Tab 1	**CS/SB 58** by **HP, Book (CO-INTRODUCERS) Harrell, Stewart, Cruz**; (Compare to CS/H 00177) Prescription Drug Donation Repository Program

The Florida Senate

COMMITTEE MEETING EXPANDED AGENDA

APPROPRIATIONS SUBCOMMITTEE ON HEALTH AND HUMAN SERVICES
Senator Bean, Chair
Senator Harrell, Vice Chair

MEETING DATE: Wednesday, January 15, 2020
TIME: 4:00—6:00 p.m.
PLACE: *Pat Thomas Committee Room,* 412 Knott Building

MEMBERS: Senator Bean, Chair; Senator Harrell, Vice Chair; Senators Book, Diaz, Farmer, Flores, Hooper, Passidomo, Rader, and Rouson

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
1	**CS/SB 58** Health Policy / Book (Compare CS/H 177)	Prescription Drug Donation Repository Program; Designating the "Prescription Drug Donation Repository Program Act"; creating the program within the Department of Health; prohibiting donations to specific patients; requiring inspection of donated prescription drugs and supplies by a licensed pharmacist; prohibiting the sale of donated prescription drugs and supplies under the program; requiring the department or contractor to establish, maintain, and publish a registry of participating local repositories and available donated prescription drugs and supplies; authorizing the Governor to waive program patient eligibility requirements during a declared state of emergency, etc. HP 10/15/2019 Fav/CS AHS 01/15/2020 Favorable AP	Favorable Yeas 10 Nays 0

TAB	OFFICE and APPOINTMENT (HOME CITY)	FOR TERM ENDING	COMMITTEE ACTION
	Senate Confirmation Hearing: A public hearing will be held for consideration of the below-named executive appointment to the office indicated.		
	State Surgeon General		
2	Rivkees, Scott A. (Tallahassee)	Pleasure of Governor	Recommend Confirm Yeas 8 Nays 2

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
	Other Related Meeting Documents		

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.

By the Committee on Health Policy; and Senators Book, Harrell, and Stewart

588-00880-20 202058c1

A bill to be entitled

An act relating to the Prescription Drug Donation Repository Program; creating s. 465.1902, F.S.; providing a short title; defining terms; creating the Prescription Drug Donation Repository Program within the Department of Health; specifying the purpose of the program; authorizing the department to contract with a third-party vendor to administer the program; specifying entities that are eligible donors; providing criteria and procedures for eligible donations; prohibiting donations to specific patients; providing that certain prescription drugs eligible for return to stock must be credited to Medicaid and may not be donated under the program; prohibiting the donation of certain drugs; clarifying that a repository is not required to accept donations of prescription drugs or supplies; requiring inspection of donated prescription drugs and supplies by a licensed pharmacist; providing inspection, inventory, and storage requirements for centralized and local repositories; requiring a local repository to notify the centralized repository within a specified timeframe after receiving a donation of prescription drugs or supplies; authorizing the centralized repository to redistribute prescription drugs or supplies; authorizing a local repository to transfer prescription drugs or supplies to another local repository with authorization from the centralized repository; requiring a local repository to notify the

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department of its intent to participate in the program; providing notification requirements; providing a procedure for a local repository to withdraw from participation in the program; requiring the department to adopt rules regarding the disposition of prescription drugs and supplies of a withdrawing local repository; specifying conditions for dispensing donated prescription drugs and supplies to eligible patients; providing intake collection form requirements; requiring a local repository to issue an eligible patient who completes an intake collection form a program identification card; prohibiting the sale of donated prescription drugs and supplies under the program; authorizing a repository to charge the patient a nominal handling fee for the preparation and dispensing of prescription drugs or supplies under the program; requiring repositories to establish a protocol for notifying recipients of a prescription drug recall; providing for destruction of donated prescription drugs under certain circumstances; providing recordkeeping requirements; requiring the centralized repository to submit annual reports to the department; requiring the department or contractor to establish, maintain, and publish a registry of participating local repositories and available donated prescription drugs and supplies; requiring the department to publish certain information and forms on its website; providing immunity from civil and criminal liability and from professional disciplinary

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

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

review and repeal of provisions relating to the direct-support organization; requiring the department to adopt rules; amending s. 252.36, F.S.; authorizing the Governor to waive program patient eligibility requirements during a declared state of emergency; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 465.1902, Florida Statutes, is created to read:

465.1902 Prescription Drug Donation Repository Program.—

(1) SHORT TITLE.—This section may be cited as the "Prescription Drug Donation Repository Program Act."

