Proposed Committee Substitute by the Committee on Appropriations
(Appropriations Subcommittee on Health and Human Services)

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; creating the Prescription
Drug Donation Repository Program within the Department
of Health; providing purpose; authorizing the
department to contract with a third party to implement
and administer the program; providing definitions;
specifying entities that are eligible donors;
providing criteria for eligible donations; prohibiting
donations to specific patients; providing that certain
prescription drugs eligible for return to stock must
be credited to Medicaid under specified conditions and
are not program eligible; prohibiting the donation of
certain drugs pursuant to federal restrictions;
authorizing repositories to refuse 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 a
centralized repository to redistribute prescription
drugs or supplies; requiring local repositories to
notify the department regarding participation in the
program; providing conditions for dispensing donated
prescription drugs and supplies to eligible patients;
requiring repositories to establish a protocol for
notifying recipients of a prescription drug recall;
providing for destruction of donated prescription
drugs in the event of a drug recall; providing
recordkeeping requirements; requiring the department
to maintain and publish a registry of participating
local repositories and available donated prescription
drugs and supplies; specifying certain notice to
patients; providing immunity from civil and criminal
liability for participants under certain
circumstances; authorizing the department to establish
a direct-support organization to provide assistance
funding and promotional support for program
activities; specifying direct-support organization
purposes and objectives; prohibiting such direct-
support organization from lobbying and specifying that
such direct-support organization is not a lobbying
firm; 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 membership of such board; specifying
requirements relating to a direct-support
organization’s use of department property; specifying
requirements for the deposit of funds by the direct-
support organization; providing for audits of a
direct-support organization; specifying a repeal,
unless reviewed and saved from repeal by the Legislature on a specified date; requiring the department to adopt rules; amending s. 252.36, F.S.; authorizing the Governor to waive the patient eligibility requirements of s. 465.1902, F.S., 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) PRESCRIPTION DRUG DONATION REPOSITORY PROGRAM.—The Prescription Drug Donation Repository Program is created within the Department of Health for the purpose of authorizing and facilitating the donation of prescription drugs and supplies to eligible patients. The department may contract with a third party to implement and administer the program.

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

(a) “Centralized repository” means a distributor permitted pursuant to chapter 499 which 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
(c) “Contractor” means the third-party vendor approved by the department to implement and administer the program.

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

(e) “Department” means Department of Health.

(f) “Direct-support organization” means an entity that is established pursuant to 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.

(g) “Dispenser” means a dispensing health care practitioner or pharmacist licensed to dispense medicinal drugs in the state.

(h) “Donor” means an entity that meets the requirements of subsection (4).

(i) “Eligible patient” means a Florida resident who is indigent, uninsured, or underinsured and has a valid prescription for a prescription drug or supply that is eligible for dispensing under the program.

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

(k) “Health care practitioner” or “practitioner” means a practitioner licensed under chapter 458, chapter 459, chapter 461, chapter 463, chapter 464, chapter 465, or chapter 466.

(l) “Indigent” means a person with an 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.

(m) “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, a free clinic, or a nonprofit health clinic that is licensed or permitted to dispense medicinal drugs in the state.

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

(o) “Nursing home facility” has the same meaning as in s. 400.021(12).

(p) “Prescriber” means a prescribing physician, prescribing practitioner, or other health care practitioner authorized by the laws of this state to prescribe medicinal drugs.

(q) “Prescription drug” has the same meaning as defined in s. 465.003(8), but does not include controlled substances or cancer drugs donated under s. 499.029.

(r) “Program” means the Prescription Drug Donation Repository Program created by this section.
(s) “Supplies” means any supply used in the administration of a prescription drug.

(t) “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.

(u) “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 has exhausted these benefits or does not have prescription drug coverage for the drug prescribed.

(v) “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.

(4) DONOR ELIGIBILITY.—The program may only accept a donation of a prescription drug or supply from:

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

(b) Hospices that have maintained control of a patient’s prescription drug.

(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.

(5) PRESCRIPTION DRUGS AND SUPPLIES ELIGIBLE FOR DONATION.—

(a) All prescription drugs and supplies that have been approved for medical use in the United States and meet the criteria for donation established by this section may be accepted for donation under the program.

(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 contains 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 central repository or a local repository may only accept supplies that are in their original, unopened, sealed
packaging and have not been adulterated or misbranded.

(d) Prescription drugs and supplies may be donated 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.

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

(f) 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 are not eligible for donation under the program.

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

(h) Nothing in this section requires the central repository or a local repository to accept a donation of a prescription drug or supplies.

(6) 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 the donated prescription drugs or supplies:

1. Are eligible for donation under the program;
2. Have been adulterated or misbranded; and
3. Are safe and suitable for dispensing.

(b) The pharmacist who inspects the donated prescription drugs or supplies shall sign an inspection record on a form prescribed by the department and adopted in rule verifying that
the criteria of paragraph (a) have been met and attach such record to the copy of the inventory record. If a local repository receives drugs and supplies from the centralized repository, the local repository is not required to reinspect the drugs and supplies.

(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 United States Pharmacopeia for the prescription drugs or supplies being stored. Donated prescription drugs and supplies may not be stored with nondonated inventory. A local repository shall quarantine any donated prescription drugs or supplies from all dispensing stock until the donated prescription drugs or supplies are inspected and approved for dispensing under the program.

(d) A local repository shall maintain an inventory of all donated prescription drugs or supplies it receives. Such inventory shall be recorded on a form prescribed by the department and adopted in 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 shall be on a form prescribed by the department and adopted by rule.

(f) The centralized repository shall maintain an inventory of all prescription drugs and supplies donated to the program.

