HEALTH AND SAFETY CODE

TITLE 6. FOOD, DRUGS, ALCOHOL, AND HAZARDOUS SUBSTANCES

SUBTITLE A. FOOD AND DRUG HEALTH REGULATIONS

CHAPTER 442. DONATION OF PRESCRIPTION DRUGS

SUBCHAPTER A. GENERAL PROVISIONS

Sec. 442.001. DEFINITIONS. In this chapter:

(1) "Donor" means an individual, a prescription drug manufacturer, or a health care facility, including a pharmacy, that donates unused prescription drugs under this chapter to a participating provider.

(2) "Health care facility" means a facility that provides health care services to patients and maintains a pharmacy in the facility. The term includes the following facilities if a pharmacy is maintained in the facility:

(A) a general or special hospital as defined by Chapter 241;

(B) an ambulatory surgical center licensed under Chapter 243; and

(C) an institution licensed under Chapter 242.

(3) "Health care professional" means an individual licensed, certified, or otherwise authorized to administer health care and prescribe prescription drugs, for profit or otherwise, in the ordinary course of business or professional practice. The term does not include a health care facility.

(4) "Participating provider" means a health care facility or pharmacy, or a pharmacist who is an employee of the facility or pharmacy, that elects to participate in the collection and redistribution of donated prescription drugs under this chapter.

(5) "Pharmacist" means a person licensed under Chapter 558, Occupations Code.

(6) "Pharmacy" means an entity licensed under Chapter 560, Occupations Code.

(6-a) "Prepackage" means the act of repackaging and relabeling varying quantities of prescription drugs from a

manufacturer's original commercial container into a prescription container, unit-dose packaging, or a multi-compartment container for a pharmacist to dispense to a consumer.

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

(8) "Recipient" means an individual who voluntarily receives donated prescription drugs under this chapter.

(9) "Tamper-evident" means packaging that allows for detection of unauthorized access to a prescription drug.

Added by Acts 2017, 85th Leg., R.S., Ch. 485 (H.B. 2561), Sec. 7(a), eff. September 1, 2017.

Amended by:

Acts 2023, 88th Leg., R.S., Ch. 761 (H.B. 4331), Sec. 1, eff. September 1, 2023.

Acts 2023, 88th Leg., R.S., Ch. 762 (H.B. 4332), Sec. 1, eff. September 1, 2023.

Sec. 442.002. RULEMAKING AUTHORITY. The executive commissioner may adopt rules to implement this chapter.

Added by Acts 2017, 85th Leg., R.S., Ch. 485 (H.B. 2561), Sec. 7(a), eff. September 1, 2017.

Sec. 442.003. CONSTRUCTION WITH OTHER LAW. This chapter does not limit the authority of this state or a political subdivision of this state to regulate or prohibit a prescription drug.

Added by Acts 2017, 85th Leg., R.S., Ch. 485 (H.B. 2561), Sec. 7(a), eff. September 1, 2017.

SUBCHAPTER B. DONATION AND REDISTRIBUTION OF UNUSED PRESCRIPTION DRUGS

Sec. 442.051. DONATION AND REDISTRIBUTION OF PRESCRIPTION DRUGS. (a) A donor may donate unused prescription drugs to a participating provider in accordance with this chapter and rules adopted under this chapter.

(b) A participating provider may dispense donated

prescription drugs to a recipient in accordance with this chapter and rules adopted under this chapter.

Added by Acts 2017, 85th Leg., R.S., Ch. 485 (H.B. 2561), Sec. 7(a), eff. September 1, 2017.

Sec. 442.0515. REDISTRIBUTION OF DONATED PREPACKAGED PRESCRIPTION DRUGS. (a) A participating provider may dispense to a recipient donated prescription drugs that are prepackaged and labeled in accordance with this section and rules adopted by the Texas State Board of Pharmacy.

(b) A prepackaged prescription drug a participating provider dispenses to a recipient must contain a label that includes:

(1) the drug's brand name or, for a generic version of the drug, the drug's generic name and the manufacturer or distributor of the drug;

(2) the amount of the drug in a given dose;

(3) the drug's lot number;

(4) the earliest expiration date of the drug for that drug lot number; and

(5) the quantity of any drug the provider dispenses in more than one dose.

(c) A participating provider shall maintain a record of each prepackaged prescription drug dispensed to a recipient. The record must include:

(1) the drug's name, the amount of the drug in a given dose, and the dosage size or frequency;

(2) the provider's lot number for that drug;

(3) the drug's manufacturer or distributor;

(4) the manufacturer's lot number for that drug;

(5) the expiration dates of the drug from that drug's lot number;

(6) the quantity of the drug in each prepackaged unit;

(7) the number of prepackaged units that include the drug;

(8) the date the drug was prepackaged;

(9) the name, initials, or written or electronic

signature of the individual who prepackaged the drug; and

(10) the written or electronic signature of the pharmacist responsible for the drug's prepackaging.

Added by Acts 2023, 88th Leg., R.S., Ch. 762 (H.B. 4332), Sec. 2, eff. September 1, 2023.

Sec. 442.052. STANDARDS FOR DONATION AND REDISTRIBUTION. (a) The executive commissioner by rule shall adopt standards and procedures for:

(1) accepting, storing, labeling, and dispensing donated prescription drugs; and

(2) inspecting donated prescription drugs to determine whether the drugs are adulterated and whether the drugs are safe and suitable for redistribution.