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

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

(b) "Closed drug delivery system" means a system in which the actual control of the unit-dose medication package is maintained by the facility, rather than by the individual patient.

(c) "Contractor" means the third-party vendor approved by the department to implement and administer the program as authorized in subsection (4).

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

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

(f) "Dispenser" means a health care practitioner who, within the scope of his or her practice act, is authorized to dispense medicinal drugs and who does so under this section.

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

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

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

(j) "Health care practitioner" or "practitioner" means a practitioner licensed under this chapter, chapter 458, chapter 459, chapter 461, chapter 463, chapter 464, or chapter 466.

(k) "Indigent" means an individual whose family income for the 12 months preceding the determination of income is below 200 percent of the federal poverty level as defined by the most recently revised poverty income guidelines published by the United States Department of Health and Human Services.

(l) "Local repository" means a health care practitioner's office, a pharmacy, a hospital with a closed drug delivery system, a nursing home facility with a closed drug delivery system, or a free clinic or nonprofit health clinic that is licensed or permitted to dispense medicinal drugs in this state.

(m) "Nonprofit health clinic" means a nonprofit legal entity that provides medical care to patients who are indigent, uninsured, or underinsured. The term includes, but is not

limited to, a federally qualified health center as defined in 42 U.S.C. s. 1396d(l)(2)(B) and a rural health clinic as defined in 42 U.S.C. s. 1396d(l)(1).

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

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

(p) "Prescription drug" has the same meaning as the term "medicinal drugs" or "drugs," as those terms are defined in s. 465.003(8), but does not include controlled substances or cancer drugs donated under s. 499.029.

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

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

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

(t) "Underinsured" means a person who has third-party insurance or is eligible to receive prescription drugs or supplies through the Medicaid program or any other prescription drug program funded in whole or in part by the Federal Government, but who has exhausted these benefits or does not have prescription drug coverage for the drug prescribed.

(u) "Uninsured" means a person who has no third-party insurance and is not eligible to receive prescription drugs or supplies through the Medicaid program or any other prescription

drug program funded in whole or in part by the Federal Government.

(3) PRESCRIPTION DRUG DONATION REPOSITORY PROGRAM; CREATION; PURPOSE.—The Prescription Drug Donation Repository Program is created within the department for the purpose of authorizing and facilitating the donation of prescription drugs and supplies to eligible patients.

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

(5) DONOR ELIGIBILITY.—The centralized repository or a local repository may accept a donation of a prescription drug or supply only from:

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

(b) Hospices that have maintained control of a patient's prescription drugs.

(c) Hospitals with closed drug delivery systems.

(d) Pharmacies.

(e) Drug manufacturers or wholesale distributors.

(f) Medical device manufacturers or suppliers.

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

(6) PRESCRIPTION DRUGS AND SUPPLIES ELIGIBLE FOR DONATION; DONATION REQUIREMENTS; PROHIBITED DONATIONS.—

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

accepted for donation under the program. Donations must be made on the premises of the centralized repository or a local repository to a person designated by the repository. A drop box may not be used to accept donations.

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

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

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

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

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

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

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

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

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

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

specific patient.

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

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

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

(7) INSPECTION AND STORAGE.—

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

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

(c) The centralized repository and local repositories shall store donated prescription drugs and supplies in a secure storage area under the environmental conditions specified by the manufacturer or the United States Pharmacopeia for the respective prescription drugs or supplies. Donated prescription

drugs and supplies may not be stored with other inventory. A local repository shall quarantine donated prescription drugs or supplies until they are inspected and approved for dispensing under this section.

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

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

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

(8) PROGRAM PARTICIPATION.—

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

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

including the name of the issuing agency.

2. The name and telephone number of the pharmacist employed by or under contract with the intended local repository who is responsible for the inspection of donated prescription drugs and supplies.

3. A statement signed and dated by the responsible pharmacist which affirms that the intended local repository meets the eligibility requirements of this section.

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

(9) DISPENSING REQUIREMENTS; PROHIBITIONS.—

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

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

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

3. A statement signed and dated by the eligible patient which affirms that he or she meets the eligibility requirements of this section.

