The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Appropriations

BILL:	PCS/CS/SB 710 (471064)
INTRODUCER:	Appropriations Committee (Recommended by Appropriations Subcommittee on Health and Human Services); Health Policy Committee; and Senator Book
SUBJECT:	Prescription Drug Donation Program
DATE:	February 21, 2018 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Lloyd	Stovall	HP	**Fav/CS**
2.	Loe	Williams	AHS	**Recommend: Fav/CS**
3.	Loe	Hansen	AP	**Pre-meeting**

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

PCS/CS/SB 710 creates the Prescription Drug Donation Repository Program (Program) within the Department of Health (DOH) to facilitate the donation and distribution of prescription drugs and supplies to eligible patients in the state. The Program:

- Permits Florida residents with valid prescriptions who are either indigent, uninsured, or underinsured to receive donated prescription drugs and supplies under the Program.
- Limits entities that may donate prescription drugs to those that can ensure the drugs have been maintained entirely by licensed or permitted professionals and not by patients.
- Limits dispensing of prescription drugs under the Program to persons who are licensed, registered, or otherwise permitted by state law.
- Establishes eligibility criteria for prescription drugs donated to the Program.
- Provides procedures for inventorying, storing, dispensing, recalling, and destroying prescription drugs under the Program.
- Provides recordkeeping and reporting requirements for participating facilities.
- Requires DOH to maintain and publish on its website registries of all participating facilities and available donated drugs and supplies.
- Creates a direct-support organization (DSO) to provide funding for the Program.
- Requires DOH to adopt rules necessary to implement the Program.

The bill amends s. 252.36(5), F.S., to allow the Governor to waive the patient eligibility requirements of the Program during a declared state of emergency.

The DOH will experience an increase in workload to administer the Program; however, these costs should be absorbed through funding collected by the DSO in support of the Program.

The bill is effective July 1, 2018.

II. Present Situation:

State Prescription Drug Donation and Reuse Programs

State prescription drug donation and reuse programs have been in effect for two decades beginning with a pilot program in Georgia in 1997.[1] Such drug donation and reuse programs permit unused prescription or non-prescription drugs to be donated and re-dispensed to patients within certain federal guidelines. More than 38 states have passed laws authorizing such programs; however, many are not currently operational.[2] Georgia's program started with a prescription drug reuse program only in long-term care facilities and has been expanded to a collection and donation program that accepts prescription and non-prescription drugs.[3]

Pharmaceutical donation programs and reuse programs involve the voluntary collection of donated, unused prescription and non-prescription drugs from patients. States vary in the types of drugs and supplies that are accepted, the number and types of sites that are considered eligible locations where patients or donors may deposit donations, participant eligibility requirements, and the dispensing fees for the donated drugs. Generally, the drugs are not controlled substances. Some programs, such as Florida's, are limited to only cancer treatment drugs. Twelve other states besides Florida - Colorado, Kentucky, Michigan, Minnesota, Montana, Nebraska, Nevada, Ohio, Pennsylvania, Utah, Washington, and Wisconsin - have prescription drug donation and reuse programs limited to only cancer treatment drugs.

Pharmacies, charitable clinics, and hospitals are locations where such donations are accepted. In Florida's Cancer Drug Donation Program,[4] only Class II hospital pharmacies that elect or volunteer to participate in the program are eligible to accept donations of cancer drugs from designated individuals or entities.[5]

Individuals may be required to meet certain eligibility requirements beyond a cancer diagnosis to participate in the donation program such as proof of state residency (Minnesota), lack of access to other insurance coverage, or Medicaid ineligibility (Florida). Dispensing fees are set based on a maximum relative threshold above the Medicaid dispensing fee or capped at an absolute dollar amount that typically ranges from $10 to $15.

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[1] National Conference of State Legislatures, *State Prescription Drug Return, Reuse and Recycling Laws* (March 31, 2017), http://www.ncsl.org/research/health/state-prescription-drug-return-reuse-and-recycling.aspx (last visited Nov. 28, 2017).
[2] *Supra* note 1.
[3] GA. CODE ANN. § 31-8-301-304 (2017).
[4] Section 499.029, F.S.
[5] *See* s. 465.019, F.S. Class II institutional pharmacies are those institutional pharmacies that employ the services of a registered pharmacist or pharmacists who, in practicing institutional pharmacy, provide dispensing and consulting services on the premises to the patients of that institution, for use on the premises of that institution.