(b) In adopting standards and procedures under this section, the executive commissioner shall ensure that the donation and redistribution process is consistent with public health and safety standards.

Added by Acts 2017, 85th Leg., R.S., Ch. 485 (H.B. 2561), Sec. 7(a), eff. September 1, 2017.

Sec. 442.053. REQUIREMENTS FOR DONATED PRESCRIPTION DRUGS. (a) A donated prescription drug may be accepted or dispensed under this chapter only if the drug is in its original, unopened, sealed, and tamper-evident bottle, container, or unit-dose packaging. A drug packaged in single unit doses may be accepted and dispensed if the outside packaging is opened but the single unit-dose packaging is unopened.

(b) A donated prescription drug may not be accepted or dispensed under this chapter if:

(1) the drug is a controlled substance;

(2) the drug is adulterated or misbranded;

(3) the drug is not stored in compliance with the drug's product label; or

(4) the United States Food and Drug Administration requires the drug to have a risk evaluation or mitigation strategy.

(c) A participating provider shall comply with all

applicable provisions of state and federal law relating to the inspection, storage, labeling, and dispensing of prescription drugs.

Added by Acts 2017, 85th Leg., R.S., Ch. 485 (H.B. 2561), Sec. 7(a), eff. September 1, 2017.

Amended by:

Acts 2023, 88th Leg., R.S., Ch. 758 (H.B. 4166), Sec. 1, eff. September 1, 2023.

Sec. 442.054. DONATION PROCESS. (a) Before being dispensed to a recipient, a prescription drug donated under this chapter must be inspected by the participating provider in accordance with federal law, laws of this state, and department rule to determine whether the drug is adulterated or misbranded and whether the drug has been stored in compliance with the requirements of the product label.

(b) A donated prescription drug dispensed to a recipient under this chapter must be prescribed by a health care professional for use by the recipient.

(c) A participating provider may charge a handling fee not to exceed $20 to a recipient to cover the costs of inspecting, storing, labeling, and dispensing the donated prescription drug. A participating provider may not resell a prescription drug donated under this chapter. A donor may not sell a prescription drug to a participating provider.

(d) A participating provider may not submit a claim or otherwise seek reimbursement from any public or private third-party payor for donated prescription drugs dispensed to a recipient under this chapter. A public or private third-party payor is not required to provide reimbursement for donated drugs dispensed to a recipient under this chapter.

Added by Acts 2017, 85th Leg., R.S., Ch. 485 (H.B. 2561), Sec. 7(a), eff. September 1, 2017.

Sec. 442.055. DONOR FORM. Before donating a prescription drug under this chapter, a donor shall sign a form prescribed by the department stating that:

(1) the donor is the owner of the donated prescription drug;

(2) the donated prescription drug has been properly stored and the container has not been opened or tampered with;

(3) the donated prescription drug has not been adulterated or misbranded; and

(4) the donor is voluntarily donating the prescription drug.

Added by Acts 2017, 85th Leg., R.S., Ch. 485 (H.B. 2561), Sec. 7(a), eff. September 1, 2017.

Sec. 442.056. RECIPIENT FORM. Before accepting a donated prescription drug under this chapter, a recipient shall sign a form prescribed by the department stating that:

(1) the recipient acknowledges that if the donor is an individual, prescription drug manufacturer, or health care facility other than a pharmacy, the donor is not a pharmacist and the donor took ordinary care of the prescription drug;

(2) the recipient acknowledges that the donor is known to the participating provider and that there is no reason to believe that the prescription drug was improperly handled or stored;

(3) by accepting the prescription drug, the recipient accepts any risk that an accidental mishandling could create; and

(4) the recipient releases the donor, participating provider, and manufacturer of the drug from liability related to the prescription drug.

Added by Acts 2017, 85th Leg., R.S., Ch. 485 (H.B. 2561), Sec. 7(a), eff. September 1, 2017.

Amended by:

Acts 2023, 88th Leg., R.S., Ch. 761 (H.B. 4331), Sec. 2, eff. September 1, 2023.

Sec. 442.057. LIMITATION OF LIABILITY. (a) A donor or participating provider who acts in good faith in donating, accepting, storing, labeling, distributing, or dispensing prescription drugs under this chapter:

(1) is not criminally liable and is not subject to

professional disciplinary action for those activities; and

(2) is not civilly liable for damages for bodily injury, death, or property damage that arises from those activities unless the injury, death, or damage arises from the donor or participating provider's recklessness or intentional conduct.

(b) A manufacturer of a prescription drug that donates a drug under this chapter is not, in the absence of bad faith, criminally or civilly liable for bodily injury, death, or property damage arising from the donation, acceptance, or dispensing of the drug, including the manufacturer's failure to communicate to a donor or other person:

(1) product or consumer information about the donated prescription drug; or

(2) the expiration date of the donated prescription drug.

Added by Acts 2017, 85th Leg., R.S., Ch. 485 (H.B. 2561), Sec. 7(a), eff. September 1, 2017.

Sec. 442.058. DATABASE OF PARTICIPATING PROVIDERS. The department shall establish and maintain an electronic database that lists each participating provider. The department shall post the database on its Internet website.

Added by Acts 2017, 85th Leg., R.S., Ch. 485 (H.B. 2561), Sec. 7(a), eff. September 1, 2017.