(b) Upon receipt of a completed and signed intake collection form, the local repository shall issue him or her a

program identification card, which is valid for 1 year after its date of issuance. The card must be in a form prescribed by the department by rule.

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

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

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

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

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

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

(10) RECALLED PRESCRIPTION DRUGS AND SUPPLIES.—

(a) The centralized repository and each local repository shall establish and follow a protocol for notifying recipients in the event of a prescription drug recall.

(b) Local repositories shall destroy all recalled or expired prescription drugs and all prescription drugs that are

not suitable for dispensing in the repository. Local repositories must complete a destruction information form for all such drugs, in accordance with department rule.

(11) RECORDKEEPING.—

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

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

(12) REGISTRIES; PUBLICATION OF FORMS.—

(a) The department or contractor shall establish and maintain a registry of all local repositories and of prescription drugs and supplies available under the program. The registry of local repositories must include each repository's name, address, website, and telephone number. The registry of available prescription drugs and supplies must include the name, strength, available quantity, and expiration date of the prescription drug or supplies and the name and contact information of each repository where such drug or supplies are available. The department shall publish the registry on its website.

(b) The department shall publish all forms required by this section on its website.

(13) IMMUNITY FROM LIABILITY, DISCIPLINARY ACTION.—

(a) Any donor of prescription drugs or supplies and any

participant in the program who exercises reasonable care in donating, accepting, distributing, or dispensing prescription drugs or supplies under the program is immune from civil or criminal liability and from professional disciplinary action by the state for any injury, death, or loss to person or property relating to such activities.

(b) A pharmaceutical manufacturer who exercises reasonable care is not liable for any claim or injury arising from the donation of any prescription drug or supply under this section, including, but not limited to, liability for failure to transfer or communicate product or consumer information regarding the donated prescription drug, including its expiration date.

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

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

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

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

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

(a) *Entity organization.*—The direct-support organization

must operate in accordance with s. 20.058 and is:

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

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

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

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

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

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

1. The contract must require the direct-support

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

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

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

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

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

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

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

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

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

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

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

the benefit of the program if the direct-support organization ceases to exist or if the contract is terminated.

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

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

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

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

1. The department may prescribe any condition with which the direct-support organization must comply in order to use fixed property or facilities of the department.

2. The department may not allow the use of any fixed property or facilities of the department by the direct-support

organization if the organization does not provide equal membership and employment opportunities to all persons regardless of race, color, religion, sex, age, or national origin.

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

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

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

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

(k) *Repeal.*—This subsection is repealed on October 1, 2025, unless reviewed and saved from repeal by the Legislature.

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

Section 2. Paragraph (o) is added to subsection (5) of section 252.36, Florida Statutes, to read:

252.36 Emergency management powers of the Governor.—

(5) In addition to any other powers conferred upon the

Governor by law, she or he may:

(o) Waive the patient eligibility requirements of s. 465.1902.

Section 3. This act shall take effect July 1, 2020.

2020 AGENCY LEGISLATIVE BILL ANALYSIS

AGENCY: Florida Department of Health

BILL INFORMATION	
BILL NUMBER:	SB 58
BILL TITLE:	Prescription Drug Donation Repository Program
BILL SPONSOR:	Book
EFFECTIVE DATE:	7/1/2020

COMMITTEES OF REFERENCE
1) Health Policy
2) Appropriations Subcommittee on Health and Human Services
3) Appropriations
4) Click or tap here to enter text.
5) Click or tap here to enter text.

CURRENT COMMITTEE
Click or tap here to enter text.

SIMILAR BILLS	
BILL NUMBER:	177
SPONSOR:	Yarborough

PREVIOUS LEGISLATION	
BILL NUMBER:	Click or tap here to enter text.
SPONSOR:	Click or tap here to enter text.
YEAR:	Click or tap here to enter text.
LAST ACTION:	Click or tap here to enter text.

IDENTICAL BILLS	
BILL NUMBER:	Click or tap here to enter text.
SPONSOR:	Click or tap here to enter text.

Is this bill part of an agency package?
No

BILL ANALYSIS INFORMATION

DATE OF ANALYSIS:	Click or tap here to enter text.
LEAD AGENCY ANALYST:	Click or tap here to enter text.
ADDITIONAL ANALYST(S):	Click or tap here to enter text.
LEGAL ANALYST:	Click or tap here to enter text.
FISCAL ANALYST:	Click or tap here to enter text.