(g) The centralized repository may redistribute prescription drugs and supplies to facilitate dispensing to either the centralized repository or to a local repository, as
(7) LOCAL REPOSITORY NOTICE OF PARTICIPATION.—

(a) A local repository must notify the department of its intent to participate in the program before accepting or dispensing any prescription drugs or supplies pursuant to this section. The notification shall be on a form prescribed by the department and adopted by rule and must, at a minimum, include:

1. The name, street address, website, and telephone number of the local repository and any state-issued license or registration number issued to the 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 local repository who is responsible for the inspection of donated prescription drugs and supplies.

3. A statement signed and dated by the responsible pharmacist affirming that the 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 on a form prescribed by the department and adopted by rule. The department shall adopt rules addressing the disposition of any prescription drugs in the possession of the local repository.

(8) DISPENSING.—

(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 form shall be prescribed by the department and
adopted by rule and, at a minimum, must include:

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) A local repository shall collect a signed and dated intake collection form from each eligible patient receiving prescription drugs or supplies under the program. The local repository must issue a program identification card upon receipt of a duly executed intake collection form. The program identification card is valid for 1 year after issuance and must be in a form prescribed by the department and adopted in rule.

(c) A local repository must send a summary of the intake collection form data to the centralized pharmacy within 5 days after receipt of a duly executed intake collection form.

(d) A dispenser may only dispense a donated prescription drug or supplies, if available, to an eligible patient with a program identification card or a duly executed intake collection form.

(e) A dispenser shall inspect the donated prescription drugs or supplies prior to dispensing such drugs or supplies.

(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 this 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 to any patient under this program. However, a repository may charge a nominal handling fee, established by department rule, for the preparation and dispensing of prescription drugs or supplies under the program.

(i) 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.

(9) RECALL AND DESTRUCTION OF PRESCRIPTION DRUGS AND SUPPLIES.—

(a) The centralized repository and a local repository shall be responsible for drug recalls and shall have an established protocol to notify recipients in the event of a prescription drug recall.

(b) Local repositories shall destroy all of the recalled or expired prescription drugs or prescription drugs that are not suitable for dispensing in the repository and complete a destruction information form for all donated prescription drugs destroyed, in accordance with rules adopted by the department.

(10) RECORDKEEPING.—

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

(b) All records required to be maintained as a part of the program shall be maintained in accordance with any applicable practice acts. 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.

(11) REGISTRIES AND FORMS.—

(a) The department shall establish and maintain registries
of all local repositories and available drugs and supplies under
the program. The registry of local repositories must include the
repository’s name, address, website, and telephone number. The
registry of available drugs and supplies must include the name,
strength, available quantity, and expiration date of the drug or
supply and the name and contact information of the repositories
where such drug or supply is 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.—

(a) Any donor of prescription drugs or supplies, or any
participant in the program, who exercises reasonable care in
donating, accepting, distributing, or dispensing prescription
drugs or supplies under the program, and the rules adopted
pursuant thereto, is immune from civil or criminal liability and
from professional disciplinary action of any kind 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
transfer of any prescription drug under this section, including
but not limited to, liability for failure to transfer or
communicate product or consumer information regarding the
transferred drug, including the expiration date of the
transferred drug.

(13) NOTICE TO PATIENTS.—Before dispensing a prescription drug that has been donated under this program, the dispenser must provide written notification to the patient, or to his or her legal representative, receipt of which must be acknowledged in writing, that:

(a) The prescription drug was donated to the program;
(b) The donors and participants in the program are granted certain immunities as described in subsection (12); and
(c) The patient may not be required to pay for the prescription drug, except for a nominal handling fee which may not exceed the amount established by department rule.

(14) DIRECT-SUPPORT ORGANIZATION.—The department may establish a direct-support organization to provide assistance, funding, and promotional support for the activities authorized for the program.

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

(b) Prohibition against lobbying.—The direct-support organization is not considered a lobbying firm within the meaning of s. 11.045. All expenditures of the direct-support organization must be used for the program. No expenditures of the direct-support organization may be used for the purpose of lobbying as defined in s. 11.045.

(c) Contract.—The direct-support organization shall operate under a written contract with the department. The contract must
provide for a submission by the direct-support organization to the department, by each August 1, and posting on the direct-support organization’s and department’s websites, the following information:

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

2. An annual budget for the approval of the department.

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

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

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

6. A brief description of the direct-support organization’s plans for the next 3 fiscal years.

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

8. 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 direct-support organization.

9. The reversion, without penalty, of moneys and property held in trust by the direct-support organization for the benefit of the program to the state if the department ceases to exist; or reversion to the department if the direct-support
organization is no longer approved to operate or ceases to exist.

10. The fiscal year of the direct-support organization, which must begin on July 1 of each year and end on June 30 of the following year.

11. The disclosure of material provisions of the contract, and the distinction between the department and the direct-support organization, to donors of gifts, contributions, or bequests, including such disclosure on all promotional and fundraising publications.

12. All prescription drugs solicited by the direct-support organization to be distributed to the centralized repository or a local repository. The direct-support organization may not possess any prescription drugs on behalf of the program.

(d) Board of directors.—The State Surgeon General shall appoint a board of directors of the direct-support organization. The board of directors shall consist of at least 5 members, but not more than 15 members, who serve at the pleasure of the State Surgeon General. The board members 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.

(e) 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, subject to this subsection. For the 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 permit the use of any fixed property or facilities of the department by the direct-support organization if it 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.

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

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

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

(i) Repeal.—This subsection shall stand repealed on October 1, 2023, unless reviewed and saved from repeal by the Legislature.

(15) RULEMAKING.—The department shall adopt rules necessary to implement the requirements of 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, 2018.