S.B. No. 2173 1-1 By: Alvarado (In the Senate - Filed March 9, 2023; March 22, 2023, read first time and referred to Committee on Health & Human Services; 1-2 1-3 1-4 April 20, 2023, reported adversely, with favorable Committee 1-5 Substitute by the following vote: Yeas 9, Nays 0; April 20, 2023, 1-6 sent to printer.) COMMITTEE VOTE 1-7 1-8 Absent PNV Nay Χ 1-9 Kolkhorst 1-10 1-11 Perry Blanco 1-12 Hall X 1-13 Χ Hancock Hughes Χ 1-14 1**-**15 1**-**16 LaMantia Miles 1-17 Sparks Χ 1-18 COMMITTEE SUBSTITUTE FOR S.B. No. 2173 By: Perry 1-19 A BILL TO BE ENTITLED 1-20 AN ACT 1-21 relating to a pilot program for the safe disposal of prescription 1-22 drugs, including controlled substance prescription drugs. 1-23 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS: SECTION 1. Subtitle A, Title 6, Health and Safety Code, is amended by adding Chapter 442A to read as follows: 1-24 1-25 CHAPTER 442A. PRESCRIPTION DRUG SAFE DISPOSAL PILOT PROGRAM SUBCHAPTER A. GENERAL PROVISIONS

Sec. 442A.001. DEFINITIONS. In this chapter: 1-26 1-27 1-28 "Board" means the Texas State Board of Pharmacy.
"Controlled substance" has the meaning assigned by 1-29 (1)1-30 (2) .002. 1-31 Section 481 (3) 1-32 "Pharmacy" means a <u>facility licensed under Chapter</u> 560, Occupations Code. 1-33 "Pilot program" means the prescription drug safe 1-34 (4)1-35 disposal pilot program established under this chapter. "Prescription drug" 1-36 has the meaning assigned by Occupations Code.
"Ultimate user" has the meaning assigned by 21 1-37 .003, Section 551 1-38 (6) U.S.C. Section 802. 1-39 1-40 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 1-41 1-42 1-43 number of locations in this state where unused, unwanted, or 1-44 expired prescription drugs are collected from the public for safe disposal. 1-45 1-46 SUBCHAPTER B. PHARMACY PARTICIPATION 442A.051. PHARMACY ELIGIBILITY. A pharmacy operating 1-47 1-48 in this state may apply to the board to participate in the pilot 1-49 program if the pharmacy: 1-50 (1) is registered as an authorized drug collection site with the United States Drug Enforcement Administration; 1-51 1-52 (2) is not the subject of state or federal 1-53 litigation; and 1-54 (3) meets the eligibility requirements established by 1-55 21 C.F.R. Section 1317.40 and board rules. 1-56 Sec. 442A.052. APPLICATION AND SELECTION PROCESSES. (a) The board shall adopt rules prescribing: 1-57 1-58 (1) the form and manner for a pharmacy to apply for 1**-**59

(2) evaluation and selection criteria and processes.

participation in the pilot program; and

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(b) The board shall give priority to a pharmacy applicant 2-1 2-2

that: 2-3

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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

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designates.

(c) A pharmacy that operates multiple locations must submit

442A.053. COLLECTION RECEPTACLE REQUIREMENTS. Sec. (a) participating pharmacy that provides a collection receptacle for disposal of prescription drugs shall ensure the safe 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 substance prescription drugs listed in Schedules II, controlled III, IV, and V; and

(4) provides disposal of unused prescription drugs at

no cost to the ultimate user.

(b) Controlled substance prescription drugs noncontrolled substance prescription drugs may be collected

together and comingled.

Sec. 442A.054. MAIL-BACK PROGRAM REQUIREMENTS. 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 meet the requirements of 21 C.F.R. Section (2)

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.

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.

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.

SUBCHAPTER C. BOARD DUTIES 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 pharmacy for costs the pharmacy incurs under Subsection (a); and

2-67 (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 2-68 2-69

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      Enforcement Administration.

(c) Subject to money available for purposes of this chapter,
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                   may provide financial incentives to a pharmacy to
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            board
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      continue providing prescription drug collection services or expand
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      those services to accommodate controlled substance prescriptions.
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      The board may provide financial incentives to a chain retail
      pharmacy for not more than 15 locations.
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                   442A.102.
                               COMMUNITY OUTREACH.
                                                       (a) The board shall:
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                    (1) develop and distribute educational outreach
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                         the public
                   for
                                         about the
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      materials
                                                                       of safe
      prescription drug disposal in this state;
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                   (2)
                        post
                                the
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                                                       the board's
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      website; and
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                         provide the materials to other state agencies for
      those agencies to conduct the community outreach.
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                   The educational outreach materials must be in English,
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       Spanish, and for specific areas of this state as the board
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      determines appropriate, another language spoken by a substantial
      portion of the area's residents.
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       Sec. 442A.103. REPORT. Not later than December 1 of each even-numbered year, the board shall submit to the governor and the
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      legislature a report that:
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                   (1)
                         summarizes
                                      the results of the pilot program,
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      including:
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                               the number and geographic distribution of
                          (A)
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      collection receptacles at participating pharmacies;
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                         (B) the estimated amount of prescription drugs
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      collected by participating pharmacies under the program, measured
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      by:
      (i) the number of inner liners fully filled with collected prescription drugs and sent for incineration by the
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      pharmacies;
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                                      the_
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                                (ii)
                                            number of mail-back envelopes
      distributed by the pharmacies; and
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                                        the weight, measured in pounds, of:
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                                                    liners
                                                               described
                                           inner
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      Subparagraph (i); and
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                                      (b)
                                           returned
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      filled with collected prescription drugs;
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      (C) the amount of money distributed under the pilot program and the identity of each participating pharmacy to
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      which money is distributed; and
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                          (D) a description of the board's educational
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      efforts and outcomes; and
                  (2) recommends whether the pilot program should be expanded, or terminate or whether the board should
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      continue,
      permanently implement a prescription drug safe disposal program.
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                               SUBCHAPTER D. FUNDING
             Sec. 442A.151.
      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
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      Legislature, Regular Session, 2021, may be appropriated to the
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      board to fund the pilot program established under this chapter.
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              (b)
                   The board may collect gifts, grants, and donations to
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      fund the program.
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                              SUBCHAPTER E. EXPIRATION
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              Sec. 442A.201. EXPIRATION. This chapter expires September
      1, 2029.
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             SECTION 2.
                          As soon as practicable after the effective date
      of this Act, the Texas State Board of Pharmacy shall implement the
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      prescription drug safe disposal pilot program developed under
      Chapter 442A, Health and Safety Code, as added by this Act.
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SECTION 3. This Act takes effect September 1, 2023.