

## **BILL ANALYSIS**

Senate Research Center  
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S.B. 316  
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Health & Human Services  
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As Filed

### **AUTHOR'S / SPONSOR'S STATEMENT OF INTENT**

This bill aims to help curb the rampant abuse of prescription opioids. According to a July 2012, *USA Today* article, the White House Office on National Drug Policy counts prescription drug abuse as the nation's fastest-growing drug problem. The Centers for Disease Control and Prevention has classified the misuse of these powerful narcotics as an epidemic, with 1.3 million emergency room visits in 2010, a 115 percent increase since 2004. Perhaps most troubling, fatalities due to overdosing on opioid pain relievers surpassed deaths from heroin and cocaine for the first time in 2008.

Studies show that addicts tend to crush or otherwise break down timed-release products into a form that can be snorted or injected for a more intense high. Thus, formulations that make it more difficult to crush or otherwise manipulate such products help mitigate the potential for abuse.

In an effort to combat such abuse, S.B. 316 stipulates that when a physician prescribes an opioid analgesic drug that incorporates a tamper resistant technology, no substitution or interchange shall be permitted for that drug without the pharmacy verifying that the substitute provides substantially similar tamper-resistant properties or obtaining the prior consent of the prescribing physician.

As proposed, S.B. 316 amends current law relating to the substitution by a pharmacist of certain opioid analgesic drugs.

### **RULEMAKING AUTHORITY**

Rulemaking authority is expressly granted to the Texas State Board of Pharmacy in SECTION 1 (Section 562.016, Occupations Code) and SECTION 2 of this bill.

### **SECTION BY SECTION ANALYSIS**

SECTION 1. Amends Subchapter A, Chapter 562, Occupations Code, by adding Section 562.016, as follows:

Sec. 562.016. SUBSTITUTION OF CERTAIN OPIOID DRUGS. (a) Defines "opioid analgesic drug" in this section.

(b) Requires the Texas State Board of Pharmacy (TSBP) by rule to 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 (FDA) 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 FDA.

(c) Requires TSBP to include on the list under Subsection (b) a determination of which listed opioid analgesic drugs provide substantially similar tamper-resistant properties, based on the study described by Subsection (b)(2).

(d) Prohibits a pharmacist, notwithstanding Section 562.008 (Generic Equivalent Authorized), from substituting an opioid analgesic drug unless the pharmacist:

(1) verifies:

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

(b) from the most recent version of the FDA publication Approved Drug Products with Therapeutic Equivalence Evaluations that the substituted drug is considered to be equivalent to the prescribed drug; or

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

SECTION 2. Requires TSBP to adopt the rules necessary to implement Section 562.016, Occupations Code, as added by this Act, not later than December 1, 2013.

SECTION 3. Makes application of this Act prospective to January 1, 2014.

SECTION 4. Effective date: September 1, 2013.