

## **BILL ANALYSIS**

Senate Research Center  
88R23229 KKR-D

C.S.S.B. 2173  
By: Alvarado  
Health & Human Services  
4/17/2023  
Committee Report (Substituted)

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

Prescriptions are currently the fifth-most abused substance after alcohol (65.5 percent usage) and tobacco products (26.7 percent usage). While Texas participates in Drug Enforcement Administration (DEA)-sponsored National Drug Take-Back Days biannually, there are few sites consistently available to collect unused prescription drugs, especially in rural areas.

C.S.S.B. 2173 creates the Controlled Substance Prescription Drug Safe Disposal Pilot Program to which pharmacies operating in Texas may apply for an on-site collection receptacle for consumer drug take-back. Take-back programs serve multiple purposes: they provide a convenient and responsible way to get medications out of homes, ensure that medications are safely disposed of in accordance with DEA rules, and raise awareness about the dangers of diversion, misuse, and accidental overdose associated with leftover or unused prescription medications.

C.S.S.B. 2173 will ensure that DEA-registered pharmacies can receive funds for expanded prescription drug take-back efforts. This will make take-back programs more accessible, encourage the public to remove unused medications from their homes, and prevent medication misuse and opioid addiction from ever starting.

C.S.S.B. 2173 makes changes in order to provide clarity to the filed language and prevent conflict between state and federal law. Aside from technical changes, it clarifies that the pilot program includes all prescription drugs and not just controlled substances, adds the term "ultimate user" and replaces "controlled substance" language with this term where appropriate and limits the mail-back provision to 250 envelopes annually per pharmacy to ensure the mail-back option is used only in limited circumstances.

C.S.S.B. 2173 amends current law relating to a pilot program for the safe disposal of prescription drugs, including controlled substance prescription drugs.

### **RULEMAKING AUTHORITY**

Rulemaking authority is expressly granted to the Texas State Board of Pharmacy in SECTION 1 (Sections 442A.002 and 442A.052, Health and Safety Code) of this bill.

### **SECTION BY SECTION ANALYSIS**

SECTION 1. Amends Subtitle A, Title 6, Health and Safety Code, by adding Chapter 442A, as follows:

#### CHAPTER 442A. PRESCRIPTION DRUG SAFE DISPOSAL PILOT PROGRAM

##### SUBCHAPTER A. GENERAL PROVISIONS

Sec. 442A.001. DEFINITIONS. Defines "board," "controlled substance," "pharmacy," "pilot program," "prescription drug," and "ultimate user."

Sec. 442A.002. PRESCRIPTION DRUG SAFE DISPOSAL PILOT PROGRAM. Requires the Texas State Board of Pharmacy (TSBP) by rule to develop and implement a

prescription drug safe disposal pilot program to increase the number of locations in this state where unused, unwanted, or expired prescription drugs are collected from the public for safe disposal.

#### SUBCHAPTER B. PHARMACY PARTICIPATION

Sec. 442A.051. PHARMACY ELIGIBILITY. Authorizes a pharmacy operating in this state to apply to TSBP to participate in the pilot program if the pharmacy is registered as an authorized drug collection site with the United States Drug Enforcement Administration, is not the subject of state or federal opioid litigation, and meets the eligibility requirements established by 21 C.F.R. Section 1317.40 and TSBP rules.

Sec. 442A.052. APPLICATION AND SELECTION PROCESSES. (a) Requires TSBP to adopt rules prescribing the form and manner for a pharmacy to apply for participation in the pilot program and prescribing evaluation and selection criteria and processes.

(b) Requires TSBP to give priority to a pharmacy applicant that does not collect unused ultimate user prescription drugs under 21 C.F.R. Part 1317 at the time the applicant submits the application or that is located in a rural or underserved area TSBP designates.

(c) Requires a pharmacy that operates multiple locations to submit an application for each location.

Sec. 442A.053. COLLECTION RECEPTACLE REQUIREMENTS. (a) Requires a participating pharmacy that provides a collection receptacle for the safe disposal of prescription drugs to ensure the receptacle meets the requirements of 21 C.F.R. Section 1317.75, is accessible during the pharmacy's regular hours of operation, allows anonymous deposit of unused controlled substance prescription drugs listed in Schedules II, III, IV, and V, and provides disposal of unused prescription drugs at no cost to the ultimate user.

(b) Authorizes controlled substance prescription drugs and noncontrolled substance prescription drugs to be collected together and comingled.

