CHAPTER 2020-23

Committee Substitute for House Bill No. 177

An act relating to the Prescription Drug Donation Repository Program; creating s. 465.1902, F.S.; providing a short title; defining terms; creating the Prescription Drug Donation Repository Program within the Department of Health; specifying the purpose of the program; specifying entities that may participate as repositories; requiring a repository to notify the department of its intent to participate in the program; providing notification requirements; providing a procedure for a repository to withdraw from participation in the program; requiring the department to adopt rules regarding the disposition of prescription drugs and supplies of a withdrawing repository; specifying entities that may donate prescription drugs or supplies under the program; providing criteria and procedures for eligible donations; prohibiting donations to specific patients; providing inspection, inventory, and storage requirements for repositories; requiring inspection of donated prescription drugs and supplies by a licensed pharmacist; requiring a repository to submit its inventory records to the department monthly; authorizing the department to facilitate the redistribution of donated prescription drugs and supplies; authorizing a repository to transfer prescription drugs and supplies to another repository after notifying the department; specifying patients eligible to receive donated prescription drugs and supplies; specifying conditions for dispensing donated prescription drugs and supplies to eligible patients; providing intake collection form requirements; requiring that such form provide certain notice to patients; prohibiting the sale of donated prescription drugs and supplies under the program; requiring repositories to establish a protocol for notifying recipients of a prescription drug recall; providing for destruction of donated prescription drugs under certain circumstances; providing recordkeeping requirements; requiring the department to establish, maintain, and publish a registry of participating repositories and available donated prescription drugs and supplies; requiring the department to publish certain information and forms on its website; providing immunity from civil and criminal liability and professional disciplinary action for program donors and participants under certain circumstances; providing specified immunity to pharmaceutical manufacturers under certain circumstances; requiring the department to adopt rules; amending s. 252.36, F.S.; authorizing the Governor to waive program patient eligibility requirements during a declared state of emergency; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 465.1902, Florida Statutes, is created to read:

<u>465.1902 Prescription Drug Donation Repository Program.—</u>

(1) SHORT TITLE.—This section may be cited as the "Prescription Drug Donation Repository Program Act."

(2) DEFINITIONS.—As used in this section, the term:

(a) "Closed drug delivery system" means a system in which the actual control of the unit-dose medication package is maintained by the facility, rather than by the individual patient.

(b) "Controlled substance" means any substance listed in Schedule II, Schedule III, Schedule IV, or Schedule V of s. 893.03.

(c) "Dispenser" means a health care practitioner who, within the scope of his or her practice act, is authorized to dispense medicinal drugs and who does so under this act.

(d) "Free clinic" means a clinic that delivers only medical diagnostic services or nonsurgical medical treatment free of charge to low-income recipients.

(e) "Health care practitioner" or "practitioner" means a practitioner licensed under this chapter, chapter 458, chapter 459, chapter 461, chapter 463, chapter 464, or chapter 466.

(f) "Indigent" means having a family income during the 12 months preceding the determination of income that is below 200 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.

(g) "Nonprofit health clinic" means a nonprofit legal entity that provides medical care to patients who are indigent, uninsured, or underinsured. The term includes, but is not limited to, a federally qualified health center as defined in 42 U.S.C. s. 1396d(l)(2)(B) and a rural health clinic as defined in 42 U.S.C. s. 1396d(l)(1).

(h) "Nursing home facility" has the same meaning as in s. 400.021.

(i) "Prescriber" means a health care practitioner who, within the scope of his or her practice act, is authorized to prescribe medicinal drugs.

(j) "Prescription drug" has the same meaning as the term "medicinal drugs" or "drugs," as those terms are defined in s. 465.003(8), but does not include controlled substances, cancer drugs donated under s. 499.029, or drugs with an approved United States Food and Drug Administration risk evaluation and mitigation strategy that includes elements to assure safe use.

(k) "Program" means the Prescription Drug Donation Repository Program created by this section.

(l) "Supply" means a material or an instrument used to administer a prescription drug.

(m) "Tamper-evident packaging" means a package that has one or more indicators or barriers to access which, if breached or missing, can reasonably be expected to provide visible evidence to consumers that tampering has occurred. The term includes, but is not limited to, unopened unit-dose packaging, multiple-dose packaging, and medications with a seal on their immediate, outer, secondary, or tertiary packaging.

