HLS 12RS-1198 **ORIGINAL**

Regular Session, 2012

HOUSE BILL NO. 607

BY REPRESENTATIVE ANDERS

DRUGS/PRESCRIPTION: Regulates substitution of certain opioid drugs

AN ACT

To enact R.S. 37:1182(A)(25) and R.S. 40:1238.5, relative to opioid drugs; to provide for definitions; to provide for certain duties of the Louisiana Board of Pharmacy; to prohibit substitution for certain prescription drugs; to provide for exceptions; to require promulgation of rules; to provide for effective dates; and to provide for related matters.

Be it enacted by the Legislature of Louisiana:

Section 1. R.S. 37:1182(A)(25) is hereby enacted to read as follows:

§1182. Powers and duties of the board

A. The board shall be responsible for the control and regulation of the practice of pharmacy and shall:

* * *

(25) Establish and maintain a listing of opioid drugs which incorporate a tamper-resistant technology for the purpose of regulating substitution of opioid drugs in accordance with R.S. 40:1238.5.

* * *

Section 2. R.S. 40:1238.5 is hereby enacted to read as follows:

§1238.5. Substitution of certain opioid drugs

A. As used in this Section, the following terms shall have the meaning herein ascribed to them:

(1) "Board" means the Louisiana Board of Pharmacy.

(2) "FDA" means the United States Food and Drug Administration.

(3) "Opioid drug" shall mean a drug in the opioid drug class that is prescribed to treat moderate to severe pain or other conditions. "Opiod drug" shall include the following:

(a) Immediate-release and extended-release forms of the drug.

(b) A drug formed by a combination of drugs, one of which is an opioid.

B. The board shall promulgate such rules as are necessary to establish a list of opioid drugs which meet all of the following criteria:

(1) Incorporate a tamper-resistant technology.

(2) Have been approved by the FDA based upon an application which included at least one of the following:

(a) A human tampering or abuse potential study.

(b) A laboratory study comparing the tamper-resistant or abuse-resistant properties of the drug to a control opioid drug approved by the FDA.

C. The board shall include on the list provided for in Subsection B of this Section, an indication of which listed opioid drugs provide substantially similar tamper-resistant properties. The board shall base such indication on a study provided for in Paragraph (B)(2) of this Section. When the board considers a drug for inclusion on the list provided for in Subsection B of this Section, the board shall not require that the drug bear on its FDA-approved labeling a claim regarding the reduction of tampering, abuse, or abuse potential.

D. Notwithstanding the provisions of R.S. 37:1241(17), a pharmacist shall not substitute an opioid drug unless he obtains consent for the substitution from the prescribing physician and verifies all of the following:

(1) That according to the list provided for in Subsection B of this Section, the opioid drug to be substituted has tamper-resistant properties which are substantially similar to the originally prescribed drug.

(2) That the opioid drug to be substituted is equivalent to the originally prescribed drug as indicated in the most recent publication of the Approved Drug Products with Therapeutic Equivalence Evaluations of the FDA.

Section 3. The Louisiana Board of Pharmacy shall promulgate, in accordance with the Administrative Procedure Act, any rules necessary to implement the provisions of this Act on or before December 1, 2012.

Section 4. The provisions of this Act enacting R.S. 40:1238.5(D), relative to dispensing of opioid drugs, shall become effective on January 1, 2013; otherwise, this Act shall become effective on September 1, 2012.

DIGEST

The digest printed below was prepared by House Legislative Services. It constitutes no part of the legislative instrument. The keyword, one-liner, abstract, and digest do not constitute part of the law or proof or indicia of legislative intent. [R.S. 1:13(B) and 24:177(E)]

Anders HB No. 607

Abstract: Regulates substitution of certain opioid drugs.

Proposed law provides that the La. Board of Pharmacy shall establish and maintain a listing of opioid drugs which meet all of the following criteria:

(1) Incorporate a tamper-resistant technology.

(2) Have been approved by the FDA based upon an application which included at least one of the following:

(a) A human tampering or abuse potential study.

(b) A laboratory study comparing the tamper-resistant or abuse-resistant properties of the drug to a control opioid drug approved by the FDA.

Proposed law requires such listing to indicate which opioid drugs provide substantially similar tamper-resistant properties.

Proposed law provides that, notwithstanding the provisions of present law (R.S. 37:1241(17)), a pharmacist shall not substitute an opioid drug unless he obtains consent for the substitution from the prescribing physician and verifies all of the following:

(1) That per the list provided for in proposed law, the opioid drug to be substituted has tamper-resistant properties which are substantially similar to the originally prescribed drug.

(2) That the opioid drug to be substituted is equivalent to the originally prescribed drug as indicated in the most recent publication of the Approved Drug Products with Therapeutic Equivalence Evaluations of the FDA.

Proposed law requires the La. Board of Pharmacy to promulgate, in accordance with the APA, any rules necessary to implement the provisions of proposed law on or before Dec. 1, 2012.

Proposed law provides that the provisions of proposed law relative to dispensing of opioid drugs become effective on Jan. 1, 2013. Otherwise, provides that proposed law becomes effective on Sept. 1, 2012.

(Adds R.S. 37:1182(A)(25) and R.S. 40:1238.5)