

## CHAPTER 135M

## PRESCRIPTION DRUG DONATION REPOSITORY

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**135M.1 Purpose.**

The purpose of this chapter is to improve the health of low-income Iowans and Iowans who have been victims of a state of disaster emergency proclaimed by the governor pursuant to section 29C.6 or a public health disaster as defined in section 135.140, subsection 6, through a prescription drug donation repository that authorizes medical facilities, pharmacies, and the department to redispense prescription drugs and supplies that would otherwise be destroyed.

2005 Acts, ch 97, §1; 2009 Acts, ch 127, §1

**135M.2 Definitions.**

1. “*Anti-rejection drug*” means a prescription drug that suppresses the immune system to prevent or reverse rejection of a transplanted organ.

2. “*Cancer drug*” means a prescription drug that is used to treat any of the following:

a. Cancer or the side effects of cancer.

b. The side effects of any prescription drug that is used to treat cancer or the side effects of cancer.

3. “*Controlled substance*” means the same as defined in section 155A.3.

4. “*Department*” means the Iowa department of public health.

5. “*Indigent*” means a person with an income that is below two hundred percent of the federal poverty level as defined by the most recently revised poverty income guidelines published by the United States department of health and human services.

6. “*Medical facility*” means any of the following:

a. A physician’s office.

b. A hospital.

c. A health clinic.

d. A nonprofit health clinic which includes a federally qualified health center as defined in 42 U.S.C. § 1396d(l)(2)(B); a rural health clinic as defined in 42 U.S.C. § 1396d(l)(1); and a nonprofit health clinic that provides medical care to patients who are indigent, uninsured, or underinsured.

e. A free clinic as defined in section 135.24.

f. A charitable organization as defined in section 135.24.

g. A nursing facility as defined in section 135C.1.

7. “*Pharmacy*” means a pharmacy as defined in section 155A.3.

8. “*Prescription drug*” means the same as defined in section 155A.3, and includes cancer drugs and anti-rejection drugs, but does not include controlled substances.

9. “*Supplies*” means the supplies necessary to administer the prescription drugs donated.

2005 Acts, ch 97, §2

**135M.3 Prescription drug donation repository program authorized.**

1. The department, in cooperation with the board of pharmacy, may establish and maintain a prescription drug donation repository program under which any person may donate prescription drugs and supplies for use by an individual who meets eligibility criteria specified by the department by rule. The department may contract with a third party to implement and administer the program.

2. Donations of prescription drugs and supplies under the program may be made on the

premises of a medical facility or pharmacy that elects to participate in the program and meets the requirements established by the department.

3. The medical facility or pharmacy may charge an individual who receives a prescription drug or supplies a handling fee that shall not exceed an amount established by rule by the department.

4. a. A medical facility or pharmacy that receives prescription drugs or supplies may distribute the prescription drugs or supplies to another eligible medical facility or pharmacy for use pursuant to the program.

b. The department may receive prescription drugs or supplies directly from the prescription drug donation repository contractor and may distribute such prescription drugs and supplies through persons licensed to dispense prescription drugs and supplies to an eligible individual for use by the individual pursuant to the program. The department may receive and distribute such prescription drugs or supplies under this paragraph during or in preparation for a state of disaster emergency proclaimed by the governor pursuant to section 29C.6 or during or in preparation for a public health disaster as defined in section 135.140, subsection 6.

5. Participation in the program shall be voluntary.

2005 Acts, ch 97, §3; 2007 Acts, ch 10, §22; 2009 Acts, ch 127, §2

#### **135M.4 Prescription drug donation repository program requirements.**

1. A prescription drug or supplies may be accepted and dispensed under the prescription drug donation repository program if all of the following conditions are met:

a. The prescription drug is in its original sealed and tamper-evident packaging. However, a prescription drug in a single-unit dose or blister pack with the outside packaging opened may be accepted if the single-unit dose packaging remains intact.

b. The prescription drug bears an expiration date that is more than six months after the date the prescription drug was donated. However, a donated prescription drug bearing an expiration date that is six months or less after the date the prescription drug was donated may be accepted and distributed if the drug is in high demand and can be dispensed for use prior to the drug's expiration date.

c. The prescription drug or supplies are inspected before the prescription drug or supplies are dispensed by a licensed pharmacist employed by or under contract with the medical facility or pharmacy, and the licensed pharmacist determines that the prescription drug or supplies are not adulterated or misbranded.

d. The prescription drug or supplies are prescribed by a health care practitioner for use by an eligible individual and are dispensed by a pharmacist or are dispensed to an eligible individual by the prescribing health care practitioner or the practitioner's authorized agent.