POLICY ANALYSIS

1. EXECUTIVE SUMMARY

Section 465.1902, Florida Statutes is created to read 465.1902 Prescription Drug Donation Repository Program, or “The Prescription Drug Donation Repository Program Act." The purpose is to establish a means to authorize and facilitate the donation of prescription drugs and supplies to eligible patients.

2. SUBSTANTIVE BILL ANALYSIS

1. PRESENT SITUATION:

DOH does not have a Drug Donation Repository Program meeting the specification outlined in the bill. Currently, there is a program under the PDMP law (Section 893.055, F.S.), that authorized the Department of Health to establish a program to encourage safer prescribing of controlled substances and to reduce drug abuse and diversion within the state of Florida called The Florida Prescription Drug Monitoring Program, known also as E-FORCSE® (Electronic-Florida Online Reporting of Controlled Substance Evaluation Program). Other federally sponsored programs, such as prescription drug disposal or take-back programs, are administered and monitored by the EPA and the FDA.

Cancer Drug Donation Program - A similar program exists under Florida Statutes Section 499.029 - Cancer Drug Donation Program. (Fla. Stat. § 499.029), or the “Cancer Drug Donation Program Act," which has the purpose of authorizing and facilitating the donation of cancer drugs and supplies to eligible patients.

Recipient Eligibility Requirements - Under the program, a Florida resident who is diagnosed with cancer and has a valid prescription from their physician is eligible to receive drugs or supplies through the Cancer Drug Donation Program (program). A person is ineligible to participate in the program if he or she is eligible to receive cancer drugs or supplies through the Medicaid program, third-party insurer, or any other prescription drug program funded in whole or in part by the Federal Government, unless these benefits have been exhausted, or a certain cancer drug or supply need is not covered by the program.

Donor Eligibility Requirements - Cancer drugs and supplies may be donated to a participant facility by a patient or a patient representative, donated through a closed drug delivery system by the facility where the patient is receiving treatment, or health care facilities, nursing homes, hospices, or hospitals with a closed drug delivery system, or pharmacies, drug manufacturers, medical device manufacturers or suppliers, or wholesalers of drugs or supplies; or a licensed allopathic or osteopathic physician who receives cancer drugs or supplies directly from a pharmacy, drug manufacturer, or drug wholesaler.

2. EFFECT OF THE BILL:

Under Section 465.1902, Florida Statutes Prescription Drug Donation Repository Program, or “The Prescription Drug Donation Repository Program Act”:

Recipient Eligibility Requirements –

- Each eligible patient without a program identification card must submit an intake collection form to a local repository before receiving prescription drugs or supplies under the program. The department shall prescribe a form by rule, which must include at least all of the following:
- The name, street address, and telephone number of the eligible patient.
- The basis for eligibility, which must specify that the patient is indigent, uninsured, or underinsured.
- A statement signed and dated by the eligible patient affirming that he or she meets the eligibility requirements of this section.
- Upon receipt of a completed and signed intake collection form, the local repository shall issue him or her a program identification card, which is valid for 1 year after its date of issuance. The card must be in a form prescribed by the department by rule.
- The local repository shall send a summary of each intake collection form to the centralized pharmacy within 5 days after receiving it.
- A dispenser may dispense donated prescription drugs or supplies only to an eligible patient who has a program identification card or who has submitted a completed intake collection form.
- A dispenser shall inspect the donated prescription drugs or supplies before dispensing them.
- A dispenser may provide dispensing and consulting services to an eligible patient.
- Donated prescription drugs and supplies may not be sold or resold under the program.
- A dispenser of donated prescription drugs or supplies may not submit a claim or otherwise seek reimbursement from any public or private third-party payor for donated prescription drugs or supplies dispensed under this program. However, a repository may charge the patient a nominal handling fee, established by department rule, for the preparation and dispensing of prescription drugs or supplies under the program.

Donor Eligibility Requirements - The centralized repository or a local repository may accept a donation of a prescription drug or supply only from:

- Nursing home facilities with closed drug delivery systems;
- 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;
- Prescribers who receive prescription drugs or supplies directly from a drug manufacturer, wholesale distributor, or pharmacy.
- Prescription drugs and supplies eligible for donation; donation requirements; Prohibited donations.
- Only prescription drugs and supplies that have been approved for medical use in the United States and that meet the criteria for donation established by this section may be accepted for donation under the program.
- Donations must be made on the premises of the centralized repository or a local repository to a person designated by the repository.
- A drop box may not be used to accept donations.
- The centralized repository or a local repository may accept a prescription drug only if:
- The drug is in its original sealed and tamper-evident packaging. Single-unit-dose drugs may be accepted if the single-unit-dose packaging is unopened.