The statutory provisions of many pharmaceutical donation programs have several common requirements:

- No controlled substances are accepted as donations;
- No adulterated or misbranded medications are allowed;
- All pharmaceuticals must be checked by a pharmacist prior to being dispensed;
- Pharmaceuticals must not be expired and most pharmaceuticals must have at least six months or longer before expiration;
- All pharmaceuticals must be unopened and in original, sealed, tamper-evident packaging; and
- Liability protection is assured for both donors and recipients.[6]

Most states permit the donation of any non-controlled substance to a designated medical facility, clinic, or pharmacy that has elected to participate in the program. Twenty states have operational repository programs – either cancer drug programs or broader collection programs – including states such as Iowa, which has served over 70,000 patients and re-distributed $15 million in donated supplies since 2007.[7] The Iowa program is limited to residents with incomes at or below 200 percent of the federal poverty level (FPL), or $49,200 for a family of four under the current guidelines, who are uninsured or underinsured, and are eligible to receive the donated medications and supplies.[8] The Iowa program accepts donations from any organization or individual in the country with the medication provided in its sealed or original, tamper-resistant packaging. Any pharmacy or medical facility with authorization to dispense under Iowa administrative rules may then re-dispense the donated medication or supplies.[9]

Wyoming has also had a long-running Medication Donation Program. The state's program filled over 150,000 prescriptions since its inception in 2007 and provided more than $2.4 million worth of donated prescriptions in 2016.[10] Assistance under the program is time-limited and recipients must have incomes under 200 percent of the FPL, and be without prescription insurance or Medicaid coverage. A dispensing site may also charge a recipient up to $10 per prescription to cover dispensing fees. Controlled substances are not covered in the program.[11]

Florida Cancer Drug Donation Program

The Florida Cancer Drug Donation Program (CDDP) was created in 2006[12] and is administratively housed within the DBPR. The CDDP allows eligible donors to donate cancer drugs and related supplies to participating facilities that may dispense the donations to eligible cancer patients. Eligible donors include patients, patient representatives, health care facilities,

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[6] *Supra* note 1.
[7] *Supra* note 1.
[8] Iowa Department of Public Health, *SafeNetRx Program*, https://idph.iowa.gov/ohds/rural-health-primary-care/repository, (last visited Nov. 28, 2017).
[9] *Id.*
[10] Wyoming Department of Health, *Wyoming Medication Donation Program*, https://health.wyo.gov/healthcarefin/medicationdonation/ (last visited Nov. 28, 2017).
[11] *Id.*
[12] Chapter 2006-310, Laws of Fla. (creating s. 499.029, effective July 1, 2006). It was originally created within the Department of Health, but was part of a programmatic transfer by the 2010 Legislature to DBPR effective October 1, 2011.

nursing home facilities, hospices, or hospitals with a closed drug delivery system; or pharmacies, drug manufacturers, medical device manufacturers, or suppliers or wholesalers of drugs or supplies.[13]

Eligible participating facilities that may collect donations are limited to only those Florida hospital pharmacies with a Class II institutional pharmacy permit.[14] These pharmacies participate on a voluntary basis and must agree to accept, inspect, and dispense the donated drugs to the eligible patients in accordance with the statute. The DBPR is required to establish and maintain a participant facility registry for the CDDP. The law provides the content for the registry and a requirement for a website posting. Currently, 14 hospital pharmacies participate in the CDDP.[15]

Florida's recipient eligibility requirements limit participation to Florida residents who:

- Have been diagnosed with cancer; and
- Are ineligible for the Medicaid program, or any other prescription drug program funded in whole or in part by the federal government, or do not have third party insurance unless the benefits have been exhausted or a certain cancer drug is not covered.[16]

