By the Committee on Health Policy; and Senator Book

588-02164-19 2019104c1

A bill to be entitled

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; authorizing the department to contract with a third-party vendor to administer the program; specifying entities that are eligible donors; authorizing certain local repositories to accept a donation from specified persons under certain conditions; prohibiting a centralized repository or a local repository from accepting donations from unauthorized donors; providing criteria and procedures for eligible donations; prohibiting donations to specific patients; providing that certain prescription drugs eligible for return to stock must be credited to Medicaid and may not be donated under the program; prohibiting the donation of certain drugs pursuant to federal restrictions; clarifying that a repository is not required to accept donations of prescription drugs or supplies; providing inspection, inventory, and storage requirements for centralized and local repositories; requiring inspection of donated prescription drugs and supplies by a licensed pharmacist; requiring a local repository to notify the centralized repository within a specified timeframe after receiving a donation of prescription drugs or supplies; authorizing the centralized repository to

redistribute prescription drugs or supplies; authorizing a local repository to transfer prescription drugs or supplies to another local repository with authorization from the centralized repository; requiring a local repository to notify the department of its intent to participate in the program; providing notification requirements; providing a procedure for a local 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 local repository; specifying conditions for dispensing donated prescription drugs and supplies to eligible patients; providing intake collection form requirements; requiring a local repository to issue an eligible patient who completes an intake collection form a program identification card; prohibiting the sale of donated prescription drugs and supplies under the program; authorizing a repository to charge the patient a nominal handling fee for the preparation and dispensing of prescription drugs or 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 centralized repository to submit an annual report to the department; requiring the department or contractor to establish, maintain, and publish a registry of

participating local 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 from professional disciplinary action for participants under certain circumstances; providing immunity to pharmaceutical manufacturers, under certain circumstances, from any claim or injury arising from the donation of any prescription drug or supply under the program; requiring dispensers to provide certain notice to patients; authorizing the department to establish a direct-support organization to provide assistance, funding, and promotional support for program activities; providing organizational requirements for a direct-support organization; specifying direct-support organization purposes and objectives; prohibiting the direct-support organization from lobbying; specifying that the direct-support organization is not a lobbying firm; prohibiting the direct-support organization from possessing prescription drugs on behalf of the program; providing limitations on expenditures of such direct-support organizations; specifying that the direct-support organization must operate under contract with the department; specifying required contract terms; providing for the direct-support organization board of directors; specifying the board's membership requirements; specifying requirements and requiring the department to adopt

rules relating to a direct-support organization's use of department property; specifying requirements for the deposit and use of funds by the direct-support organization; providing for annual audits of a direct-support organization; providing for future legislative review and repeal of provisions relating to the direct-support organization; 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:

465.1902 Prescription Drug Donation Repository Program.—

(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) "Centralized repository" means a distributor permitted under chapter 499 who is approved by the department or the contractor to accept, inspect, inventory, and distribute donated drugs and supplies under this section.

(b) "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.

(c) "Contractor" means the third-party vendor approved by

the department to implement and administer the program as authorized in subsection (4).

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

(e) "Direct-support organization" means the entity created under subsection (15).

(f) "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.

(g) "Donor" means an entity specified in subsection (5).

(h) "Eligible patient" means a Florida resident who is indigent, uninsured, or underinsured and who has a valid prescription for a prescription drug or supply that may be dispensed under the program.

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

(j) "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.

(k) "Indigent" means an individual whose family income for the 12 months preceding the determination of income 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.

(l) "Local repository" means a health care practitioner's office, a pharmacy, a hospital with a closed drug delivery system, a nursing home facility with a closed drug delivery

system, or a free clinic or nonprofit health clinic that is licensed or permitted to dispense medicinal drugs in the state.

(m) "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).

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

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

(p) "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 or cancer drugs donated under s. 499.029.

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

(r) "Supplies" means any supply used in the administration of a prescription drug.

(s) "Tamper-evident packaging" means a package that has one or more indicators or barriers to entry which, if breached or missing, can reasonably be expected to provide visible evidence to consumers that tampering has occurred.

(t) "Underinsured" means a person who has third-party insurance or is eligible to receive prescription drugs or supplies through the Medicaid program or any other prescription drug program funded in whole or in part by the Federal

Government, but who has exhausted these benefits or does not have prescription drug coverage for the drug prescribed.

