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 Appropriations Subcommittee on Health and Human Services

BILL:	CS/SB 58
INTRODUCER:	Health Policy Committee and Senator Book and others
SUBJECT:	Prescription Drug Donation Repository Program
DATE:	January 14, 2020 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Kibbey	Brown	HP	**Fav/CS**
2.	Howard	Kidd	AHS	**Recommend: Favorable**
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 58 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:

- Enables Florida residents with valid prescriptions who are indigent, uninsured, or underinsured to receive donated prescription drugs and supplies under the Program;
- Specifies a list of entities that may donate prescription drugs or medical devices to the Program and establishes requirements that must be met before donations may be accepted;
- Limits dispensing of prescription drugs under the Program to persons who are licensed, registered, or otherwise permitted by state law;
- Provides procedures for inventorying, storing, dispensing, recalling, and destroying prescription drugs under the Program;
- Provides recordkeeping and reporting requirements for participating facilities;
- Requires the DOH to maintain and publish on its website registries of all participating facilities and available donated drugs and supplies;
- Authorizes the creation of a direct-support organization (DSO) to provide funding for the Program; and
- Requires the DOH to adopt rules necessary to implement the Program.

The bill authorizes 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 may be absorbed through funding collected by the DSO in support of the program. The projected increased costs to the DOH total $483,671, which includes five new positions to support the program.

The bill is effective on July 1, 2020.

II. Present Situation:

State Prescription Drug Donation and Reuse Programs

State prescription drug donation and reuse programs have been in effect since 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. Currently, 38 states have passed laws authorizing such programs; however, not all of these states have operationalized their programs.[2]

Pharmaceutical donation and reuse programs involve the voluntary collection and re-distribution of donated, unused prescription and non-prescription drugs from participating donors to eligible 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 donors may deposit donations, participant eligibility requirements, and the dispensing fees for the donated drugs. Generally, the donated 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 cancer treatment drugs only.

Pharmacies, charitable clinics, and hospitals are locations where such donations are accepted. In Florida's Cancer Drug Donation Program,[3] only Class II hospital pharmacies that elect or volunteer to participate are eligible to accept donations of cancer drugs from designated individuals or entities.[4]

Individuals receiving donated drugs 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.

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

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[1] National Conference of State Legislatures, *State Prescription Drug Return, Reuse and Recycling Laws* (As of Oct. 1, 2018), http://www.ncsl.org/research/health/state-prescription-drug-return-reuse-and-recycling.aspx (last visited: Oct. 7, 2019).
[2] *Supra* note 1.
[3] Section 499.029, F.S.
[4] *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.

- No controlled substances are accepted as donations;
- No adulterated or misbranded medications are allowed;
- All donated pharmaceuticals must be checked by a pharmacist prior to being dispensed;
- Pharmaceuticals must not be expired;
- All pharmaceuticals must be unopened and in original, sealed, tamper-evident packaging; and
- Liability protection is assured for both donors and recipients.[5]

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. Currently, 15 states allow a non-institutional donor to donate prescription drugs to a donation program under varying degrees of quality control.[6] Twenty other states have operational repository programs – either cancer drug programs or broader collection programs – including states such as Iowa, which has served over 71,000 patients and re-distributed $17.7 million in donated prescriptions and 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 $51,500 for a family of four under the 2019 guidelines,[8] who are uninsured or underinsured, and are eligible to receive the donated medications and supplies.[9] The Iowa program accepts donations from any organization or individual in the country with the medication provided in its sealed or original sealed container or in tamper-resistant packaging. Any pharmacy or medical facility with authorization to dispense under Iowa administrative rules may re-dispense the donated medication or supplies.[10]

Wyoming also has 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.[11]A recipient must be a Wyoming resident, have an income under 200 percent of the FPL, and be without prescription insurance or Medicaid coverage. Prescriptions are mailed to the recipient at no cost to the patient; however, neither controlled substances nor refrigerated prescriptions are covered in the program.[12]