(n) "Underinsured" means having health care coverage or prescription drug coverage, but having exhausted these benefits or not having prescription drug coverage for the drug prescribed.

(o) "Uninsured" means not having health care coverage and being ineligible for prescription drug coverage under a program funded in whole or in part by the Federal Government.

(3) PRESCRIPTION DRUG DONATION REPOSITORY PROGRAM; CREATION; PURPOSE.—The Prescription Drug Donation Repository Program is created within the department to facilitate the donation of prescription drugs and supplies to eligible patients.

(4) REPOSITORIES.—

(a) A repository may accept and dispense eligible donations to eligible patients under the program. The repository must inspect, store, and dispense donations and report to the department in accordance with this section.

(b) The following entities may participate as a repository:

1. A health care practitioner's office.

2. A pharmacy.

3. A hospital with a closed drug delivery system.

4. A nursing home facility with a closed drug delivery system.

5. A free clinic or nonprofit health clinic that is licensed or permitted to dispense medicinal drugs in the state.

(c) An eligible entity must notify the department of its intent to participate in the program as a repository before accepting or dispensing any donations under the program. The notification must be made on a physical or an electronic form prescribed by the department in rule and must, at a minimum, include:

1. The name, street address, website, and telephone number of the intended repository and any license or registration number issued by the state to the intended repository, including the name of the issuing agency.

2. The name and telephone number of the pharmacist employed by or under contract with the intended repository who is responsible for the inspection of donated prescription drugs and supplies.

3. A signed and dated statement by the responsible pharmacist affirming that the intended repository meets the eligibility requirements of this subsection.

(d) A repository may withdraw from participation in the program at any time by providing written notice to the department, as appropriate, on a physical or an electronic form prescribed by the department in rule. The department shall adopt rules addressing the disposition of prescription drugs and supplies in the possession of the withdrawing repository.

(5) ELIGIBLE DONORS.—The following entities may donate prescription drugs or supplies to a repository under the program:

(a) Nursing home facilities with closed drug delivery systems.

(b) Hospices that have maintained control of a patient's prescription drugs.

(c) Hospitals with closed drug delivery systems.

(d) Pharmacies.

(e) Drug manufacturers or wholesale distributors.

(f) Medical device manufacturers or suppliers.

(g) Prescribers who receive prescription drugs or supplies directly from a drug manufacturer, wholesale distributor, or pharmacy.

(6) ELIGIBLE DONATIONS; DONATION REQUIREMENTS; PROHIBITED DONATIONS.—

(a) An eligible donor may only donate a prescription drug to a repository if:

1. The drug is approved for medical use in the United States.

2. The drug is in unopened, tamper-evident packaging.

3. The drug requires storage at normal room temperature per the manufacturer or federal storage requirements.

4. The drug has been stored according to manufacturer or federal storage requirements.

5. The drug does not have any physical signs of tampering or adulteration and there is no reason to believe that the drug is adulterated.

6. The packaging does not have any physical signs of tampering, misbranding, deterioration, compromised integrity, or adulteration.

7. The packaging indicates the expiration date of the drug. If the lot number is not retrievable, all specified medications must be destroyed in the event of a recall.

8. The drug has an expiration date that is more than 3 months after the date on which the drug was donated.

(b) An eligible donor may donate a prescription drug or supply to a repository only if it is in unopened, tamper-evident packaging.

(c) Donations must be made on the premises of a repository to a person designated by the repository. A drop box may not be used to accept donations.

(d) A prescription drug or supply may not be donated to a specific patient.

(7) INSPECTION AND STORAGE.—

(a) Upon receipt of a proposed donation, a licensed pharmacist employed by or under contract with a repository shall inspect the donation to determine whether it meets the requirements of subsections (5) and (6). The repository shall quarantine a donation until such inspection is complete and the donation is approved for dispensing.

(b) The inspecting pharmacist must sign an inspection record on a physical or an electronic form prescribed by the department in rule which verifies that the prescription drug or supply meets the criteria of subsections (5) and (6) and must attach the record to the inventory required in paragraph (d). A repository that receives prescription drugs and supplies from another repository is not required to reinspect such drugs and supplies.

(c) A repository shall store donations in a secure storage area under the environmental conditions specified by the manufacturer or federal storage requirements. Donations may not be stored with other inventory.