Donated drugs may only be prescribed by a licensed practitioner and dispensed by a licensed pharmacist to an eligible patient.[17] Dispensed drugs and supplies under the CDDP are not eligible for reimbursement by third parties, either public or private. However, the facility may charge the recipient of the donated drug a handling fee of no more than 300 percent of the Medicaid dispensing fee or no more than $15, whichever is less, for each cancer drug that is dispensed.[18]

The DBPR, Division of Drugs, Devices, and Cosmetics, maintains a list of available donated medications on its website; however, no cancer medications are currently reported on the list.[19] As of November 2017, the DBPR does not require the participating facilities to report the medications that are available for inclusion on the CDDP website or the number of donated drugs that have been administered.[20] A facility is required to maintain its data for three years.[21]

The CDDP will only accept drugs if:

- The drug expires at least six months after the date of donation and the drug's tamper-resistant packaging is intact;
- The drug is in its original, unopened, sealed, tamper-evident unit dose packaging with lot number and expiration date, if so packaged; and
- The drug is not a substance listed on Schedule II, III, IV, or V of s. 893.03, F.S.[22]

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[13] Section 499.029(3)(c), F.S.
[14] Section 499.029(2)(e), F.S.
[15] Florida Department of Business and Professional Regulation, *Cancer Drug Donation Program Participation Report*, http://www.myfloridalicense.com/dbpr/ddc/documents/ParicipatingHospital.pdf (last visited Nov. 28, 2017).
[16] Rule 61N-1.026(1), F.A.C.
[17] Section 499.029(5), F.S.
[18] Section 409.029(7)(b), F.S. and Rule 61N-1.026(5), F.A.C.
[19] Florida Department of Business and Professional Regulation, *Medication Supply Availability List*.
[20] Email correspondence from Colton Madill, Department of Business and Professional Regulation (Nov. 29, 2017) (on file with the Senate Committee on Health Policy).
[21] *Id.*
[22] Rule 61N-1.026(6), F.A.C.

Under the act, a donor or a participant in the program who acts with reasonable care in donating, accepting, distributing, or dispensing prescription drugs or supplies is immune from civil or criminal liability or professional disciplinary action for any kind of injury, death, or loss relating to such activities.[23]

Regulation of Pharmacy

The DBPR is the state agency charged with the regulation and licensure of businesses and professionals.[24] Under the provisions of chapter 499, F.S., the Division of Drugs, Devices, and Cosmetics safeguards the health, safety, and welfare of the state's citizens from injury due to the use of adulterated, contaminated, and misbranded drugs, drug ingredients and cosmetics. The Division oversees: the CDDP; issuance and regulation of licensure and permits for drug manufacturers, wholesalers, and distributers; controlled substance reporting requirements for certain wholesale distributors; issuance and regulation of other permits and licenses; and the Drug Wholesale Distributor Advisory Council.[25]

The Florida Drug and Cosmetic Act (Act) is codified as ss. 499.001 – 499.081, F.S. The Act provides uniform legislation to be administered so far as practicable in conformity with the provisions of, and regulations issued under the authority of, the Federal Food, Drug, and Cosmetic Act and that portion of the Federal Trade Commission Act which expressly prohibits the false advertisement of drugs, devices, and cosmetics. The Act provides definitions for what is considered a device, drug, and, specifically, a prescription drug.[26]

Chapter 465, F.S., governs the regulation of the practice of pharmacy by the Board of Pharmacy in the Department of Health. Section 465.019(2)(b), F.S., provides requirements for institutional pharmacies. "Class II institutional pharmacies" are those institutional pharmacies that employ the services of a registered pharmacist or pharmacists who, in practicing institutional pharmacy, provide dispensing and consulting services on the premises to patients of that institution for use on the premises of that institution.