- The drug requires storage at normal room temperature per the manufacturer or the United States Pharmacopeia.
- The drug has been stored according to manufacturer or United States Pharmacopeia storage requirements.
- The drug does not have any physical signs of tampering or adulteration and there is no reason to believe that the drug is adulterated.
- The packaging does not have any physical signs of tampering, misbranding, deterioration, compromised integrity, or adulteration.
- The packaging indicates the lot number and expiration date of the drug. If the lot number is not retrievable, all specified medications must be destroyed in the event of a recall.
- The drug has an expiration date that is more than 3 months after the date that the drug was donated.
- The centralized repository or a local repository may accept supplies only if they are in their original, unopened, sealed packaging and have not been tampered with or misbranded.
- Prescription drugs or supplies may not be donated to a specific patient.
- Prescription drugs billed to and paid for by Medicaid in long-term care facilities which are eligible for return to stock under federal Medicaid regulations must be credited to Medicaid and may not be donated under the program.
- Prescription drugs with an approved Federal Food and Drug Administration Risk Evaluation and Mitigation Strategy that includes Elements to Assure Safe Use are not eligible for donation under the program.

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

3. DOES THE BILL DIRECT OR ALLOW THE AGENCY/BOARD/COMMISSION/DEPARTMENT TO DEVELOP, ADOPT, OR ELIMINATE RULES, REGULATIONS, POLICIES, OR PROCEDURES? Y☒ N☐

If yes, explain:	The bill suggests protocols will be necessary to notify the department of its intent to participate in the program as a local repository before accepting or dispensing any prescription drugs or supplies pursuant to this bill; designate protocols for setting up locations to keep donated drugs separate from other pharmacy drugs; develop application process and forms for designating pharmacist or technician responsibilities, CE certification programs and requirements. Other protocols may be necessary based on further review and input from other entities.
Is the change consistent with the agency's core mission?	Y☒ N☐
Rule(s) impacted (provide references to F.A.C., etc.):	Florida Statutes • Chapter 465: Pharmacy • Chapter 893: Drug Abuse Prevention and Control • Chapter 499: Drugs; Devices; Cosmetics; Household Products • Chapter 456: Health Professions and Occupations: General Provisions • Chapter 120: Administrative Procedure Act

	Florida Administrative Code Rules • Title 64B16: Florida Administrative Code • Rule 64B16 ER12-1: Immediate Notification of Compounding Status and Inspections

4. **WHAT IS THE POSITION OF AFFECTED CITIZENS OR STAKEHOLDER GROUPS?**

Proponents and summary of position:	Unknown
Opponents and summary of position:	Unknown

5. ARE THERE ANY REPORTS OR STUDIES REQUIRED BY THIS BILL? Y☒ N☐

If yes, provide a description:	Local repositories shall maintain records of prescription drugs and supplies that are accepted, donated, dispensed, distributed, or destroyed under the program and that should be reported to the centralized repository, quarterly. The centralized repository shall store this records and report to the DOH on an annual basis.
Date Due:	Click or tap here to enter text.
Bill Section Number(s):	Section 1

6. ARE THERE ANY NEW GUBERNATORIAL APPOINTMENTS OR CHANGES TO EXISTING BOARDS, TASK FORCES, COUNCILS, COMMISSIONS, ETC. REQUIRED BY THIS BILL? Y☒ N☐

Board:	The bill authorizes the DOH to establish a "Direct-Support Organization"
Board Purpose:	To provide assistance, funding, and promotional support for the program activities. The purpose and objectives of the organization must be consistent with the goal of the DOH, in the best interest of the state, and in accordance with the adopted goals and the mission of the DOH.
Who Appoints:	State Surgeon General
Changes:	N/A
Bill Section Number(s):	N/A

FISCAL ANALYSIS

1. DOES THE BILL HAVE A FISCAL IMPACT TO LOCAL GOVERNMENT? Y☐ N☒

Revenues:	None
Expenditures:	None
Does the legislation increase local taxes or fees? If yes, explain.	No
If yes, does the legislation provide for a local referendum or local governing body public vote prior to implementation of the tax or fee increase?	N/A