(d) A repository shall maintain an inventory of the name, strength, available quantity, and expiration date of donations; the transaction date; and the name, street address, and telephone number of the donor. The repository shall record such inventory on a physical or an electronic form prescribed by the department in rule.

(e) By the 5th day of each month, a repository shall submit to the department its inventory records of donations received during the previous month.

(f) The department may facilitate the redistribution of donations between repositories. A repository that receives donations may, after notifying the department, distribute the donations to another repository.

(8) ELIGIBLE PATIENTS; DISPENSING REQUIREMENTS; PATIENT NOTICE; PROHIBITIONS.—

(a) A repository may dispense an eligible donation to a state resident who is indigent, uninsured, or underinsured, and who has a valid prescription for such donation, as applicable.

(b) Each new eligible patient must submit an intake collection form to a repository to receive a donation using a physical or an electronic form prescribed by the department in rule. Such form shall, at a minimum, include:

1. The name, street address, and telephone number of the eligible patient.

2. The basis for the patient's eligibility, which must specify that the patient is indigent, uninsured, or underinsured.

3. A statement physically or electronically signed and dated by the patient affirming that the patient meets the eligibility requirements of this section and will inform the repository if the patient's eligibility changes.

4. Notice that the prescription drug or supply was donated to the program, that the donors and participants in the program are immune from civil or criminal liability or disciplinary action, and that the eligible patient is not required to pay for the prescription drug or supply.

5. A statement physically or electronically signed and dated by the eligible patient acknowledging receipt of notice required under this paragraph.

(c) By the 5th day of each month, a repository shall submit to the department a summary of each intake collection form obtained during the previous month.

(d) A dispenser may dispense donations, if available, only to an eligible patient who has submitted a completed intake collection form.

(e) A dispenser may provide dispensing and consulting services to an eligible patient.

(f) Donations may not be sold or resold.

(g) A dispenser may not submit a claim or otherwise seek reimbursement from any public or private third-party payor for donations.

(9) RECALLED PRESCRIPTION DRUGS.—

(a) Each repository shall establish and follow a protocol for notifying recipients in the event that a prescription drug donated under the program is recalled.

(b) A repository shall destroy all donated prescription drugs that are recalled, expired, or unsuitable for dispensing. A repository must complete a destruction form for all such drugs using a physical or an electronic form prescribed by the department in rule.

(10) RECORDKEEPING.—

(a) A repository shall maintain records of prescription drugs and supplies that are accepted, donated, dispensed, distributed, or destroyed under the program using a physical or an electronic form prescribed by the department in rule.

(b) All required records must be maintained in accordance with any applicable practice act. A repository shall submit these records monthly to the department for data collection.

(11) REGISTRIES; PUBLICATION OF FORMS.—

(a) The department shall establish and maintain registries of all repositories and prescription drugs and supplies available under the program. The registry of repositories must include each repository's name, street address, website, and telephone number. The registry of available prescription drugs and supplies must include the name, strength, available quantity, and expiration date of the prescription drugs or supplies and the name and contact information of each repository where such drugs or supplies are available. The department shall publish the registries on its website.

(b) The department shall publish all forms required by this section on its website.

(12) IMMUNITY FROM LIABILITY; DISCIPLINARY ACTION.—

(a) Any donor of prescription drugs or supplies and any participant in the program who exercises reasonable care in donating, accepting, distributing, or dispensing prescription drugs or supplies under the program is immune from civil or criminal liability and professional disciplinary action by the state for any injury, death, or loss to person or property relating to such activities.

(b) A pharmaceutical manufacturer who exercises reasonable care is not liable for any claim or injury arising from the donation of any prescription drug or supply under this section, including, but not limited to, liability for failure to transfer or communicate product or consumer information regarding the donated prescription drug or supply, including its expiration date.

(13) RULEMAKING.—The department shall adopt rules necessary to administer this section.

Section 2. Paragraph (o) is added to subsection (5) of section 252.36, Florida Statutes, to read:

252.36 Emergency management powers of the Governor.—

(5) In addition to any other powers conferred upon the Governor by law, she or he may:

(o) Waive the patient eligibility requirements of s. 465.1902.

Section 3. This act shall take effect July 1, 2020.

Approved by the Governor June 9, 2020.

Filed in Office Secretary of State June 9, 2020.