Section 465.015(2)(c), F.S., makes it unlawful for a pharmacist to sell or dispense drugs without first being furnished a prescription. Section 465.016(1)(l), F.S., prohibits a pharmacist from placing into stock any part of any prescription compounded or dispensed which is returned by the patient. Additionally, the Board of Pharmacy has adopted an administrative rule that prohibits a pharmacist from placing into the stock of any pharmacy any part of any prescription compounded or dispensed, which is returned by a patient, except as specified in the Board of Pharmacy rules.[27] There is an exception for a closed drug delivery system in which unit dose or

[23] Section 409.029(11), F.S.
[24] Section 20.165, F.S.
[25] Department of Business and Professional Regulation, *Division of Drugs, Devices, and Cosmetics*, http://www.myfloridalicense.com/dbpr/ddc/index.html (last visited Nov. 29, 2017).
[26] A "prescription drug" under s. 499.003(40) is defined as a "prescription, medicinal, or legend drug, including, but not limited to, finished dosage forms or active ingredients subject to, defined by, or described by, s. 503(b) of the federal act or s. 465.003(8), s. 499.007(13), subsection (31), or subsection (47), except that an active pharmaceutical ingredient is a prescription drug only if substantially all finished dosage forms in which it may be lawfully dispensed or administered in this state are also prescription drugs.
[27] Rule 64B16-28.118(2), F.A.C.

customized patient medication packages are dispensed to in-patients. The unused medication may be returned to the pharmacy for re-dispensing only if each unit dose or customized patient medication package is individually sealed and if each unit dose or the unit dose system – or the customized patient medication package container or the customized patient medication package unit of which it is clearly a part – is labeled with the name of the drug, dosage strength, manufacturer's control number, and expiration date, if any. In the case of controlled substances, such drugs may only be returned as permitted under federal law.[28] A "closed drug delivery system" means a system in which control of the unit-dose medication is maintained by the facility rather than by the individual patient. A "unit dose system" means a system in which all the individually sealed unit doses are physically connected as a unit.[29]

For nursing facility residents, s. 400.141(1)(d), F.S., requires a pharmacist licensed in Florida that is under contract with a nursing home to repackage a resident's bulk prescription medication that has been packaged by another pharmacist into a unit-dose system compatible with the system used by the nursing facility, if requested by the facility. In order to be eligible for the repacking service, the resident or the resident's spouse's prescription medication benefits must be covered through a former employer as part of his or her retirement benefits, a qualified pension plan as specified in s. 4972 of the Internal Revenue Code, a federal retirement program as specified under 5 C.F.R. part 831, or a long-term care policy as defined under specified state law. A pharmacist who correctly repackages and relabels the medication, and the nursing home who correctly administers the repackaged medication, cannot be held liable in any civil or administrative action arising from the repackaging. The pharmacist may charge a reasonable fee for costs of the repackaging.

A nursing home typically has a Class I institutional permit. This permit authorizes the nursing home to have patient-specific medications that have already been dispensed to the resident. Prescription drugs may not be dispensed in a Class I pharmacy.[30]

Federal Law and Regulations

The federal Controlled Substances Act (CSA) was enacted by Congress in 1970 and codified as 21 U.S.C. §801, et seq. The CSA regulates the manufacture and distribution of controlled substances in the United States. The federal Drug Enforcement Agency (DEA) is responsible for the enforcement of the CSA.

The CSA categorizes drugs into five "schedules" based on their potential for abuse and safety or dependence liability.[31] The CSA provides for specific dispensing requirements for controlled

[28] Rule 64B16-28-118(2), F.A.C.
[29] Rule 64B16-28-118(1), F.A.C.
[30] Section 465.019(2)(a), F.S.
[31] U.S. Department of Justice, Diversion Control Division, *Controlled Substance Security Manual*, https://www.deadiversion.usdoj.gov/pubs/manuals/sec/app_law.htm (last visited Nov. 28, 2017). Drugs classified as Schedule I are those that are considered to have no medical use in the United States and have a high abuse potential and include drugs such as heroin, LSD, and marijuana. Schedule II substances have a high abuse potential with severe psychological or physical dependency, but have accepted medical use. Examples of Schedule II drugs include opium, morphine, codeine, and oxycodone. Schedule III drugs have an abuse potential and dependency liability less than Schedule II with an accepted medical use. Schedule III drugs may also contain limited quantities of certain narcotic and non-narcotic drugs. Schedule IV drugs have an abuse potential and dependency liability less than those drugs in Schedule III and have an

substances, including written prescriptions, retention requirements, and refill restrictions, depending on the drug's schedule.[32] Prescriptions must also meet specific labeling and packaging requirements. For Schedule II, III, and IV drugs, the label must clearly contain a warning that it is a crime to transfer the drug to any person other than the patient.[33]