2. DOES THE BILL HAVE A FISCAL IMPACT TO STATE GOVERNMENT? Y☒ N☐

Revenues:	The bill states that a repository may charge the patient a nominal handling fee, established by the Department rule, for the preparation and dispensing of prescription drugs and supplies under this program.
Expenditures:	The following assumed costs could be experienced (these are estimates based on like activity): Space and Housing: Current market cost for lease space by our existing pharmacy is $12.02 per sq./ft. (5,000 sq. Ft.) not to include utilities; annual amount estimated at $60,100/year recurring not including utilities which could add another $14,000 annually. Total Space Rental: $74,100 Staffing 1 full-time Sr. Pharmacist, 3 full-time pharmacy techs, 1 full-time admin support. Total Staffing (Year 1) $251,577 Recurring/Non-recurring Total Expense Standard (Year 1) $52,694 Existing System Enhancements to QS1 (Dispensing) and Pharmaceutical Forms System (PFS-Inventory)

	Enhancements may be required of both systems to create separate accounts for the donated drug program. Average hourly cost for system enhancements by the provider ranges from $75 - $95/hour. It is difficult to determine the actual required hours, but the last inventory enhancement in PFS required approximately 300 hours to complete. The estimated cost for each system could approximately be $35,000. The hosting costs would be assumed in the current annual cost and minimal in impact. Total non-recurring cost for enhancements approximately $70,000. Other Potential Costs: Shipping of product to eligible clients: approximately $35,000 annually (figure based on current shipping costs for prescriptions and related supplies.) A restricted Prescription Drug Distributor License - $300/annually ($600/bi-annually) Total Other Costs: $35,300 Total Overall Cost: $483,671 (Year 1)
Does the legislation contain a State Government appropriation?	No
If yes, was this appropriated last year?	N/A

3. DOES THE BILL HAVE A FISCAL IMPACT TO THE PRIVATE SECTOR? Y☐ N☒

Revenues:	Unknown
Expenditures:	Unknown
Other:	N/A

4. DOES THE BILL INCREASE OR DECREASE TAXES, FEES, OR FINES? Y☐ N☒

If yes, explain impact.	Click or tap here to enter text.
Bill Section Number:	Click or tap here to enter text.

TECHNOLOGY IMPACT

1. DOES THE BILL IMPACT THE AGENCY'S TECHNOLOGY SYSTEMS (I.E. IT SUPPORT, LICENSING SOFTWARE, DATA STORAGE, ETC.)? Y☐ N☒

If yes, describe the anticipated impact to the agency including any fiscal impact.	N/A

FEDERAL IMPACT

1. DOES THE BILL HAVE A FEDERAL IMPACT (I.E. FEDERAL COMPLIANCE, FEDERAL FUNDING, FEDERAL AGENCY INVOLVEMENT, ETC.)? Y☐ N☒

If yes, describe the anticipated impact including any fiscal impact.	Click or tap here to enter text.

ADDITIONAL COMMENTS

Bill includes leasing costs of $74,100/year. An addition of 5 FTEs with salaries and standard expense package totaling $304,271. A Restricted Prescription Drug Distributor – Charitable Organization permit with a total recurring cost of $600/bi-annually. Non-recurring cost for system enhancements of $70,000. And other recurring costs of $35,000 for shipping payments, additional equipment and additional supplies. Total year 1 costs $483,671

Bureau Public Health Pharmacy (BPHP) doesn't currently have the facility space to house this new program or industry.

BPHP doesn't regulate facilities or determine client eligibility.

BPHP doesn't currently have a place for drugs to be dropped on the premises as the bill states must happen in section (6)(a)

