DIGEST

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SB 39 Reengrossed 2015 Regular Session Mills

Proposed law changes the name of the Louisiana Board of Wholesale Drug Distributors to the Louisiana Board of Drug and Device Distributors, referred to hereafter as "the board".

Proposed law changes the name of the Louisiana Wholesale Drug Distributors Act to the Louisiana Drug and Device Distributors Act.

Proposed law changes "wholesale drug distribution business" to "legend drug or legend device distribution business".

Proposed law redefines "applicant" to mean a person who applies for licensure as a legend drug or legend device distributor.

Proposed law defines "designated responsible party" to mean a natural person designated by the applicant or licensee as responsible for facility operations of the applicant or licensee facility.

Proposed law defines "distribution" to mean the sale or facilitation of delivery 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 distributors.

Proposed law defines "distributor" to mean 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.

Proposed law repeals the definition of "legend drug pedigree".

Proposed law amends the definition of "licensure" to include permit or registration.

Proposed law amends the definition of "manufacturer" to mean any of the following:

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

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

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

(4) An affiliate of a person described in proposed law that receives the legend drugs or legend devices directly from a person described in proposed law.

(5) A co-licensed partner of the person described in proposed law that obtains the legend drugs or legend devices directly from a person described in proposed law.

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

Proposed law repeals the definition of "responsible party".

Proposed law defines "prescription drug" to mean 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 an FDA new drug application to use under the professional supervision of a practitioner licensed by law to administer such drug.

Proposed law defines "product" to mean a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing. Provides that "product" does not include blood or blood components intended for transfusion; a radioactive drug or radioactive biological product; an imaging drug; 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; any medical gas; a homeopathic drug marketed in accordance with applicable federal guidance; or a drug compounded in compliance with federal law.

Proposed law defines "repackager" to mean 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:

(1) Further sale.

(2) Distribution without a further transaction.

Proposed law amends the definition of "third-party logistics provider" to mean a person that provides or coordinates warehousing, facilitation of delivery, or other logistic services for a legend drug or legend device in interstate and intrastate commerce on behalf of a manufacturer, distributor, or dispenser of a legend drug or legend device but does not take ownership of the legend drug or legend device nor have responsibility to direct the sale or disposition of the legend drug or legend device.

Proposed law defines "transaction" to mean the transfer of a product between persons in which a change of ownership occurs. Provides that such term does not include a transaction that is exempted from the definition by rules of the board or federal law.

Proposed law defines "transaction history" to mean a statement, in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product.

Proposed law defines "transaction information" to mean:

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

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

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

(4) The container size.

(5) The number of containers.

(6) The lot number of the product.

(7) The date of the transaction.

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

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

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

Proposed law defines "transaction statement" to mean a statement, in paper or electronic form, that the entity transferring ownership in a transaction:

(1) Is authorized as required under the Federal Drug Supply Chain Security Act.

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

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

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

(5) Had systems and processes in place to comply with verification requirements under the Federal Drug Supply Chain Security Act and as required by the board.

(6) Did not knowingly provide false transaction information.

(7) Did not knowingly provide false transaction history.

Proposed law defines "wholesale distribution" to mean the distribution of legend drugs or legend devices to a person other than the consumer or patient except as exempted in the standards of the Federal Drug Supply Chain Security Act as the act pertains to wholesale distribution.

Proposed law defines "wholesale distributor" to mean any person engaged in wholesale distribution.

Proposed law increases the number of members of the board from seven to eight. Provides that one member shall be actively engaged in the medical device industry.

Proposed law amends the qualifications of board members to require each one to be at least 21 years of age, of good moral character and temperate habits, and a resident of Louisiana and shall have engaged in distribution as defined by law.

Proposed law amends the duties and powers of board to not only approve, deny, revoke, or suspend licenses but to also limit or restrict a license. Grants the board the authority to impose a fine, assess cost, or otherwise discipline a licensee and to require a licensee to provide transaction history, transaction information, and a transaction statement. Requires the board to make rules and regulations to comply with the requirements of the Federal Drug Supply Chain Security Act pertaining to distribution as defined by law.

Proposed law authorizes the board to require all distributors and wholesale distributors to furnish a bond or other equivalent means of security, and provides that any such requirement shall be in accordance with regulations promulgated by the U.S. Department of Health and Human Services. However, stipulates that such requirement to furnish bonds or other equivalent means of security shall not apply to manufacturers or affiliates or co-licensed partners of manufacturers.

Proposed law amends requirements for licensure to specify that every applicant for licensure shall meet all qualifications and requirements designated by the board in accordance with present law and proposed law.

Proposed law changes "responsible party" to "designated responsible party".

Proposed law makes changes for inspections from "facilities" to "distribution and sales facilities".

Proposed law changes "wholesale drug distributor" to "distributor".