The CSA permits the delivery of controlled substances by an "ultimate user,"[34] who has lawfully obtained the drug, to a designated covered entity for disposal and destruction such as through a prescription drug take-back program.[35] An authorized covered entity is defined in federal law as:

- A specified law enforcement agency;
- A manufacturer, distributor, or reverse distributor of prescription medications;
- A retail pharmacy;
- A registered narcotic treatment program;
- A hospital or clinic with an onsite pharmacy;
- An eligible long-term care facility; or
- Any other entity authorized by the DEA to dispose of prescription medications.[36]

The last National Prescription Take Back Day sponsored by the DEA resulted in more than 912,305 pounds of expired, unused, and unwanted prescription drugs returned at 5,300 sites on November 7, 2017.[37] The goal of the take-back program is to prevent the diversion of unwanted drugs to misuse and abuse and to avoid the potential safety hazard of drugs flushed down the toilet.[38]

Citizen-Support Organizations and Direct-Support Organizations

Citizen-support organizations (CSOs) and direct-support organization (DSOs) are statutorily created non-profit organizations[39] authorized to carry out specific tasks in support of public entities or public causes.[40] The function and purpose of a CSO or DSO are prescribed by an enacting statute and a written contract with the agency the CSO or DSO supports.[41]

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accepted medical use and include drugs such as Valium, Xanax, and Darvon. The drugs in the fifth and final schedule, Schedule V, have an abuse potential less than those listed in Schedule IV, have an accepted medical use, and are often available without a prescription, including some for antitussive and antidiarrheal purposes.

[32] 21 U.S.C. §829 and 21 CFR §§1306.21 and 1306.22.

[33] 21 U.S.C. §825.

[34] An "ultimate user" is defined under 21 U.S.C. 802(27), as the person who has lawfully obtained, and who possesses, a controlled substance for his own use or the use of a member of his household or for an animal owned by him or by a member of his household.

[35] 21 U.S.C. 822a.

[36] *Id.*

[37] Drug Enforcement Administration, *Drug Enforcement Administration collects record number of unused pills as part of its 14th Prescription Drug Take Back Day* (November 7, 2017), https://www.dea.gov/divisions/hq/2017/hq110717.shtml (last visited Nov. 28, 2017).

[38] *Id.*

[39] Chapter 617, F.S.

[40] *E.g.*, ss. 1009.983 and 413.0111, F.S.

[41] *See* ss. 14.29(9)(a), 16.616(1), and 258.015(1), F.S. *See also* Rules of the Florida Auditor General, Audits of Certain Nonprofit Organizations (effective June 30, 2016), Rule 10.720(1)(b) and (d), *available at* http://www.myflorida.com/audgen/pages/pdf_files/10_700.pdf.

CSO and DSO Transparency and Reporting Requirements

In 2014, the Legislature created s. 20.058, F.S., establishing a comprehensive set of transparency and reporting requirements for CSOs and DSOs.[42] Specifically, the law requires each CSO and DSO to annually submit the following information to the appropriate agency by August 1:[43]

- The name, mailing address, telephone number, and website address of the organization;
- The statutory authority or executive order that created the organization;
- A brief description of the mission of, and results obtained by, the organization;
- A brief description of the organization's plans for the next three fiscal years;
- A copy of the organization's ethics code; and
- A copy of the organization's most recent Internal Revenue Service (IRS) Form 990.[44]

Each agency receiving information from a CSO or DSO pursuant to law must make such information available to the public through the agency's website.[45] If the organization maintains a website, the agency's website must provide a link to the organization's website.[46] Any contract between an agency and a CSO or DSO must be contingent upon the CSO or DSO submitting and posting the required information to the agency as specified in law.[47] If a CSO or DSO fails to submit the required information to the agency for two consecutive years, the agency head must terminate any contract between the agency and the CSO or DSO.[48]

By August 15 of each year, the agency must report to the Governor, President of the Senate, Speaker of the House of Representatives, and the Office of Program Policy Analysis and Government Accountability (OPPAGA) the information submitted by each CSO or DSO along with the agency's recommendation and supporting rationale to continue, terminate, or modify the agency's association with the CSO or DSO.[49]

