

By: Uresti

S.B. No. 1644

A BILL TO BE ENTITLED

AN ACT

relating to the prescription of tamper-resistant opioid analgesic drugs; providing an administrative penalty.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Subchapter A, Chapter 562, Occupations Code, is amended by adding Section 562.0143 to read as follows:

Sec. 562.0143. TAMPER-RESISTANT OPIOID ANALGESIC DRUG SELECTION RESTRICTED. (a) In this section:

(1) "Interchange" means the substitution of an opioid analgesic drug, whether brand name or generic, for a prescribed tamper-resistant opioid analgesic drug.

(2) "Opioid analgesic drug" means a drug in the opioid analgesic drug class that is prescribed to treat moderate to severe pain or other conditions, including a drug in immediate release or extended release form and a drug combined with other drug substances to form a single tablet or other dosage form.

(3) "Tamper-resistant opioid analgesic drug" means an opioid analgesic drug included on the list created and maintained by the board under Subsection (e).

(b) Except as provided by Subsection (c), a pharmacist may not interchange an opioid analgesic drug for a tamper-resistant opioid analgesic drug, regardless of whether:

(1) the substituted drug is rated as pharmaceutically equivalent and therapeutically equivalent to the prescribed drug by

1 the United States Food and Drug Administration or the board; or

2 (2) the prescribed drug bears a labeling claim with  
3 respect to reduction of tampering, abuse, or abuse potential.

4 (c) A pharmacist may interchange an opioid analgesic drug  
5 for a tamper-resistant opioid analgesic drug if:

6 (1) the substituted drug is a tamper-resistant opioid  
7 analgesic drug included on the list created by the board under  
8 Subsection (e) and the board has determined under Subsection (f)  
9 that the substituted drug provides substantially similar  
10 tamper-resistant properties as the prescribed drug; or

11 (2) the pharmacist obtains prior written consent to  
12 the interchange from the prescribing physician.

13 (d) To comply with Subsection (c)(2), a pharmacist shall  
14 notify the prescribing practitioner orally or electronically to  
15 secure permission to interchange a tamper-resistant opioid  
16 analgesic drug. The practitioner's authorization or denial of  
17 authorization must be documented in writing and signed by the  
18 practitioner.

19 (e) The board shall create and maintain a list of  
20 tamper-resistant opioid analgesic drugs based on evidence  
21 submitted by drug manufacturers or distributors. To qualify for  
22 inclusion on the list, a drug:

23 (1) must incorporate a tamper-resistant technology;  
24 and

25 (2) be approved by the United States Food and Drug  
26 Administration pursuant to an application including at least one  
27 human tampering or abuse potential study or laboratory study

1 comparing the tamper-resistant or abuse-resistant properties of  
2 the drug to one or more opioid analgesic drugs approved by the  
3 administration and serving as a positive control.

4 (f) Based solely on evidence submitted by drug  
5 manufacturers and distributors described by Subsection (e), the  
6 board shall determine which tamper-resistant opioid analgesic  
7 drugs included on the list required by Subsection (e) provide  
8 substantially similar tamper-resistant properties. The board  
9 shall include such information on the list.

10 (g) A drug is not required to bear a labeling claim with  
11 respect to reduction of tampering, abuse, or abuse potential in  
12 order to be included on the list required by Subsection (e).

13 SECTION 2. (a) The Texas State Board of Pharmacy shall  
14 adopt rules necessary to administer the changes in law made by this  
15 Act and shall create the list required by Subsection (e), Section  
16 562.0143, Occupations Code, as added by this Act, not later than  
17 December 1, 2011.

18 (b) The changes in law made by this Act apply only to an  
19 opioid analgesic drug dispensed on or after January 1, 2012. An  
20 opioid analgesic drug dispensed before January 1, 2012, is governed  
21 by the law as it existed immediately before that date, and that law  
22 is continued in effect for that purpose.

23 SECTION 3. This Act takes effect immediately if it receives  
24 a vote of two-thirds of all the members elected to each house, as  
25 provided by Section 39, Article III, Texas Constitution. If this  
26 Act does not receive the vote necessary for immediate effect, this  
27 Act takes effect September 1, 2011.