(u) "Uninsured" means a person who has no third-party insurance and is not eligible to receive prescription drugs or supplies through the Medicaid program or any other prescription drug 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 for the purpose of authorizing and facilitating the donation of prescription drugs and supplies to eligible patients.

(4) PROGRAM IMPLEMENTATION; ADMINISTRATION.—The department may contract with a third-party vendor to administer the program.

(5) DONOR ELIGIBILITY.—

(a) The centralized repository or a local repository may accept a donation of a prescription drug or supply from:

1. Nursing home facilities with closed drug delivery systems.

2. Hospices that have maintained control of a patient's prescription drugs.

3. Hospitals with closed drug delivery systems.

4. Pharmacies.

5. Drug manufacturers or wholesale distributors.

6. Medical device manufacturers or suppliers.

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

(b) In addition to the donors specified in paragraph (a), a local repository that qualifies as a free clinic or nonprofit health clinic may accept a donation from a patient or a patient's legal representative or next of kin if the following requirements are met:

1. An affidavit, in a format approved by the department, signed by the donor must accompany the donation, identify the prescribing health care practitioner, and attest to the authenticity of the prescription drug or medical supply being donated;

2. The prescription drug or medical supply being donated is in its original tamper-evident packaging, in accordance with subparagraph (6)(b)1., and does not have any physical signs of tampering, misbranding, deterioration, compromised integrity, or adulteration;

3. Any drug being donated has an expiration date that is more than 3 months after the date of the donation; and

4. A licensed pharmacist inspects the prescription drug or medical supply and can attest to the authenticity of the donated prescription drug or medical supply and that it meets the requirements of this paragraph.

Prescription drugs and supplies accepted under this paragraph are exempt from subparagraph (6)(b)3. but are subject to all other applicable requirements of subsections (6) and (7).

(c) Donations of prescription drugs or supplies may not be accepted by the centralized repository or a local repository from any donor not authorized under this subsection.

(6) PRESCRIPTION DRUGS AND SUPPLIES ELIGIBLE FOR DONATION;

DONATION REQUIREMENTS; PROHIBITED DONATIONS.—

(a) Only prescription drugs and supplies that have been approved for medical use in the United States and that meet the criteria for donation established by this section may be accepted for donation under the program. Donations must be made on the premises of the centralized repository or a local repository to a person designated by the repository. A drop box may not be used to accept donations.

(b) The centralized repository or a local repository may accept a prescription drug only if:

1. The drug is in its original sealed and tamper-evident packaging. Single-unit-dose drugs may be accepted if the single-unit-dose packaging is unopened.

2. The drug requires storage at normal room temperature per the manufacturer or the United States Pharmacopeia.

3. The drug has been stored according to manufacturer or United States Pharmacopeia storage requirements.

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

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

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

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

(c) The centralized repository or a local repository may accept supplies only if they are in their original, unopened, sealed packaging and have not been tampered with or misbranded.

(d) Prescription drugs or supplies may not be donated to a specific patient.

(e) Prescription drugs billed to and paid for by Medicaid in long-term care facilities which are eligible for return to stock under federal Medicaid regulations must be credited to Medicaid and may not be donated under the program.

(f) Prescription drugs with an approved Federal Food and Drug Administration Risk Evaluation and Mitigation Strategy that includes Elements to Assure Safe Use are not eligible for donation under the program.

(g) This section does not require the centralized repository or a local repository to accept a donation of prescription drugs or supplies.

(7) INSPECTION AND STORAGE.—

(a) A licensed pharmacist employed by or under contract with the centralized repository or a local repository shall inspect donated prescription drugs and supplies to determine whether they meet the requirements of subsections (5) and (6).

(b) The inspecting pharmacist must sign an inspection record on a form prescribed by the department by rule which verifies that the prescription drugs and supplies meet the criteria of subsections (5) and (6) and must attach the record to the inventory required by paragraph (d). A local repository that receives drugs and supplies from the centralized repository is not required to reinspect them.

(c) The centralized repository and local repositories shall

store donated prescription drugs and supplies in a secure storage area under the environmental conditions specified by the manufacturer or the United States Pharmacopeia for the respective prescription drugs or supplies. Donated prescription drugs and supplies may not be stored with other inventory. A local repository shall quarantine donated prescription drugs or supplies until they are inspected and approved for dispensing under this section.