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[5] *Supra* note 1.
[6] *Supra* note 1.
[7] *Supra* note 1.
[8] U.S. Department of Health and Human Services, *U.S. Federal Poverty Guidelines Used to Determine Financial Eligibility for Certain Federal Programs (Effective January 11, 2019)*, https://aspe.hhs.gov/poverty-guidelines (last visited Oct. 7, 2019).
[9] Iowa Department of Public Health, *SafeNetRx Program*, https://idph.iowa.gov/ohds/rural-health-primary-care/repository, (last visited Oct. 7, 2019).
[10] *Id.*
[11] Wyoming Department of Health, *Wyoming Medication Donation Program*, https://health.wyo.gov/healthcarefin/medicationdonation/ (last visited: Oct. 7, 2019).
[12] Wyoming Department of Health, *Wyoming Medication Donation Program*, https://health.wyo.gov/healthcarefin/medicationdonation/application-and-eligibilty/ (last visited: Oct. 7, 2019).

Florida Cancer Drug Donation Program

The Florida Cancer Drug Donation Program (CDDP) was created in 2006[13] and is administratively housed within the Florida Department of Business and Professional Regulation (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. The hospital pharmacies accept donations of cancer drugs and supplies from drug manufacturers and wholesalers; health care facilities, including nursing home facilities, hospices, or hospitals with a closed drug delivery system; or pharmacies, medical device manufacturers, or suppliers; and patients or their representatives.[14] However, all donations to the CDDP must be maintained in a closed drug delivery system.[15]

Eligible participating facilities are limited to only those Florida hospital pharmacies with a Class II institutional pharmacy permit.[16] 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, the following 15 hospital pharmacies participate in the CDDP.

Cancer Drug Donation Program Participants[17]:	
Health Care Facility	**Location**
Moffitt Cancer Center	Tampa
Shands Hospital at the University of Florida	Gainesville
Sacred Heart Health	Pensacola
Halifax Medical Center	Daytona Beach
Jackson Memorial Hospital	Miami
Adventist Health System/Sunbelt Health Care	Celebration
Indian River Medical Center	Vero Beach
Tallahassee Memorial	Tallahassee
Baptist Medical Center	Jacksonville
Lower Keys Medical Center	Key West
Sun City Hospital, Inc.	Sun City Center
Mt. Sinai Medical Center	Miami Beach
Healthsouth Rehabilitation Hospital of Spring Hill	Brooksville
Baptist Hospital of Miami	Kendall
Palm Bay Hospital	Palm Beach

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

[13] 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 the DBPR effective October 1, 2011.
[14] Section 499.029(3)(c), F.S.
[15] Section 499.029(3)(b), F.S. A "closed drug delivery system" means a system in which the actual control of the unit-dose medication package is maintained by the facility rather than by the individual patient.
[16] Section 499.029(3)(e), F.S.
[17] Florida Department of Business and Professional Regulation, *Cancer Drug Donation Program Participation Report,* http://www.myfloridalicense.com/DBPR/drugs-devices-and-cosmetics/cancer-drug-donation-program/ (last visited Oct. 7, 2019).

- 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.[18]

Donated drugs may only be prescribed by a licensed practitioner and dispensed by a licensed pharmacist to an eligible patient.[19] 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.[20]

The Division of Drugs, Devices, and Cosmetics within the DBPR does not maintain a list of available donated medications on its website. The DBPR also does not require the participating facilities to report the medications that are available for re-dispensing in the CDDP or the number of donated drugs that have been administered.[21] A facility is required to maintain its own data for three years.[22]

The CDDP site will only accept drugs if:
- The donation is accompanied by a Program Donation and Destruction Record Form;
- The donation occurs at least six months before the drug's expiration date;
- The donated drug is in the original, unopened tamper-evident unit dose packaging;
- The drug must not be adulterated, misbranded, or mislabeled;
- The donated drug was maintained by a health care facility; and
- The drug is not a substance listed on Schedule II, III, IV, or V of s. 893.03, F.S.[23]

