HEALTH AND SAFETY CODE

TITLE 6. FOOD, DRUGS, ALCOHOL, AND HAZARDOUS SUBSTANCES SUBTITLE A. FOOD AND DRUG HEALTH REGULATIONS

For expiration of this chapter, see Section 442A.201.

CHAPTER 442A. PRESCRIPTION DRUG SAFE DISPOSAL PILOT PROGRAM

SUBCHAPTER A. GENERAL PROVISIONS

Sec. 442A.001. DEFINITIONS. In this chapter:

(1) "Board" means the Texas State Board of Pharmacy.

(2) "Controlled substance" has the meaning assigned by Section 481.002.

(3) "Pharmacy" means a facility licensed under Chapter560, Occupations Code.

(4) "Pilot program" means the prescription drug safe disposal pilot program established under this chapter.

(5) "Prescription drug" has the meaning assigned by Section 551.003, Occupations Code.

(6) "Ultimate user" has the meaning assigned by 21 U.S.C. Section 802. Added by Acts 2023, 88th Leg., R.S., Ch. 293 (S.B. 2173), Sec. 1, eff. September 1, 2023.

Sec. 442A.002. PRESCRIPTION DRUG SAFE DISPOSAL PILOT PROGRAM. The board by rule shall 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.

Added by Acts 2023, 88th Leg., R.S., Ch. 293 (S.B. 2173), Sec. 1, eff. September 1, 2023.

SUBCHAPTER B. PHARMACY PARTICIPATION

Sec. 442A.051. PHARMACY ELIGIBILITY. A pharmacy operating in this state may apply to the board to participate in the pilot program if the pharmacy:

(1) is registered as an authorized drug collection site with the United States Drug Enforcement Administration;

(2) is not the subject of state or federal opioidlitigation; and

(3) meets the eligibility requirements established by 21 C.F.R. Section 1317.40 and board rules. Added by Acts 2023, 88th Leg., R.S., Ch. 293 (S.B. 2173), Sec. 1, eff. September 1, 2023.

Sec. 442A.052. APPLICATION AND SELECTION PROCESSES. (a) The board shall adopt rules prescribing:

(1) the form and manner for a pharmacy to apply for participation in the pilot program; and

(2) evaluation and selection criteria and processes.

(b) The board shall give priority to a pharmacy applicant that:

(1) does not collect unused ultimate user prescription drugs under 21 C.F.R. Part 1317 at the time the applicant submits the application; or

(2) is located in a rural or underserved area the board designates.

(c) A pharmacy that operates multiple locations must submit an application for each location.

Added by Acts 2023, 88th Leg., R.S., Ch. 293 (S.B. 2173), Sec. 1, eff. September 1, 2023.

Sec. 442A.053. COLLECTION RECEPTACLE REQUIREMENTS. (a) A participating pharmacy that provides a collection receptacle for the safe disposal of prescription drugs shall ensure the receptacle:

(1) meets the requirements of 21 C.F.R. Section
1317.75;

(2) is accessible during the pharmacy's regular hours of operation;

(3) allows for the anonymous deposit of unused controlled substance prescription drugs listed in Schedules II, III, IV, and V; and

(4) provides disposal of unused prescription drugs at no cost to the ultimate user.

(b) Controlled substance prescription drugs and noncontrolled substance prescription drugs may be collected together and comingled.

Added by Acts 2023, 88th Leg., R.S., Ch. 293 (S.B. 2173), Sec. 1, eff. September 1, 2023.

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

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

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

(b) A participating pharmacy may provide not more than 250 mail-back envelopes during the duration of the pilot program to encourage use of the pharmacy's collection receptacle. Added by Acts 2023, 88th Leg., R.S., Ch. 293 (S.B. 2173), Sec. 1, eff. September 1, 2023.

Sec. 442A.055. PHARMACY MANAGEMENT; RECORDS. A participating pharmacy is responsible for the daily management and recordkeeping of the pharmacy's prescription drug safe disposal program in accordance with the pharmacy's United States Drug Enforcement Administration registration and board rules. Added by Acts 2023, 88th Leg., R.S., Ch. 293 (S.B. 2173), Sec. 1, eff. September 1, 2023.

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

(b) A participating pharmacy may use the designation for

marketing purposes.

Added by Acts 2023, 88th Leg., R.S., Ch. 293 (S.B. 2173), Sec. 1, eff. September 1, 2023.

SUBCHAPTER C. BOARD DUTIES

Sec. 442A.101. PILOT PROGRAM INCENTIVES. (a) The board shall 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 the board determines appropriate.

(b) The board:

(1) shall directly reimburse a participating pharmacyfor costs the pharmacy incurs under Subsection (a); and

(2) may not reimburse 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) Subject to money available for purposes of this chapter, the board may provide financial incentives to a pharmacy to continue providing prescription drug collection services or expand those services to accommodate controlled substance prescriptions. The board may provide financial incentives to a chain retail pharmacy for not more than 15 locations. Added by Acts 2023, 88th Leg., R.S., Ch. 293 (S.B. 2173), Sec. 1, eff. September 1, 2023.

Sec. 442A.102. COMMUNITY OUTREACH. (a) The board shall: (1) develop and distribute educational outreach

materials for the public about the availability of safe prescription drug disposal in this state;

(2) post the materials on the board's Internet website; and

(3) provide the materials to other state agencies for those agencies to conduct the community outreach.

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

Added by Acts 2023, 88th Leg., R.S., Ch. 293 (S.B. 2173), Sec. 1, eff. September 1, 2023.

Sec. 442A.103. REPORT. Not later than December 1 of each even-numbered year, the board shall 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 the board's educational

efforts and outcomes; and

(2) recommends whether the pilot program should continue, be expanded, or terminate or whether the board should permanently implement a prescription drug safe disposal program. Added by Acts 2023, 88th Leg., R.S., Ch. 293 (S.B. 2173), Sec. 1, eff. September 1, 2023.

SUBCHAPTER D. FUNDING

Sec. 442A.151. FUNDING. (a) Money contained in the opioid abatement account established under Section 403.505, Government Code, as added by Chapter 781 (S.B. 1827), Acts of the 87th Legislature, Regular Session, 2021, may be appropriated to the board to fund the pilot program established under this chapter.

(b) The board may collect gifts, grants, and donations to fund the program. Added by Acts 2023, 88th Leg., R.S., Ch. 293 (S.B. 2173), Sec. 1, eff. September 1, 2023.

SUBCHAPTER E. EXPIRATION

Sec. 442A.201. EXPIRATION. This chapter expires on the second anniversary of the date that all money appropriated for the pilot program has been expended.

Added by Acts 2023, 88th Leg., R.S., Ch. 293 (S.B. 2173), Sec. 1, eff. September 1, 2023.