HEALTH AND SAFETY CODE

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

SUBTITLE A. FOOD AND DRUG HEALTH REGULATIONS

CHAPTER 439. MANUFACTURE AND DISTRIBUTION OF CERTAIN DRUGS

SUBCHAPTER A. LAETRILE

Sec. 439.001. DEFINITION. In this chapter, "laetrile" means amygdalin.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

Sec. 439.002. MANUFACTURE AND SALE. Unless prohibited by federal law, laetrile may be manufactured in this state in accordance with Chapter 431 (Texas Food, Drug, and Cosmetic Act) and may be sold in this state for distribution by licensed physicians.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

Amended by:

Acts 2015, 84th Leg., R.S., Ch. 1 (S.B. 219), Sec. 3.1141, eff. April 2, 2015.

Sec. 439.003. PRESCRIPTION AND ADMINISTRATION. (a) Unless prohibited by federal law, a licensed physician may prescribe or administer laetrile in the treatment of cancer.

(b) A physician acting in accordance with federal and state law is not subject to disciplinary action by the Texas Medical Board for prescribing or administering laetrile to a patient under the physician's care who has requested the substance unless that board makes a formal finding that the substance is harmful.

(c) A finding under Subsection (b) must be made in a hearing conducted as provided by Chapter 2001, Government Code.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989. Amended by Acts 1995, 74th Leg., ch. 76, Sec. 5.95(49), eff. Sept. 1, 1995.

Amended by:

Acts 2015, 84th Leg., R.S., Ch. 1 (S.B. 219), Sec. 3.1142, eff. April 2, 2015.

Sec. 439.005. RECORDS; DISCIPLINARY ACTIONS. (a) A physician shall keep records of the physician's purchases and disposals, including sales and dispensations, of laetrile. The records shall include the date of each purchase or disposal by the physician, the name and address of the person receiving laetrile, and the reason for the disposal of laetrile to that person.

(b) The Texas Medical Board may suspend, cancel, or revoke the license of any physician who:

(1) fails to keep complete and accurate records of purchases and disposals of laetrile;

(2) prescribes or dispenses laetrile to a person known to be a habitual user of narcotic or dangerous drugs or to a person who the physician should have known was a habitual user of narcotic or dangerous drugs;

(3) uses any advertising that tends to mislead or deceive the public; or

(4) is unable to practice medicine with reasonable skill and safety to patients because of any mental or physical condition, including age, illness, or drunkenness, or because of excessive use of drugs, narcotics, chemicals, or any other type of material.

(c) Subsection (b)(2) does not apply to a person being treated by the physician for narcotic use after the physician notifies the Texas Medical Board in writing of the name and address of the patient being treated.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

Amended by:

Acts 2015, 84th Leg., R.S., Ch. 1 (S.B. 219), Sec. 3.1143, eff. April 2, 2015.

SUBCHAPTER B. DIMETHYL SULFOXIDE

Sec. 439.011. DEFINITION. In this subchapter, "DMSO" means sterile and pyrogen-free dimethyl sulfoxide.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

Sec. 439.012. MANUFACTURE AND SALE. DMSO may be

manufactured in this state and may be sold in this state for human use when prescribed or administered by a licensed physician or dispensed by a licensed pharmacist as prescribed by a licensed physician.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

Sec. 439.013. PRESCRIPTION, ADMINISTRATION, AND DISPENSATION. (a) Except as prohibited by Subsection (b), a licensed physician may prescribe or administer DMSO.

(b) A physician may not prescribe or administer DMSO in a formulation not approved for human use by the Food and Drug Administration of the United States Department of Health and Human Services unless the physician:

(1) provides a written statement to the patient informing the patient that DMSO, in the formulation to be prescribed or administered, has not been approved for human use by the United States Food and Drug Administration; and

(2) informs the patient of the alternative methods of treatment for the patient's disorder and the potential of alternative methods for cure.

(c) A licensed pharmacist may dispense DMSO on the written prescription of a licensed physician.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

Sec. 439.014. REGULATION BY HEALTH CARE FACILITY. (a) A hospital or health care facility may not forbid or restrict the use of DMSO prescribed or administered by a licensed physician having staff privileges at that hospital or facility unless the hospital or facility:

(1) makes a formal finding that the DMSO as prescribed or administered by the physician is or will be harmful to the patient; or

(2) determines that the prescription or administration of DMSO creates an immediate danger to the public.

(b) A hospital or health care facility that forbids or restricts the use of DMSO under Subsection (a)(2) shall conduct a hearing on the restriction or prohibition as soon as practicable

after its determination.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

Sec. 439.015. RECORDS; DISCIPLINARY ACTIONS. (a) A physician shall keep records of the physician's purchases and disposals, including sales and dispensations, of DMSO. The records shall include the date of each purchase or disposal by the physician, the name and address of the person receiving DMSO, and the reason for the disposal of DMSO to that person.

(b) The Texas Medical Board may suspend, cancel, or revoke the license of any physician who:

(1) fails to keep complete and accurate records of purchases and disposals of DMSO in a formulation not approved for human use; or

(2) prescribes or administers DMSO in a manner that has been proven, in a formal hearing held by the board, to be harmful to the patient.