Any law creating, or authorizing the creation of a CSO or DSO must state that the authorization for the organization repeals on October 1 of the 5th year after enactment, unless reviewed and reenacted by the Legislature. CSOs and DSOs in existence prior to July 1, 2014, must be reviewed by the Legislature by July 1, 2019.[50]

CSO and DSO Audit Requirements

Section 215.981, F.S., requires each CSO and DSO with annual expenditures in excess of $100,000 to provide for an annual financial audit of its accounts and records.[51] An independent certified public accountant in accordance with rules adopted by the Auditor General must

[42] Section 3, ch. 2014-96, L.O.F
[43] Section 20.058(1), F.S.
[44] The IRS Form 990 is an annual information return required to be filed with the IRS by most organizations exempt from federal income tax under 26 U.S.C. 501. 26 C.F.R. 1.6033-2.
[45] Section 20.058(2), F.S.
[46] *Id.*
[47] Section 20.058(4), F.S.
[48] *Id.*
[49] *Id.* at (3).
[50] *Id.* at (5).
[51] The independent audit requirement does not apply to a CSO or DSO for a university, district board of trustees of a community college, or district school board. Additionally, the expenditure threshold for an independent audit is $300,000 for a CSO or DSO for the Department of Environmental Protection and the Department of Agriculture and Consumer Services.

conduct the audit. The audit report must be submitted within nine months after the end of the fiscal year to the Auditor General and to the state agency the CSO or DSO supports.[52] Additionally, the Auditor General may, pursuant to his or her own authority, or at the direction of the Legislative Auditing Committee, conduct audits or other engagements of a CSO's or DSO's accounts and records.[53]

CSO and DSO Ethics Code Requirement

Section 112.3251, F.S., requires a CSO or DSO to adopt a code of ethics. The code of ethics must contain the specified standards of conduct and disclosures provided in ss. 112.313 and 112.3143(2), F.S.[54] A CSO or DSO may adopt additional or more stringent standards of conduct and disclosure requirements and must post its code of ethics on its website.[55]

Governor's Executive Powers

During a declared state of emergency, the Governor has extensive authority to act as he or she deems necessary. Section 252.36(1), F.S., provides, in part, that "in the event of an emergency beyond local control, the Governor…may assume" or delegate "direct operational control over all or any part of the emergency management functions within this state…" In addition, the Governor may "issue executive orders, proclamations, and rules" which "shall have the force and effect of law." Subsection (5) specifically authorizes the Governor to use all resources of the state government and of each political subdivision of the state, as reasonably necessary to cope with the emergency.

The Governor is also directed to "take such action and give such direction to state and local law enforcement officers," and state health officials as may be "reasonable and necessary" to secure compliance with the State Emergency Management Act and the Florida Hazardous Materials Emergency Response and Community Right-To-Know Act in ch. 252, F.S.

A declared State of Emergency is limited to 60 days, unless renewed by the Governor or terminated by the Legislature.

III. Effect of Proposed Changes:

Section 1 creates s. 465.1902, F.S., to establish the Prescription Drug Donation Repository Program (Program) within the Department of Health (DOH). The purpose of the program is to authorize and facilitate the donation and distribution of prescription drugs and supplies to eligible patients through a system of local and centralized repositories. The DOH may contract with a third party to implement and administer the Program.

The bill authorizes the following individuals or entities to donate prescription drugs and supplies:

- Nursing home facilities with closed drug delivery systems.
- Hospices that have maintained control of a patient's prescription drug.

[52] Section 215.981(1), F.S.
[53] Section 11.45(3), F.S.
[54] Some of the standards of conduct and disclosures in ss. 112.313 and 112.3143(2), F.S., include misuse of public position, solicitation or acceptance of gifts, unauthorized compensation, and voting conflicts.
[55] Section 112.3251, F.S.

- Hospitals with closed drug delivery systems.
- Pharmacies.
- Drug manufacturers or wholesale distributors.
- Medical device manufacturers or suppliers.
- Prescribing individuals who receive prescription drugs or supplies directly from a drug manufacturer, wholesale distributor, or pharmacy.