(d) The centralized repository and local repositories shall maintain an inventory of all donated prescription drugs or supplies. Such inventory at local repositories shall be recorded on a form prescribed by the department by rule.

(e) A local repository shall notify the centralized repository within 5 days after receipt of any donation of prescription drugs or supplies to the program. The notification must be on a form prescribed by the department by rule.

(f) The centralized repository may redistribute prescription drugs and supplies by transferring them to or from the centralized repository and a local repository, as needed. A local repository that receives donated prescription drugs or supplies may, with authorization from the centralized repository, distribute the prescription drugs or supplies to another local repository.

(8) PROGRAM PARTICIPATION.—

(a) A practitioner, pharmacy, facility, or clinic must notify the department of its intent to participate in the program as a local repository before accepting or dispensing any prescription drugs or supplies pursuant to this section. The notification must be made on a form prescribed by the department

by rule and must, at a minimum, include:

1. The name, street address, website, and telephone number of the intended local repository and any license or registration number issued by the state to the intended local 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 local 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 local repository meets the eligibility requirements of this section.

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

(9) DISPENSING REQUIREMENTS; PROHIBITIONS.—

(a) Each eligible patient without a program identification card must submit an intake collection form to a local repository before receiving prescription drugs or supplies under the program. The department shall prescribe a form by rule, which must include at least all of the following:

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

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

3. A statement signed and dated by the eligible patient

affirming that he or she meets the eligibility requirements of this section.

(b) Upon receipt of a completed and signed intake collection form, the local repository shall issue him or her a program identification card, which is valid for 1 year after its date of issuance. The card must be in a form prescribed by the department by rule.

(c) The local repository shall send a summary of each intake collection form to the centralized pharmacy within 5 days after receiving it.

(d) A dispenser may dispense donated prescription drugs or supplies only to an eligible patient who has a program identification card or who has submitted a completed intake collection form.

(e) A dispenser shall inspect the donated prescription drugs or supplies before dispensing them.

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

(g) Donated prescription drugs and supplies may not be sold or resold under the program.

(h) A dispenser of donated prescription drugs or supplies may not submit a claim or otherwise seek reimbursement from any public or private third-party payor for donated prescription drugs or supplies dispensed under this program. However, a repository may charge the patient a nominal handling fee, established by department rule, for the preparation and dispensing of prescription drugs or supplies under the program.

(10) RECALLED PRESCRIPTION DRUGS AND SUPPLIES.—

(a) The centralized repository and each local repository

shall establish and follow a protocol for notifying recipients in the event of a prescription drug recall.

(b) Local repositories shall destroy all recalled or expired prescription drugs and all prescription drugs that are not suitable for dispensing in the repository. Local repositories must complete a destruction information form for all such drugs, in accordance with department rule.

(11) RECORDKEEPING.—

(a) Local repositories shall maintain records of prescription drugs and supplies that are accepted, donated, dispensed, distributed, or destroyed under the program.

(b) All required records must be maintained in accordance with any applicable practice act. Local repositories shall submit these records quarterly to the centralized repository for data collection, and the centralized repository shall submit these records and the collected data in annual reports to the department.

(12) REGISTRIES; PUBLICATION OF FORMS.—

(a) The department or contractor shall establish and maintain registries of all local repositories and of prescription drugs and supplies available under the program. The registry of local repositories must include each repository's name, 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 drug or supplies and the name and contact information of each repository where such drug 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.

(13) 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 from 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, including its expiration date.

(14) NOTICE TO PATIENTS.—Before dispensing a donated prescription drug under the program, the dispenser must provide written notification to the eligible patient or his or her legal representative, receipt of which must be acknowledged in writing, of all of the following information:

(a) The prescription drug was donated to the program.

(b) The donors and participants in the program are immune from civil or criminal liability or disciplinary action.

(c) The eligible patient is not required to pay for the prescription drug, but may be required to pay a nominal handling fee, which may not exceed the amount established by department rule.

(15) DIRECT-SUPPORT ORGANIZATION.—The department may

establish a direct-support organization to provide assistance, funding, and promotional support for the activities authorized under the act.

(a) *Entity organization.*—The direct-support organization must operate in accordance with s. 20.058 and is:

1. A Florida corporation not for profit incorporated under chapter 617, exempted from filing fees, and approved by the Department of State.