A donor or a participant in the CDDP 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.[24]

Regulation of Pharmacy

The DBPR is the state agency charged with the regulation and licensure of businesses and certain professions.[25] Under ch. 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,

[18] Rule 61N-1.026(1), F.A.C.
[19] Section 499.029(5), F.S.
[20] Section 409.029(7)(b), F.S. and Rule 61N-1.026(5), F.A.C.
[21] Email correspondence from the Department of Business and Professional Regulation (Jan. 31, 2019) (on file with the Senate Committee on Health Policy).
[22] *Id.*
[23] *See* Rule 61N-1.026(6), F.A.C. and Florida Department of Business and Professional Regulation, *Florida Cancer Drug Donation Program Brochure*, *http://www.myfloridalicense.com/dbpr/ddc/documents/CDDP.Brochure.pdf* (last viewed: Oct. 8, 2019).
[24] Section 409.029(11), F.S.
[25] Section 20.165, F.S.

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.[26]

The Florida Drug and Cosmetic Act (Act) is codified as ss. 499.001 - 499.094, F.S. The Act provides uniform legislation to be practicably administered in conformity with regulations issued under the authority of, the federal Food, Drug, and Cosmetic Act and the 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, a drug, and, specifically, a prescription drug.[27]

Chapter 465, F.S., assigns regulation of the practice of pharmacy to the Board of Pharmacy in the DOH. 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 medicinal 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 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.[28]

There is an exception for a closed drug delivery system in which unit dose or customized patient medication packages are dispensed to individuals who are admitted as inpatients[29] to a hospital. 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.[30]

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[26] Department of Business and Professional Regulation, *Division of Drugs, Devices, and Cosmetics*, *http://www.myfloridalicense.com/DBPR/drugs-devices-and-cosmetics/* (last visited Oct. 8, 2019).

[27] 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.

[28] Rule 64B16-28.118(2), F.A.C.

[29] Generally, an inpatient is an individual who is admitted to the hospital by a licensed physician or dentist with the expectation that the recipient will stay in excess of 24 hours and occupy an inpatient bed. *See* Agency for Health Care Administration, *Florida Medicaid –Inpatient Hospital Services Coverage Policy* (July 2016), http://ahca.myflorida.com/medicaid/review/specific_policy.shtml (last visited: Oct. 8, 2019).

[30] Rule 64B16-28-118(2), F.A.C.

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.[31]

For nursing facility residents, s. 400.141(1)(d), F.S., requires a pharmacist licensed in Florida who is under contract with a nursing home, to repackage a resident's bulk prescription medication which 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 repackaging 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 that 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.[32]

Federal Law and Regulations

Controlled Substances Act

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.[33] The CSA provides for specific dispensing requirements for controlled substances, including written prescriptions, retention requirements, and refill restrictions, depending on the drug's schedule.[34] Prescriptions must also meet specific labeling and packaging

[31] Rule 64B16-28-118(1), F.A.C.
[32] Section 465.019(2)(a), F.S.
[33] 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 Oct. 8, 2019). 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 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.
[34] 21 U.S.C. §829 and 21 CFR §§1306.21 and 1306.22.

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.[35]

The CSA permits the delivery of controlled substances by an "ultimate user,"[36] who has lawfully obtained the drug, to a designated covered entity for disposal and destruction such as through a prescription drug take-back program.[37] 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.[38]

The last National Prescription Take Back Day sponsored by the DEA resulted in more than 937,443 pounds of expired, unused, and unwanted prescription drugs returned at 6,258 sites on April 27, 2019, of which 35,775 pounds were collected at 204 Florida sites.[39] 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 into wastewater, sewage, or septic tank systems.[40]

Citizen-Support Organizations and Direct-Support Organizations

Citizen-support organizations (CSOs) and direct-support organization (DSOs) are statutorily created non-profit organizations[41] authorized to carry out specific tasks in support of public entities or public causes.[42] The function and purpose of a CSO or DSO are prescribed by an enacting statute and a written contract with the governmental agency the CSO or DSO supports.[43]

