

RÉSUMÉ DIGEST

ACT 443 (SB 39)

2015 Regular Session

Mills

New 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".

Changes the name of the Louisiana Wholesale Drug Distributors Act to the Louisiana Drug and Device Distributors Act.

Increases the number of board members from seven to eight, stipulating that one member shall be actively engaged in the medical device industry, and amends the qualifications of a board member.

Amends the duties and powers of the board to not only approve, deny, revoke, or suspend licenses but to also limit or restrict a license. Authorizes the board 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.

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. Requires that this requirement to furnish bonds or other equivalent means of security does not apply to manufacturers or affiliates or co-licensed partners of manufacturers.

Amends requirements for licensure to specify that every applicant for licensure shall meet all qualifications and requirements designated by the board.

Includes limitation or revocation of license as a discipline option by the board against a licensee.

Provides that the refusing to permit entry to the licensed distribution or sales facility to comply with any inspection during normal business hours is a cause for discipline.

Requires that any disciplinary actions or the denial, revocation, suspension, limitation, or restriction of a license be conducted in accordance with rules and regulations adopted pursuant to the APA.

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. New law requires the reporting but removes the preceding month language and the 15th day of each month language.

Repeals prior law related to manufacturer distribution of legend drugs and legend devices.

Effective upon signature of the governor (July 1, 2015).

(Amends R.S. 37:3461, 3462, 3463(A), 3464, 3467, 3469, 3470, 3471(A), 3472, 3473, 3474.1(A)(intro para), 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)