2. Organized and operated to conduct programs and activities; raise funds and request and receive grants, gifts, and bequests of moneys; acquire, receive, hold, and invest, in its own name, securities, funds, objects of value, or other property, either real or personal; and make expenditures or provide funding to or for the direct or indirect benefit of the program.

(b) *Purposes and objectives.*—The purposes and objectives of the direct-support organization must be consistent with the goals of the department, in the best interest of the state, and in accordance with the adopted goals and the mission of the department.

(c) *Prohibition against lobbying.*—The direct-support organization is not considered a lobbying firm, as that term is defined in s. 11.045(1). All expenditures of the direct-support organization must be directly related to program administration within the requirements of this section. Funds of the direct-support organization may not be used for the purpose of lobbying, as that term is defined in s. 11.045(1).

(d) *Possession of prescription drugs.*—The direct-support organization may not possess any prescription drugs on behalf of

the program.

(e) *Contract.*—The direct-support organization shall operate under a written contract with the department.

1. The contract must require the direct-support organization to submit to the department, annually by August 1, the following information, which must be posted on the websites of the direct-support organization and the department:

a. The articles of incorporation and bylaws of the direct-support organization, as approved by the department.

b. A proposed annual budget for the approval of the department.

c. The code of ethics of the direct-support organization.

d. The statutory authority or executive order that created the direct-support organization.

e. A brief description of the direct-support organization's mission and any results obtained by the direct-support organization.

f. A brief description of the direct-support organization's annual plan for each of the next 3 fiscal years.

g. A copy of the direct-support organization's most recent federal Internal Revenue Service Return Organization Exempt from Income Tax form (Form 990).

h. Certification by the department that the direct-support organization is complying with the terms of the contract and operating in a manner consistent with the goals and purposes of the department and the best interest of the program and the state. Such certification must be made annually and reported in the official minutes of a meeting of the board of directors of the direct-support organization.

2. The contract must, at a minimum, provide for:

a. The reversion without penalty to the department, or to the state if the department ceases to exist, of all moneys and property held in trust by the direct-support organization for the benefit of the program if the direct-support organization ceases to exist or if the contract is terminated.

b. A disclosure of material provisions of the contract and the distinction between the department and the direct-support organization to appear on all promotional and fundraising publications.

c. A list of prescription drugs solicited by the direct-support organization for distribution to the centralized repository or a local repository.

(f) *Board of directors.*—The State Surgeon General shall appoint the board of directors, which must consist of at least 5 members, but not more than 15 members, who serve at his or her pleasure. The board must elect a chair from among its members. Board members must serve without compensation but may be entitled to reimbursement of travel and per diem expenses in accordance with s. 112.061, if funds are available for this purpose.

(g) *Use of property.*—The department may allow, without charge, appropriate use of fixed property, facilities, and personnel services of the department by the direct-support organization for purposes related to the program. For purposes of this paragraph, the term "personnel services" includes full-time or part-time personnel, as well as payroll processing services.

1. The department may prescribe any condition with which

the direct-support organization must comply in order to use fixed property or facilities of the department.

2. The department may not allow the use of any fixed property or facilities of the department by the direct-support organization if the organization does not provide equal membership and employment opportunities to all persons regardless of race, color, religion, sex, age, or national origin.

3. The department shall adopt rules prescribing the procedures by which the direct-support organization is governed and any conditions with which a direct-support organization must comply to use property or facilities of the department.

(h) *Deposit of funds.*—Any moneys of the direct-support organization may be held in a separate depository account in the name of the organization and subject to the provisions of the organization's contract with the department.

(i) *Use of funds.*—Funds designated for the direct-support organization must be used for the enhancement of program projects and in a manner consistent with that purpose. Any administrative costs of running and promoting the purposes of the organization or program must be paid by private funds.

(j) *Audit.*—The direct-support organization shall provide for an annual financial audit in accordance with s. 215.981.

(k) *Repeal.*—This subsection is repealed on October 1, 2024, unless reviewed and saved from repeal by the Legislature.

(16) RULEMAKING.—The department shall adopt rules necessary to administer this section. When applicable, the rules may provide for the use of electronic forms, recordkeeping, and meeting by teleconference.

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, 2019.