The bill authorizes prescription drugs to be donated at the discretion of the centralized repository or a local repository if the drug:

- Is approved for medical use in the United States;
- Does not include a substance listed in Schedule II, Schedule III, Schedule IV, or Schedule V of s. 893.03, F.S.;
- Is in its original sealed and tamper-evident packaging, and does not have any physical signs of tampering or adulteration;
- Requires storage at normal room temperature per the manufacturer or the United States Pharmacopeia, and has been stored according to these requirements;
- Packaging contains a lot number and expiration date of the drug, and will not expire within three months after the donation is made;
- Is not eligible for return to the Medicaid program for restocking; and
- Is not subject to a Federal Food and Drug Administration Risk Evaluation and Mitigation Strategy with Elements to Assure Safe Use.

The bill requires prescription drugs or supplies be donated at a repository and prohibits the use of a drop box and donation to a specific patient. Repositories must destroy any donated drug not eligible for dispensing and make a record of the destruction on a form developed by DOH.

The bill requires a licensed pharmacist employed by, or under contract with, a repository to inspect all donated prescription drugs and supplies to determine whether they are eligible for donation under the Program, have been adulterated or misbranded, and are safe and suitable for dispensing. The pharmacist must sign an inspection record affirming the eligibility of the prescription drug or supply, and attach the form to the inventory record. The pharmacist is not required to re-inspect the prescription drug if the inspected drugs are redistributed to another repository under the Program.

The bill requires repositories to store all donated prescription drugs and supplies in a secure storage area, separate from non-donated inventory, and under the environmental conditions required by the manufacturer or the U.S. Pharmacopeia. Repositories must quarantine donated drugs and supplies from dispensing inventory until they have been inspected and approved for dispensing by the pharmacist.

The bill requires local repositories to maintain an inventory of all donated prescription drugs and supplies they receive, and to notify the centralized repository within five days of receipt. The centralized repository maintains an inventory of all prescription drugs and supplies donated to the Program, including donations made at local repositories. The centralized repository may redistribute drugs and supplies to facilitate dispensing as needed throughout the state.

The bill makes participation in the Program voluntary and requires an eligible entity to notify the DOH of its intent to participate before accepting or dispensing any prescription drugs or supplies under the Program. The DOH shall establish in rule a form for such notification, to include, at a minimum:

- 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;
- The name and telephone number of the pharmacist employed by or under contract with the local repository responsible for the inspection of donated prescription drugs and supplies; and
- A statement signed and dated by the responsible pharmacist affirming that the local repository meets the eligibility requirements.

An eligible patient wishing to receive drugs or supplies under the Program may contact a local repository, and submit an intake collection form. This form, to be created by DOH in rule, shall include, at a minimum:

- The name, street address, and telephone number of the eligible patient;
- The specific basis for eligibility, which must be indigent, uninsured, or underinsured, as defined in the Program;[56] and
- A statement signed and dated by the eligible patient affirming that he or she meets the eligibility requirements of the Program.

The bill requires local repositories to collect an executed intake form from each eligible patient receiving drugs or supplies under the Program. Upon receiving a duly executed intake form, the local repository shall issue the eligible patient an identification card that is valid for up to one year. Local repositories must send a summary of the intake collection form data to the centralized repository within five days of receipt.

The bill permits licensed pharmacists and those health care practitioners already authorized by law to dispense prescription drugs and supplies in Florida to do so under the Program. Prior to dispensing a prescription drug or supply to an eligible patient, the dispenser must:

- Verify that the patient is eligible to receive donations under the Program, either through a Program identification card or a duly executed intake collection form; and
- Inspect the donated prescription drug or supply to confirm it is still eligible for dispensing under the Program.

The bill prohibits repositories from reselling drugs, submitting claims, or otherwise seeking reimbursement from any public or private third-party payor for donated drugs or supplies dispensed under the Program. However, the dispensing facility may charge a nominal handling fee, to be determined by the DOH in rule.