Sec. 442A.054. MAIL-BACK PROGRAM REQUIREMENTS. (a) Authorizes a participating pharmacy that provides a collection receptacle for the safe disposal of prescription drugs, under limited circumstances as the pharmacy determines necessary, to provide at the time the pharmacy dispenses a prescription drug to the ultimate user a vendor's mail-back envelope, at no cost to the ultimate user. Requires that the mail-back envelope:

(1) be pre-addressed and return postage paid; and

(2) meet the requirements of 21 C.F.R. Section 1317.70.

(b) Authorizes a participating pharmacy to provide not more than 250 mail-back envelopes during the duration of the pilot program to encourage use of the pharmacy's collection receptacle.

Sec. 442A.055. PHARMACY MANAGEMENT; RECORDS. Provides that a participating pharmacy is responsible for the daily management and recordkeeping of the pharmacy's controlled substance prescription drug safe disposal program in accordance with the pharmacy's United States Drug Enforcement Administration registration and TSBP rules.

Sec. 442A.056. TEXAS PREMIER PHARMACY DESIGNATION. (a) Requires TSBP to designate each pharmacy participating in the pilot program as a Texas premier pharmacy provider committed to safe prescription drug disposal.

(b) Authorizes a participating pharmacy to use the designation for marketing purposes.

### SUBCHAPTER C. BOARD DUTIES

Sec. 442A.101. PILOT PROGRAM INCENTIVES. (a) Requires TSBP to assist each pharmacy participating in the pilot program, including by paying the costs of:

(1) maintaining one collection receptacle at each participating pharmacy location and destroying through incineration of the receptacle's full inner liner the prescription drugs deposited in the receptacle;

(2) ordering and distributing pre-addressed, return postage paid mail-back envelopes from a third-party mail-back program and destroying through incineration the returned mail-back envelopes containing the collected prescription drugs; and

(3) other operational needs TSBP determines appropriate.

(b) Provides that TSBP:

(1) is required to directly reimburse a participating pharmacy for costs the pharmacy incurs under Subsection (a); and

(2) is prohibited from reimbursing a participating pharmacy for the cost of using a third-party incineration facility unless the facility is appropriately registered with the United States Drug Enforcement Administration.

(c) Authorizes TSBP, subject to money available for purposes of this chapter, to provide financial incentives to a pharmacy to continue providing those services or expand those services to accommodate controlled substance prescriptions. Authorizes TSBP to provide financial incentives to a chain retail pharmacy for not more than 15 locations.

Sec. 442A.102. COMMUNITY OUTREACH. (a) Requires TSBP to develop and distribute educational outreach materials for the public about the availability of safe prescription drug disposal in this state, to post the materials on TSBP's Internet website, and to provide the materials to other state agencies for those agencies to conduct the community outreach.

(b) Requires that the educational outreach materials be in English, Spanish, and for specific areas of this state as TSBP determines appropriate, another language spoken by a substantial portion of the area's residents.

Sec. 442A.103. REPORT. Requires TSBP, not later than December 1 of each even-numbered year, to submit to the governor and the legislature a report that:

(1) summarizes the results of the pilot program, including:

(A) the number and geographic distribution of collection receptacles at participating pharmacies;

(B) the estimated amount of prescription drugs collected by participating pharmacies under the program, measured by:

(i) the number of inner liners fully filled with collected prescription drugs and sent for incineration by the pharmacies;

(ii) the number of mail-back envelopes distributed by the pharmacies; and

(iii) the weight, measured in pounds, of:

(a) inner liners described by Subparagraph (i); and

(b) returned mail-back envelopes filled with collected prescription drugs;

(C) the amount of money distributed under the pilot program and the identity of each participating pharmacy to which money is distributed; and

(D) a description of TSBP's educational efforts and outcomes; and

(2) recommends whether the pilot program should continue, be expanded, or terminate or whether TSBP should permanently implement a prescription drug safe disposal program.

#### SUBCHAPTER D. FUNDING

Sec. 442A.151. FUNDING. (a) Authorizes money contained in the opioid abatement account established under Section 403.505 (Opioid Abatement Account), Government Code, as added by Chapter 78 (S.B. 1827) Acts of the 87th Legislature, Regular Session, 2021, to be appropriated to TSBP to fund the pilot program established under this chapter.

(b) Authorizes TSBP to collect gifts, grants, and donations to fund the program.

#### SUBCHAPTER E. EXPIRATION

Sec. 442A.201. EXPIRATION. Provides that this chapter expires September 1, 2029.

SECTION 2. Requires TSBP, as soon as practicable after the effective date of this Act, to implement the prescription drug safe disposal pilot program developed under Chapter 442A, Health and Safety Code, as added by this Act.

SECTION 3. Effective date: September 1, 2023.