Proposed law changes for reinspections from "facilities" to "distribution and sales facilities".

Proposed law changes for applicants from other states from "wholesale drug distributors" to "distributors of the same type".

Proposed law includes limitation or revocation of license as a discipline option by the board against a licensee.

Proposed law provides the refusing to permit entry to the licensed distribution or sales facility to comply with any inspection during normal business hours as a cause for discipline.

Proposed law provides that any disciplinary actions or the denial, revocation, suspension, limitation, or restriction of a license shall be conducted in accordance with rules and regulations adopted pursuant to the Administrative Procedure Act.

Proposed law changes "wholesale drug distribution" to "distribution" regarding enforcement actions against other persons.

Proposed law changes "wholesale drug distributor" to "distributor or wholesale distributor" regarding enforcement actions against other persons.

Proposed law changes "wholesale drug distribution" to "distribution" regarding injunction proceedings.

Proposed law changes "wholesale drug distributor" to "distributor" regarding an order to quarantine a legend drug or a legend device.

Proposed law changes "wholesale drug distributors" to "distributors" regarding an annual renewal of license.

Proposed law changes "responsible party" to "designated responsible party" regarding consent to the board for the board to obtain criminal history record information.

Proposed law changes "wholesale drug distribution" to "distribution" regarding unlawful participation and changes "wholesale drug distributor" to "distributor" regarding the same.

Proposed law changes "wholesale drug distributors" to "distributors" regarding unauthorized sales and mandatory reporting.

Proposed law changes the requirement that distributors provide copies of the U.S. Enforcement Accounting Records Controlled Order Substance Reports of the preceding month to the Louisiana Board of Pharmacy by the fifteenth day of each month. Proposed law requires the reporting but removes the preceding month language and the fifteenth day of each month language.

Proposed law repeals present law related to manufacturer distribution of legend drugs and legend devices.

Effective upon signature of the governor or lapse of time for gubernatorial action.

(Amends R.S. 37:3461, 3462, 3463(A), 3464, 3467, 3469, 3470, 3471(A), 3472, 3473, 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; repeals R.S. 37:3474)

Summary of Amendments Adopted by Senate

Committee Amendments Proposed by Senate Committee on Health and Welfare to the original bill

1. Defines "applicant" to mean a person who applies for licensure as a legend drug or legend device distributor.

Senate Floor Amendments to engrossed bill

1. Technical changes.

Summary of Amendments Adopted by House

The Committee Amendments Proposed by House Committee on Health and Welfare to the reengrossed bill:

1. Add to the listing of persons included within the definition of "manufacturer" for purposes of proposed law a person who holds an approved new drug application under the U.S. Food and Drug Administration (FDA) or holds a biologics license issued by the FDA for such product; or, if such product is not the subject of an approved application or license, the person who manufactured the product.

2. Add "prescription drug" and "product" as defined terms with corresponding definitions.

3. Delete instances of the term "legend drug" and insert in lieu thereof "product" within definitions of "transaction", "transaction history", "transaction information", and "transaction statement" provided in proposed law.

4. Provide that the defined term "transaction", for purposes of proposed law, does not include a transaction that is exempted from the definition by rules of the board or federal law.

5. Revise the definition of "wholesale distribution" provided in proposed law to provide that such term means the distribution of legend drugs or legend devices to a person other than the consumer or patient except as exempted in the standards of the Federal Drug Supply Chain Security Act as the act pertains to wholesale distribution.

6. Revise definition of "wholesale distributor" provided in proposed law to provide that such term means any person engaged in wholesale distribution.

7. Increase from seven to eight the number of members of the board named "Louisiana Board of Wholesale Drug Distributors" in present law, renamed "Louisiana Board of Drug and Device Distributors" by proposed law.

8. Stipulate that one member of the La. Board of Drug and Device Distributors ("board") provided for in proposed law shall be actively engaged in the medical device industry.

9. Modify a provision in proposed law relative to the board requiring all distributors and wholesale distributors to furnish a bond or other equivalent means of security to change the requirement to an authorization for the board to require that distributors furnish such bonds or other means of security.

10. Provide that the authorization in proposed law for the board to require distributors and wholesale distributors to furnish a bond or other equivalent means of security shall be in accordance with regulations promulgated by the secretary of the U.S. Dept. of Health and Human Services.

11. Stipulate that proposed law relative to furnishing by certain distributors of bonds or other equivalent means of security shall not apply to manufacturers or affiliates or co-licensed partners of manufacturers.

12. Clarify language in present law and proposed law relative to injunctions sought by the board enjoining persons from participating in distribution of legend drugs or devices.

13. Direct the La. State Law Institute to change instances of "Louisiana Board of Wholesale Drug Distributors" to "Louisiana Board of Drug and Device Distributors" in present law as may be necessary for conformance with proposed law.

14. Make technical changes.