[35] 21 U.S.C. §825.
[36] 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.
[37] 21 U.S.C. 822a.
[38] *Id.*
[39] Drug Enforcement Administration, *17th National Take Back Day Collection Results* (April 27, 2019) https://www.deadiversion.usdoj.gov/drug_disposal/takeback/ (last visited Oct. 8, 2019).
[40] *Id.*
[41] Chapter 617, F.S.
[42] *E.g.*, ss. 1009.983 and 413.0111, F.S.
[43] *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, 2019), *available at* https://flauditor.gov/pages/pdf_files/10_700.pdf (last visited: Oct. 8, 2019).

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.[44] The law requires each CSO and DSO to annually submit the following information to the appropriate agency by August 1:[45]

- 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.[46]

Each governmental agency receiving information from a CSO or DSO pursuant to law must make such information available to the public through the agency's website.[47] If the organization maintains a website, the agency's website must provide a link to the organization's website.[48] 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.[49] 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.[50]

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.[51]

Any law creating, or authorizing the creation of, a CSO or DSO must provide 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 have been reviewed by the Legislature by July 1, 2019.[52]

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.[53] An independent certified public accountant in accordance with rules adopted by the Auditor General must

[44] Section 3, ch. 2014-96, L.O.F.
[45] Section 20.058(1), F.S.
[46] 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.
[47] Section 20.058(2), F.S.
[48] *Id.*
[49] Section 20.058(4), F.S.
[50] *Id.*
[51] *Id.* at (3).
[52] *Id.* at (5).
[53] 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 governmental agency the CSO or DSO supports.[54] 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.[55]

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.[56] 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.[57]

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." Section 252.36(5), F.S., 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;

[54] Section 215.981(1), F.S.
[55] Section 11.45(3), F.S.
[56] 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.
[57] Section 112.3251, F.S.

- Hospices that have maintained control of a patient's prescription drugs;
- Hospitals with closed drug delivery systems;
- Pharmacies;
- Drug manufacturers or wholesale distributors;
- Medical device manufacturers or suppliers; and
- Prescribing individuals who receive prescription drugs or supplies directly from a drug manufacturer, wholesale distributor, or pharmacy.

The bill provides that prescription drugs and supplies donated by a patient, a patient's legal representative, or a patient's next of kin are exempt from one, non-applicable safety provision that applies to other donations; however, these donations are subject to all applicable safety and storage requirements of the Program.

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;[58]
- Has been stored according to manufacturer or United States Pharmacopeia storage requirements;
- Will not expire within three months after the donation is made and the drug's packaging contains a lot number and expiration date of the drug;
- 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.[59]

The bill requires that prescription drugs or supplies must 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 the 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

[58] The United States Pharmacopeia is a compendium of drug information published annually by the United Stated Pharmacopeial Convention.
[59] The Federal Food and Drug Administration requires drugs with serious safety concerns to have a Risk Evaluation and Mitigation Strategy in place to avoid adverse incidents. *See* U.S. Food & Drug Administration, *Risk Evaluation and Mitigation Strategies*, https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems (last visited: Oct. 9, 2019).

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 must maintain an inventory of all prescription drugs and supplies donated to the Program, including donations made at local repositories. The centralized repository may redistribute prescription drugs and supplies to local repositories 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. The form, to be created by the DOH in rule, must 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;[60] 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 must issue the eligible patient an identification card that is valid for up to one

[60] 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.

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 payer 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:

- Have an established protocol to notify recipients of the drug;
- Destroy all of the recalled or expired 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 must submit 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 that, before a donated drug may be dispensed, the dispenser must provide written notification to the patient, or his or her legal representative:

- That the drug was donated to the Program;
- That the dispenser is not liable for any injury, death, or loss related to the dispensing of the drug; and
- Of any 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, 2025, 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, 2020.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

CS/SB 58 includes the issuance of an identification card to eligible patients who participate in the Program. These individuals are required to submit intake forms to a local repository to determine their eligibility for the Program. Eligibility is based on income and sensitive medical information. The local repository must send a summary of each intake form to the centralized pharmacy. It is not clear if that information would then be stored by the Department of Health, the repositories, or any contracted vendor if a contract is established.

