

By: Uresti

S.B. No. 316

A BILL TO BE ENTITLED

AN ACT

relating to the substitution by a pharmacist of certain opioid analgesic drugs.

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

SECTION 1. Subchapter A, Chapter 562, Occupations Code, is amended by adding Section 562.016 to read as follows:

Sec. 562.016. SUBSTITUTION OF CERTAIN OPIOID DRUGS. (a) In this section, "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:

(1) immediate-release and extended-release forms of the drug; and

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

(b) The board by rule shall establish a list of opioid analgesic drugs that:

(1) incorporate a tamper-resistant technology; and

(2) have been approved by the United States Food and Drug Administration from an application that included at least:

(A) one human tampering or abuse potential study;

or

(B) a laboratory study comparing the tamper-resistant or abuse-resistant properties of the drug to a control opioid analgesic drug approved by the United States Food

1 and Drug Administration.

2 (c) The board shall include on the list under Subsection (b)
3 a determination of which listed opioid analgesic drugs provide
4 substantially similar tamper-resistant properties, based on the
5 study described by Subsection (b)(2).

6 (d) Notwithstanding Section 562.008, a pharmacist may not
7 substitute an opioid analgesic drug unless the pharmacist:

8 (1) verifies:

9 (A) from the list under Subsection (b) that the
10 substituted opioid analgesic drug has substantially similar
11 tamper-resistant properties to the originally prescribed drug; and

12 (B) from the most recent version of the United
13 States Food and Drug Administration publication Approved Drug
14 Products with Therapeutic Equivalence Evaluations that the
15 substituted drug is considered to be equivalent to the prescribed
16 drug; or

17 (2) obtains consent for the substitution from the
18 prescribing physician.

19 SECTION 2. The Texas State Board of Pharmacy shall adopt the
20 rules necessary to implement Section 562.016, Occupations Code, as
21 added by this Act, not later than December 1, 2013.

22 SECTION 3. The changes in law made by this Act apply only to
23 an opioid analgesic drug dispensed on or after January 1, 2014.

24 SECTION 4. This Act takes effect September 1, 2013.