(3)~~ **(9)** 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)~~ **(10)** Adopt all rules and regulations necessary to implement the provisions of this Chapter.

~~(5)~~ **(11)** Require licensees to provide ~~a legend drug pedigree~~ **transaction history, transaction information, and a transaction statement.**

(12) Designate and assign license types and sub-types for distributors, which include wholesale distributors, manufacturers, repackagers, and third-party logistic providers, which it will approve, deny, revoke, suspend, limit, or restrict, and renew pursuant to Paragraph (A)(1) of this Section.

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

~~C.~~ **B.** 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~~ **federal** Food, Drug, and Cosmetic Act **and the federal Drug Supply Chain Security Act**, as ~~it pertains~~ **those acts pertain** to ~~wholesale drug~~ distribution~~;~~ **as defined by this Chapter;** and with the rules and regulations promulgated pursuant ~~thereto~~ **to those Acts**, and other pertinent federal authority.

C. (1) The board may require all distributors and wholesale distributors to furnish a bond or other equivalent means of security in accordance with regulations promulgated by the secretary of the United States Department of Health and Human Services.

(2) This Subsection shall not apply to manufacturers or affiliates or co-licensed partners of manufacturers.

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§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~~ **meet all qualifications and requirements designated by the board in accordance with this Chapter and all applicable requirements of federal law and regulation**.

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, **designated** responsible party, and any owners to determine if the applicant, **designated** responsible party, or owners have ever been convicted of a felony violation of federal or state law.

§3470. Inspections

The board, or a representative of the board, may conduct inspections of **distribution and sales** 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~~ **by** which such discrepancies must be corrected.

§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.

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§3472. Reinspection

Reinspections of **distribution and sales** 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.

§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 **of the same type** in another state, and if the standards adopted and enforced by such entity are comparable to those provided in this Chapter.

§3474.1. ~~Denial, revocation, or suspension of license~~ **Discipline for licensees**

A. Any person licensed as a ~~wholesale drug~~ distributor under this Chapter may have his license revoked**,** ~~or~~ suspended**, limited, or restricted** 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**, limitation, or restriction**.

(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.

* * *

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

* * *

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

* * *

§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 **as defined by this Chapter**.

(2) Using the term **"distributor" or** "wholesale ~~drug~~ distributor" **as defined by this Chapter,** or otherwise assuming or using such term or advertising in any manner intended to convey the impression that he is a licensed **distributor or** wholesale ~~drug~~ distributor.

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§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 **as defined by this Chapter** until such person obtains the necessary license under the provisions of this Chapter. ~~This injunction shall not be subject to being released upon bond.~~ **Posting of a bond shall not be a cause for dissolution of the injunction.**

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§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.

§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.

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§3477. Authorization to obtain criminal history record information

A. The board may require that the applicant, **designated** 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.

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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, **designated** 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, **designated** 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.

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§3478. Unlawful participation; penalty

A. No person shall participate or engage in the ~~wholesale drug distribution~~ business **of distribution as defined by this Chapter** 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 **"distributor" or** "wholesale ~~drug~~ distributor", or otherwise assume or use such term or advertise in any manner intending to convey the impression that he is a **distributor or** wholesale ~~drug~~ distributor **as defined by this Chapter**, unless such person has been duly licensed under the provisions of this Chapter.

* * *

§3480. Unauthorized sales

~~Wholesale drug distributors~~ **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.

§3481. Mandatory reporting

~~Wholesale drug distributors~~ **Distributors** shall provide copies of ~~the~~ **their** 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.

§3482. Applicability; conflicts

Nothing in this Chapter shall be construed to authorize the Louisiana Board of ~~Wholesale~~ Drug **and Device** 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.

Section 2. R.S. 37:3474 is hereby repealed.

Section 3. The Louisiana State Law Institute is hereby directed to change instances of "Louisiana Board of Wholesale Drug Distributors" to "Louisiana Board of Drug and Device Distributors" in R.S. 17:2048.51(O)(1)(c)(xviii), R.S. 36:259(W), R.S. 40:1003(6)(d), and any other provision of law as may be necessary for conformance with the provisions of R.S. 37:3463 as amended by Section 1 of this Act.

Section 4. This Act shall become effective upon signature by the governor or, if not signed by the governor, upon expiration of the time for bills to become law without signature by the governor, as provided by Article III, Section 18 of the Constitution of Louisiana. If vetoed by the governor and subsequently approved by the legislature, this Act shall become effective on the day following such approval.

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PRESIDENT OF THE SENATE

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SPEAKER OF THE HOUSE OF REPRESENTATIVES

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GOVERNOR OF THE STATE OF LOUISIANA

APPROVED: _____