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 Health Policy

BILL:	CS/SB 710
INTRODUCER:	Health Policy Committee and Senator Book
SUBJECT:	Prescription Drug Donation Program
DATE:	December 5, 2017
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Lloyd	Stovall	HP	**Fav/CS**
2.			AHS	
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 710 changes the name of the Cancer Drug Donation Program (CDDP) to the Prescription Drug Donation Program. The bill expands the program from handling cancer only drugs to permitting the donation of any prescription drug, excluding non-controlled substance, that meets the applicable safety criteria. The bill also extends participation in the program to certain, licensed nursing home facilities with a closed drug delivery system.

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

[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.

prescription drug reuse program in long-term care facilities only and has since 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 may vary in the number and types of sites that are considered to be eligible locations where patients or donors may deposit donations and in the types of drugs included in the program. Generally, the drugs are not controlled substances and 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]

The statutory provisions of many of the 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 6 months or more 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]

State programs vary by which drugs and supplies will be accepted, participant eligibility requirements, and the dispensing fees for the donated drugs. Some programs, such as Florida's, are limited to cancer treatment drugs only. Twelve other states besides Florida - Colorado, Kentucky, Michigan, Minnesota, Montana, Nevada, Ohio, Pennsylvania, Utah, Washington, and Wisconsin - have cancer drug only donation programs. Individuals may also 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).

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

[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 which 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.
[6] *Supra* note 1.
[7] *Supra* note 1.

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, 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 by the 2006 Florida Legislature[12] and is administratively housed within the Department of Business and Professional Regulation (DBPR). The CDDP allows defined 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, 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 which may collect donations are currently 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 statute 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 individuals who are:

- Florida residents who have been diagnosed with cancer; and
- 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]

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[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.
[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.

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] Facilities are required to maintain their data for 3 years.[21]

The CDDP will only accept drugs if:

- The drug expires at least 6 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]

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's agency charged with the regulation and licensure of businesses and professionals.[24] Under the provisions of chapter 499, F.S., the DBPR's 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, 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 permit and licenses; and the Drug Wholesale Distributor Advisory Council.[25]

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[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] E-Mail 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.
[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).

The Florida Drug and Cosmetic Act (Act) is codified as ss. 499.001 – 499.081, F.S. The chapter 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(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, shall 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] The exception is that in a closed drug delivery system in which unit dose or 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 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 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

[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.
[28] Rule 64B16-28-118(2), F.A.C.
[29] Rule 64B16-28-118(1), F.A.C.

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 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 does permit 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;

[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 examples of such drugs include 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 such drugs under Schedule II include opium, morphine, codeine, and oxycodone. Under Schedule III, these 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 like Valium, Xanax, and Darvon. The fifth and final schedule, Schedule V, have an abuse potential less than those listed in Schedule IV and 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.

- 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 being 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 also avoid the potential safety hazard of drugs flushed down the toilet.[38]

III. Effect of Proposed Changes:

CS/SB 710 amends s. 499.029, F.S., changing the name of the Cancer Drug Donation Program to the Prescription Drug Donation Program. The bill amends any reference that currently limits donations to "cancer drugs," replacing it with "prescription drugs" and extends participation of certain, licensed nursing home facilities with a closed drug delivery system.

The term "prescription drug" is defined in the bill as having the same meaning as provided in s. 499.003, F.S., and includes cancer drugs. This definition does not include a controlled substance which includes a substance listed in Schedules II through V of s. 893.03, F.S.

The bill also redefines the term "donor" and the term "participant facility" to include a nursing home facility licensed under part II of chapter 400 which has a closed drug delivery system. This will allow a nursing home to not only donate prescription drugs, but to receive donations and dispense applicable donations to eligible patients. Nursing homes operating with a Class I permit are currently prohibited from dispensing prescription drugs under state law. However, under s. 499.0029(13), F.S., it provides that if any conflict exists between the provisions in this section and the provisions in this chapter or chapter 465, the sections that control the CDDP would control.

The bill provides an effective date of July 1, 2018.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

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[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.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Participation in the program is voluntary; however, for the private, eligible facilities that may elect to collect pharmaceutical donations there may be a cost involved in the collecting, storing, and re-dispensing of donations. For those patients on the receiving end of these donations, there may also be a cost savings to those same health care participating facilities as those patients may be receiving needed health care services on a more timely basis. Without such donations, those same patients could return as sicker, more costlier 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.[39]

C. Government Sector Impact:

The expansion of the program to include all prescription drugs and to allow nursing homes to participate will increase the workload on the DBPR staff to process application requests for the registry. The DBPR indicates that this workload increase can be handled within current resources.[40]

Public facilities would face the same collecting, storing, and dispensing fiscal impacts if electing to participate in the expanded program and could potentially also achieve any savings through the participation of the uninsured or underinsured from their communities.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The bill redefines a "donor" and amends the definition of a "participant facility" to permit the participation of nursing home facilities licensed under part II of chapter 400 in the proposed

[39] Rule 61N-1.026(5), F.A.C.
[40] Department of Business and Professional Regulation, *House Bill 291 Analysis* (Nov. 3, 2017), p.4, (on file with the Senate Committee on Health Policy).

Prescription Drug Donation Program. A nursing home typically has a Class I institutional pharmacy permit issued under s. 465.019(2)(a), F.S. The permit does not authorize the pharmacy to dispense medicinal drugs, but to have patient-specific medications that have already been dispensed to their residents.

Under the bill, participating nursing home facilities would be authorized to collect and dispense donated prescription drugs. This change would be in conflict with the existing permit conditions for nursing home facilities. The current CDDP statute, however, does provide a conflict of laws provision providing that if there is any conflict between the provisions of this chapter or chapter 465, the provisions of this section control the operation of the CDDP.

VIII. Statutes Affected:

This bill substantially amends section 499.029 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.)

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.