

BILL ANALYSIS

Senate Research Center

C.S.H.B. 3486
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Health & Human Services
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Committee Report (Substituted)

DIGEST AND PURPOSE

Prescription drugs used in health care facilities are disposed of on a daily basis for many reasons. Often, these medications are in good condition, have not been utilized fully and could be used for other patients if initially packaged in tamper-resistant or blister packs. C.S.H.B. 3486 authorizes the return of medications to the pharmacy from which they were purchased for reuse.

RULEMAKING AUTHORITY

Rulemaking authority is expressly granted to the Texas State Board of Pharmacy in SECTION 1 (Section 562.1085, Occupations Code) and to the Health and Human Services Commission in SECTION 3 (Section 32.028, Human Resources Code) of this bill.

SECTION BY SECTION ANALYSIS

SECTION 1. Amends Subchapter C, Chapter 562, Occupations Code, by adding Sections 562.1085 and 562.1086, as follows:

Sec. 562.1085. **UNUSED DRUGS RETURNED BY CERTAIN PHARMACISTS.** (a) Authorizes a pharmacist who practices in or serves as a consultant for a health care facility in this state to return to a pharmacy certain unused drugs, other than a controlled substance as defined by Chapter 481, Health and Safety Code, purchased from the pharmacy as provided by board rule. Requires the unused drugs to meet certain requirements.

(b) Requires a pharmacist for the pharmacy to examine a drug returned under this section to ensure the integrity of the drug product. Prohibits a health care facility from returning a drug that does not meet certain requirements.

(c) Authorizes the pharmacy to restock and redistribute unused drugs returned under this section.

(d) Requires the pharmacy to reimburse or credit the state Medicaid program for an unused drug returned under this section.

(e) Requires the Texas Board of Pharmacy (TSBP) to adopt the rules, policies, and procedures necessary to administer this section, including rules that require a health care facility to inform the Health and Human Services Commission (HHSC) of drugs returned to a pharmacy under this section.

Sec. 562.1086. **LIMITATION ON LIABILITY.** (a) Provides that a pharmacist that returns unused drugs or the health care facility at which the pharmacist practices or serves and a pharmacy that accepts the unused drugs under Section 562.1085 and the employees of the pharmacist, health care facility, or pharmacy are not liable for harm caused by the accepting, dispensing, or administering of drugs returned in strict compliance with Section 562.1085 unless the harm is caused by certain conditions.

(b) Provides that this section does not limit, or in any way affect or diminish, the liability of a drug seller or manufacturer under Chapter 82, Civil Practice and Remedies Code.

(c) Provides that this section does not apply if harm results from the failure to fully and completely comply with the requirements of Section 562.1085.

SECTION 2. Amends Section 431.021, Health and Safety Code, to make a conforming change.

SECTION 3. Amends Section 32.028, Human Resources Code, by adding Subsections (i), (j), and (k), as follows:

(i) Requires HHSC to adopt rules governing the determination of the amount of reimbursement or credit for restocking drugs under Section 562.1085, Occupations Code, that recognize the costs of processing the drugs, including certain costs.

(j) Requires HHSC to provide an electronic system for the issuance of credit for returned drugs that complies with the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191), as amended. Provides that to ensure a cost-effective system, only drugs for which the credit exceeds the cost of the restocking fee by at least 100 percent are eligible for credit.

(k) Requires HHSC to establish a task force to develop the rules necessary to implement Subsections (i) and (j). Requires the task force to include representatives of nursing facilities and pharmacies.

SECTION 4. Provides that if before implementing any provision of this Act a state agency determines that a waiver or authorization from a federal agency is necessary for implementation of that provision, the agency affected by the provision must request the waiver or authorization and may delay implementing that provision until the waiver or authorization is granted.

SECTION 5. Requires HHSC to adopt the rules required by Sections 32.028(i) and (j), Human Resources Code, as added by this Act, not later than December 1, 2003.

SECTION 6. (a) Requires TSBP to adopt the rules required by Section 562.1085, Occupations Code, as added by this Act, not later than December 1, 2003.

(b) Provides that notwithstanding Section 562.1085, Occupations Code, as added by this Act, a pharmacy is not required to accept unused drugs from a health care facility before January 1, 2004.

SECTION 7. Effective date: upon passage or September 1, 2003.