BILL ANALYSIS

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C.S.S.B. 1756
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Health & Human Services
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Committee Report (Substituted)

AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

Opioid use and abuse has increased greatly in the United States since the 1990s and continues to rise. While the benefits of these products in treating and managing pain are widely recognized, the potential for misuse and abuse of these products has long been a concern of manufacturers, state and federal law enforcement, health care providers, legislators, and regulators.

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

Because health care providers are a critical line of defense in identifying and preventing opioid abuse, it is important to prohibit the substitution of specific drug products incorporating tamper-resistant technologies when a health care provider has determined that such a formulation is necessary, and not permit the pharmacy substitution without determining that the substitute incorporates substantially similar tamper resistance properties or obtaining explicit physician authorization.

C.S.S.B. 1756 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) 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, in this section, "opioid analgesic drug."

(b) Requires the Texas State Board of Pharmacy (TSBP) by rule to establish a list of opioid analgesic drugs that incorporate a tamper-resistant technology, and have been approved by the United States Food and Drug Administration (FDA) from an application that included at least one human tampering or abuse potential study, or 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) (relating to studies approved by the FDA relating to tampering or abuse).

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

(1) verifies from the list under Subsection (b) that the substituted opioid analgesic drug has substantially similar tamper-resistant properties to the originally prescribed drug, and from the most recent version of the United States Food and Drug Administration 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, 2011.

SECTION 3. Provide that the changes in law made by this Act apply only to an opioid analgesic drug dispensed on or after January 1, 2012.

SECTION 4. Effective date: September 1, 2011.