In the event of a prescription drug recall, the bill requires a local or centralized repository to:

[56] The bill defines "indigent" as persons with an income below 200 percent of the federal poverty level, "uninsured" as persons who have no third-party insurance and are not eligible under Medicaid or any other federal program, and "underinsured" as persons who have third-party insurance or are eligible under Medicaid or other federal program, but have exhausted these benefits or do not have prescription drug coverage for the drug prescribed.

- Have an established protocol to notify recipients of the drug;
- Destroy all of the recalled prescription drugs in the repository; and
- Complete a destruction information form for all donated prescription drugs that were destroyed.

The bill requires local repositories to maintain records of all prescription drugs and supplies accepted, donated, dispensed, distributed, or destroyed under the Program. Local repositories must submit these records quarterly to the centralized repository for data collection and the centralized repository submits these records and the collected data in annual reports to the DOH.

The bill requires the DOH to maintain a registry on its website of all available drugs and supplies, including the name, strength, available quantity, and expiration date of each drug and supply, as well as the contact information for the repositories where it is available. The DOH is required to maintain a registry on its website of all participating local repositories, to include each repository's name, address, website, and telephone number.

The bill grants immunity from civil or criminal liability, and professional disciplinary actions, to a donor or participant relating to activities under the Program. Additionally, a pharmaceutical manufacturer who exercises reasonable care is not liable for any claim or injury arising from the transfer of prescription drugs under the Program.

The bill requires the dispenser to provide written notification to the patient, or his or her legal representative, before dispensing a prescription drug that the drug was donated to the Program, the dispenser is not liable for any injury, death, or loss related to the dispensing of the drug, and the requirement of a nominal handling fee.

The bill authorizes the DOH to establish a direct-support organization (DSO) to provide assistance, funding, and promotional support for the activities authorized for the Program. The DSO is repealed on October 1, 2023, unless reviewed and saved from repeal by the Legislature.

The bill provides rulemaking authority to the DOH to administer the Program and establish the DSO.

Section 2 amends s. 252.36(5), F.S., to allow the Governor to waive the patient eligibility requirements of the Program during a declared state of emergency.

Section 3 provides an effective date of July 1, 2018.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Participation in the program is voluntary. Those hospitals and nursing homes volunteering to participate in the program may incur costs associated with collecting, storing, and re-dispensing of donated prescription drugs. Those same hospitals and nursing homes may enjoy cost savings to the extent their patients may be receiving needed health care services on a more timely basis. Without such donations, some patients could return as sicker, more costly patients at a later date.

Hospitals and facilities participating in the program are permitted to recoup some costs through a small handling fee. Current state regulations permit a handling fee of up to 300 percent of the Medicaid dispensing fee or $15, whichever is less, for each cancer drug or supply dispensed.[57]

C. Government Sector Impact:

The DOH will experience a significant increase in workload to administer the program. The DSO established under the bill is responsible for collecting the necessary funds for the DOH to administer the program effectively. The DOH will need to submit a legislative budget request for the Legislature to appropriate an indeterminate, yet significant, amount of general revenue funds to support the Program if the DSO is unsuccessful in collecting the required resources.

Public facilities that elect to participate in the program will face similar costs associated with collecting, storing, and dispensing the prescription drugs. Likewise, these public facilities may enjoy additional savings through the participation of the uninsured or underinsured from their communities.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

[57] Rule 61N-1.026(5), F.A.C.

VIII. Statutes Affected:

This bill substantially amends section 252.36 of the Florida Statutes.

This bill creates section 465.1902 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

Recommended CS by Appropriations Subcommittee on Health and Human Services on February 14, 2018:
The committee substitute:

- Eliminates the expansion of the Cancer Drug Donation Program and creates the Prescription Drug Donation Repository Program (Program) within the Department of Health (DOH) to facilitate the donation and distribution of prescription drugs and supplies to eligible patients in the state.
- Establishes eligibility criteria to donate, dispense, and receive prescription drugs under the program.
- Provides inspection and storage requirements for donated prescription drugs.
- Authorizes the Governor to waive the patient eligibility requirements of the Program during a declared state of emergency.

CS by Health Policy on December 5, 2017:
The CS amends the term "prescription drug" to exclude the donation of drugs to the program which fall under Schedules II through V of s. 803.03, F.S.

B. Amendments:

None.