LEGAL - GENERAL COUNSEL'S OFFICE REVIEW

Issues/concerns/comments:	Lines 103-106, definition of "centralized repository" appears that this is a distributor under s. 499.003 who may wholesale distribute under that chapter. The current proposal indicates that this could be the DOH Central Pharmacy or a contracted wholesale distributor authorized under Ch. 499. Lines 119-121, definition of "dispenser," see" Dispensing practitioner" at section 465.0276 in this chapter. Consider using "dispensing practitioner" instead of dispenser. Lines 151-153, definition of "prescriber," see definition in section 465.025, "Substitution of drugs." Consider using consistent definition. Lines 190-191 provides that hospices that have" maintained control of a patient's prescription drugs" are an entity that may be an acceptable donor under this program. How is this different from the "closed drug delivery systems" mentioned in relation to nursing home facilities and hospitals? Lines 217-222 refer to drugs and packaging not being" adulterated" or "misbranded." As these are not defined terms, are they used as defined in sections 499.006 and 499.007? Lines 246-254 states that the inspecting pharmacist at the centralized or local repository determines whether or not the donor individual or entity are eligible donors and if the donated drugs and supplies are eligible. There does not appear to be any DOH oversight in this matter and subsection 13 [Lines 376-383] appears to exempt them from liability or disciplinary action, except in the case of a lack of exercise of "reasonable care." The department should consider whether this would require some additional rulemaking to establish disciplinary standards. Lines 262-265 state that a local repository must quarantine donated drugs or supplies until they are inspected and approved for dispensing. However, Lines 254-256 in the preceding paragraph state that a local repository that receives drugs and supplies from the centralized repository is not required to reinspect the drugs and supplies. Lines 270-272 requires that a local repository notify the centralized repository within 5 days after receipt of any donated drugs or supplies. Not clear what the purpose of this notification is and it appears somewhat duplicative of the reporting requirement of paragraph (11)(b) [Lines 353-361] that local repositories must submit all records quarterly to the centralized repository. Lines 274-280 may create problems with track and trace(auditing) requirements under Chapter 499 and federal requirements. Keeping good audit trails and records will be extremely important. Lines 282-285 suggest amending as follows: "A practitioner, pharmacy, hospital or nursing facility, or free or nonprofit health clinic must notify the department or its contractor of its intent to participate ...." Lines 285-286 unclear if notification of intent to participate is all that is required. There is no language regarding department approval but would need a form provided by the department by rule. Lines 318-322 requires a patient to complete and sign an intake

	collection form (which must be provided by the department by rule) and submit to the local repository who will then issue a program identification card. It is unclear whether it is intended that these forms be reviewed and approved or just submitted and a card is issued. Line 324 appears that "centralized pharmacy" should be changed to "centralized repository." Clarification through rule may be required on what information must be included in the "summary" of each intake form must be provided in this paragraph. Lines 347-351 requires that local repositories destroy all recalled or expired drugs. This may be in conflict with the requirements of Chapter 499 if a local repository is not permitted to destroy drugs. This may be able to be addressed in any rules that would be needed for this section.

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:
Children, Families, and Elder Affairs, *Chair*
Appropriations
Appropriations Subcommittee on Education
Appropriations Subcommittee on Health and Human Services
Health Policy
Rules

JOINT COMMITTEE:
Joint Legislative Budget Commission

SENATOR LAUREN BOOK
32nd District

October 17, 2019

Chair Aaron Bean
Appropriations Subcommittee on Health and Human Services
201 The Capitol
404 S. Monroe Street
Tallahassee, FL 32399-1100

Chair Bean,

I respectfully request that **SB 58 – Prescription Drug Repository Program** be placed on the agenda for the next Appropriations Subcommittee on Health and Human Services meeting.

Should you have any questions or concerns, please feel free to contact my office or me. Thank you in advance for your consideration.

Thank you,

Senator Lauren Book
Senate District 32

Cc: Tonya Kidd, Staff Director
Robin Jackson, Administrative Assistant

REPLY TO:
❒ 967 Nob Hill Road, Plantation, Florida 33324 (954) 424-6674
❒ 202 Senate Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5032

Senate's Website: *www.flsenate.gov*

BILL GALVANO
President of the Senate

DAVID SIMMONS
President Pro Tempore

THE FLORIDA SENATE

APPEARANCE RECORD

1-15-2020 (Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting) 58

Meeting Date *Bill Number (if applicable)*

Topic Prescription Drug Donation *Amendment Barcode (if applicable)*

Name Carlos Cruz

Job Title Govt Consultant

Address 307 W Park Ave Phone 904-214-5724

Street

Tallahassee, FL 32301 Email cruz@convergegov.com

City *State* *Zip*

Speaking: ☐ For ☐ Against ☐ Information Waive Speaking: ☒ In Support ☐ Against

(The Chair will read this information into the record.)