The bill does not address how patient identification information collected during the medication donation process will be handled, or if any of the patient medical information not otherwise protected by other statutes, such as the Health Insurance Portability and Accountability Act of 1996 (HIPAA),[61] could be subject to a public records release request since the bill does not have a companion public records exemption bill. If records are subject to a public records release, it may impact participation in the Program.

C. Trust Funds Restrictions:

None.

[61] The Health Insurance Accountability and Portability Act of 1996 or HIPAA, Public Law 104-191, was enacted to address concerns about both the effectiveness and the security of health care data. HIPAA required the federal Department of Health and Human Services to adopt rules relating to national standards for electronic health transactions, health care privacy and security, and health care clearinghouses. The privacy rule component of HIPAA sets standards for the use and disclosure of individuals' health care information, specifically what was protected, who was protected, how it was protected, and how it could be released and used. *See* Health Information Privacy, *HIPAA for Professionals,* https://www.hhs.gov/hipaa/for-professionals/index.html (last visited: Oct. 7, 2019).

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Facilities participating in the program as repositories may incur costs associated with collecting, storing, and re-dispensing donated prescription drugs. Those same facilities may enjoy cost savings to the extent their patients might receive needed drugs or supplies on a more timely basis. Without such donations, some patients could return as sicker and costlier patients at a later date.

Participating facilities may recover a portion of costs by charging the patient a nominal handling fee for the preparation and dispensing of prescription drugs and supplies. The fee may not exceed the amount established by the DOH rule.

C. Government Sector Impact:

CS/SB 58 authorizes the creation of a direct-support organization (DSO) to provide assistance, funding, and promotional support for the Program's authorized activities. Sufficient funding and assistance provided by the DSO could relieve the DOH of negative fiscal impacts created by the bill. The Department of Health (DOH) may need to submit a legislative budget request for an indeterminate amount to support the Program, if the DSO is unsuccessful in collecting the necessary resources to operate the Program.

The DOH may experience an increase in workload and operational costs to administer the program. The DOH estimates a cost of $483,671 for the first year of implementation if the DOH serves as the central repository.[62]

[62] Department of Health fiscal analysis (October 31, 2019) (on file with the Senate Appropriations Subcommittee on Health and Human Services).

Department of Health Estimated Costs for Fiscal Year 2020-21	
Component	**Amount**
Facility Costs • Estimated need for a 5,000 square foot facility at current market rate of $12.02 per square foot: $60,100 • Estimated Annual Utilities: $14,000	**$74,100**
Personnel Costs • 1.0 FTE – Senior Pharmacist: • 1.0 FTE –Administrative Assistant • 3.0 FTE –Pharmacy Technicians • Standard Expense Package (5.0 FTE): ○ *Recurring/Nonrecurring Total: $52,694* •	**$304,271**
Enhancements to Pharmacy Systems Enhancements to DOH Dispensing and Pharmaceutical Forms System (PFS) Inventory systems (nonrecurring cost).	**$70,000**
Other Potential Costs Shipping of products to local repositories and a restricted Prescription Drug Distributor License	**$35,300**
TOTAL OVERALL FIRST YEAR COSTS	**$483,671**

VI. Technical Deficiencies:

None.

VII. Related Issues:

The Cancer Drug Donation Program (CDDP) as previously described is not amended or incorporated into this proposed, broader drug donation program under the bill. The two programs would continue to run simultaneously and administered separately by the DOH and the DBPR.

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

CS by Health Policy on October 15, 2019:
The CS makes a technical correction to the underlying bill by changing "centralized pharmacy" to "centralized repository" on lines 323-324.

B. Amendments:

None.