(c) The Texas Medical Board may temporarily suspend the license of a physician who prescribes or administers DMSO in a manner that, in the board's opinion, creates an immediate danger to the public. The board must conduct a hearing on the temporary suspension as soon as practicable after the suspension.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

Amended by:

Acts 2015, 84th Leg., R.S., Ch. 1 (S.B. 219), Sec. 3.1144, eff. April 2, 2015.

Sec. 439.016. MISREPRESENTATION; CRIMINAL PENALTY. (a) A person commits an offense if, in connection with advertising or promoting the sale of DMSO, the person knowingly or intentionally represents DMSO as a cure for any human disease, ailment, or disorder.

(b) An offense under this section is a Class B misdemeanor.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

Sec. 439.017. RESTRICTIONS ON MANUFACTURE, DISTRIBUTION, AND SALE; CRIMINAL PENALTY. (a) A person commits an offense if the

person manufactures, distributes, or sells a dimethyl sulfoxide formulation that is not sterile and pyrogen-free unless the substance is packaged in a container with a label that includes:

(1) information about the concentration of the dimethyl sulfoxide; and

(2) the following statement: "Avoid contact with your skin. This dimethyl sulfoxide is not sterile and pyrogen-free DMSO approved for human use. It may contain harmful impurities that can be absorbed through the skin. Dimethyl sulfoxide is a potent solvent that may have adverse effects on fabrics, plastics, and other materials."

(b) An offense under this section is a Class B misdemeanor.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

SUBCHAPTER C. PRESERVATION AND DISTRIBUTION OF CERTAIN UNUSED DRUGS

Sec. 439.021. SHIPMENT TO FOREIGN COUNTRIES. (a) A consulting pharmacist of a nursing home may select, from a supply of drugs due for destruction, certain drugs to be used for shipment to a foreign country as provided by this subchapter.

(b) The supply of drugs due for destruction are those drugs accumulated because of the death of a resident of the nursing home or because a physician has ordered the use of the drug to be discontinued.

(c) Quarterly, before the drugs are destroyed, the consulting pharmacist may, in the pharmacist's professional judgment, select the drugs to be used under this subchapter and seal them in a box for shipment.

(d) The consulting pharmacist shall account to the department for all drugs selected for shipment under this subchapter.

(e) This subchapter does not apply if the unused drug is a controlled substance as defined by Chapter 481 (Texas Controlled Substances Act).

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

Amended by:

Acts 2015, 84th Leg., R.S., Ch. 1 (S.B. 219), Sec. 3.1145,

eff. April 2, 2015.

Sec. 439.022. ADMINISTRATION. (a) The executive commissioner shall adopt rules consistent with federal and state law to implement this subchapter, including rules relating to:

(1) the packaging and inventory of drugs for shipment;

(2) the manner of shipment of the drugs from original shipment under this subchapter until the final destination; and

(3) safeguards to ensure the proper handling of and accounting for all drugs shipped.

(b) The executive commissioner by rule shall determine, in consultation with the United States Department of State and other appropriate federal agencies, the foreign countries to receive the drugs.

(c) The salvaging of drugs under this subchapter is not subject to Chapter 431 (Texas Food, Drug, and Cosmetic Act).

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

Amended by:

Acts 2015, 84th Leg., R.S., Ch. 1 (S.B. 219), Sec. 3.1146, eff. April 2, 2015.

Sec. 439.023. CONTRACTS; FUNDS. (a) The department may contract with other entities, including local governments and civic organizations, to implement this subchapter.

(b) The department may accept gifts, grants, and any other funds to implement this subchapter.

Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989.

Amended by:

Acts 2015, 84th Leg., R.S., Ch. 1 (S.B. 219), Sec. 3.1147, eff. April 2, 2015.

SUBCHAPTER D. INSULIN

Sec. 439.101. DEFINITION. In this subchapter, "manufacturer" has the meaning assigned by Section 531.070, Government Code.

Added by Acts 2023, 88th Leg., R.S., Ch. 244 (S.B. 241), Sec. 1,

eff. September 1, 2024.

Sec. 439.102. WRITTEN VERIFICATION REQUIRED FOR BRAND NAME INSULIN DRUG MANUFACTURER. (a) The manufacturer of a brand name insulin prescription drug for which a generic or biosimilar prescription drug is not available and that is included in the Medicaid vendor drug program formulary must submit to the Health and Human Services Commission a written verification stating whether or not the unavailability of the generic or biosimilar prescription drug is the result, wholly or partly, of:

(1) a scheme by the manufacturer to pay a generic or biosimilar prescription drug manufacturer to delay manufacturing or marketing the generic or biosimilar drug;

(2) a legal or business strategy to extend the life of a patent on the brand name prescription drug;

(3) the manufacturer directly manipulating a patent on the brand name prescription drug; or

(4) the manufacturer facilitating an action described by Subdivisions (1)-(3) on behalf of another entity.

(b) The executive commissioner shall adopt rules prescribing the form and manner for submission of the written verification required under Subsection (a).

Added by Acts 2023, 88th Leg., R.S., Ch. 244 (S.B. 241), Sec. 1, eff. September 1, 2024.