2. A prescription drug or supplies donated under this chapter shall not be resold.

3. a. If a person who donates prescription drugs under this chapter to a medical facility or pharmacy receives a notice from a pharmacy that a prescription drug has been recalled, the person shall inform the medical facility or pharmacy of the recall.

b. If a medical facility or pharmacy receives a recall notification from a person who donated prescription drugs under this chapter, the medical facility or pharmacy shall perform a uniform destruction of all of the recalled prescription drugs in the medical facility or pharmacy.

4. A prescription drug dispensed through the prescription drug donation repository program shall not be eligible for reimbursement under the medical assistance program.

5. The department shall adopt rules establishing all of the following:

a. Requirements for medical facilities and pharmacies to accept and dispense donated prescription drugs and supplies, including all of the following:

(1) Eligibility criteria for participation by medical facilities and pharmacies.

(2) Standards and procedures for accepting, safely storing, and dispensing donated prescription drugs and supplies.

(3) Standards and procedures for inspecting donated prescription drugs to determine if the prescription drugs are in their original sealed and tamper-evident packaging, or if the

prescription drugs are in single-unit doses or blister packs and the outside packaging is opened, if the single-unit dose packaging remains intact.

(4) Standards and procedures for inspecting donated prescription drugs and supplies to determine that the prescription drugs and supplies are not adulterated or misbranded.

b. (1) Eligibility criteria for individuals to receive donated prescription drugs and supplies dispensed by medical facilities and pharmacies under the program. The standards shall prioritize dispensing to individuals who are indigent or uninsured, but may permit dispensing to other individuals if an uninsured or indigent individual is unavailable.

(2) Eligibility criteria for individuals to receive donated prescription drugs and supplies dispensed directly by the department through persons licensed to dispense prescription drugs and supplies. The department shall accept and dispense donated prescription drugs and supplies received from the prescription drug donation repository contractor during or in preparation for a state of disaster emergency proclaimed by the governor pursuant to section 29C.6 or during or in preparation for a public health disaster as defined in section 135.140, subsection 6.

c. Necessary forms for administration of the prescription drug donation repository program, including forms for use by individuals who donate, accept, distribute, or dispense the prescription drugs or supplies under the program.

d. A means by which an individual who is eligible to receive donated prescription drugs and supplies may indicate such eligibility.

e. The maximum handling fee that a medical facility or pharmacy may charge for accepting, distributing, or dispensing donated prescription drugs and supplies under the program.

f. A list of prescription drugs that the prescription drug donation repository program will accept.

2005 Acts, ch 97, §4; 2007 Acts, ch 159, §24; 2008 Acts, ch 1058, §6; 2009 Acts, ch 127, §3

#### **135M.5 Exemption from disciplinary action, civil liability, and criminal prosecution.**

1. A drug manufacturer acting reasonably and in good faith, is not subject to criminal prosecution or civil liability for injury, death, or loss to a person or property for matters related to the donation, acceptance, or dispensing of a prescription drug manufactured by the drug manufacturer that is donated under this chapter, including liability for failure to transfer or communicate product or consumer information or the expiration date of the donated prescription drug.

2. Except as provided in subsection 3, a person including the department or the department's employees, agents, or volunteers, but not a drug manufacturer subject to subsection 1, acting reasonably and in good faith, is immune from civil liability and criminal prosecution for injury to or the death of an individual to whom a donated prescription drug is dispensed under this chapter and shall be exempt from disciplinary action related to the person's acts or omissions related to the donation, acceptance, distribution, or dispensing of a donated prescription drug under this chapter.

3. The immunity and exemption provided in subsection 2 do not extend to any of the following:

a. The donation, acceptance, distribution, or dispensing of a donated prescription drug under this chapter by a person if the person's acts or omissions are not performed reasonably and in good faith.

b. To acts or omissions outside the scope of the program.

2005 Acts, ch 97, §5; 2009 Acts, ch 127, §4

#### **135M.6 Sample prescription drugs.**

This chapter shall not be construed to restrict the use of samples by a physician or other person legally authorized to prescribe drugs under state and federal law during the course of the physician's or other person's duties at a medical facility or pharmacy.

2005 Acts, ch 97, §6; 2005 Acts, ch 179, §119

**135M.7 Resale prohibited.**

This chapter shall not be construed to authorize the resale of prescription drugs by any person.

2005 Acts, ch 97, §7