Representing Polaris Pharmacy Services

Appearing at request of Chair: ☐ Yes ☒ No Lobbyist registered with Legislature: ☒ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

1030

STATE OF FLORIDA
DEPARTMENT OF STATE

Division of Elections

I, Laurel M. Lee, Secretary of State,
do hereby certify that

Scott A. Rivkees

is duly appointed

State Surgeon General and Secretary,
Department of Health

for a term beginning on the Twentieth day of June, A.D., 2019, to serve at the pleasure of the Governor and is subject to be confirmed by the Senate during the next regular session of the Legislature.

Given under my hand and the Great Seal of the State of Florida, at Tallahassee, the Capital, this the Twenty-Ninth day of August, A.D., 2019.

Laurel M. Lee

Secretary of State

DSDE 99 (3/03)

RON DESANTIS
GOVERNOR

June 20, 2019

Secretary Laurel Lee
Department of State
R.A. Gray Building, Room 316
500 South Bronough Street
Tallahassee, FL 32399-0250

Dear Secretary Lee:

Please be advised I have made the following appointment under the provision of Section 20.43, Florida Statutes:

Mr. Scott Rivkees
406 Northeast 7th Avenue
Gainesville, Florida 32601

as State Surgeon General and State Health Official, subject to confirmation by the Senate. This appointment is effective June 20, 2019 for a term ending at the pleasure of the Governor.

Sincerely,

Ron DeSantis
Governor

RD/mm

RECEIVED
2019 AUG 29 AM 9:31
DIVISION OF ELECTIONS
TALLAHASSEE, FL

OATH OF OFFICE

(Art. II. § 5(b), Fla. Const.)

STATE OF FLORIDA

County of Leon

I do solemnly swear (or affirm) that I will support, protect, and defend the Constitution and Government of the United States and of the State of Florida; that I am duly qualified to hold office under the Constitution of the State, and that I will well and faithfully perform the duties of

State Surgeon General and Secretary, Department of Health

(Title of Office)

on which I am now about to enter, so help me God.

[NOTE: If you affirm, you may omit the words "so help me God." *See* § 92.52, Fla. Stat.]

Signature

Sworn to and subscribed before me this 22nd *day of* July, 2019

Signature of Officer Administering Oath or of Notary Public

WANDA DENESE YOUNG
Commission # GG 164701
Expires January 13, 2022
Bonded Thru Troy Fain Insurance 800-385-7019

Print, Type, or Stamp Commissioned Name of Notary Public

Personally Known ☑ ***OR*** *Produced Identification* ☐

Type of Identification Produced _____

ACCEPTANCE

I accept the office listed in the above Oath of Office.

Mailing Address: ☐ Home ☑ Office

4052 Bald Cypress Way, Bin A-00
Street or Post Office Box

Tallahassee, FL 32399-1700
City, State, Zip Code

Scott A. Rivkees, M.D.
Print Name

Signature

DS-DE 56 (Rev. 11/16)

The Florida Senate

Committee Notice Of Hearing

IN THE FLORIDA SENATE
TALLAHASSEE, FLORIDA

IN RE: Executive Appointment of

Scott A. Rivkees

State Surgeon General

NOTICE OF HEARING

TO: Dr. Scott A. Rivkees

YOU ARE HEREBY NOTIFIED that the Appropriations Subcommittee on Health and Human Services of the Florida Senate will conduct a hearing on your executive appointment on Wednesday, January 15, 2020, in the Pat Thomas Committee Room, 412 Knott Building, commencing at 4:00 p.m., pursuant to Rule 12.7(1) of the Rules of the Florida Senate.

Please be present at the time of the hearing.
DATED this the 10th day of January, 2020

Appropriations Subcommittee on Health and Human Services

Senator Aaron Bean
As Chair and by authority of the committee

cc: Members, Appropriations Subcommittee on Health and Human Services
Office of the Sergeant at Arms

THE FLORIDA SENATE

COMMITTEE WITNESS OATH

CHAIR:

Please raise your right hand and be sworn in as a witness.

Do you swear or affirm that the evidence you are about to give will be the truth, the whole truth, and nothing but the truth?

WITNESS'S NAME: Scott A. Rivkees

ANSWER: I do

Pursuant to §90.605(1), *Florida Statutes*: "The witness's answer shall be noted in the record."

COMMITTEE NAME: Appropriations Subcommittee on Health and Human Services

DATE: January 15, 2020

The Florida Senate

COMMITTEE RECOMMENDATION ON EXECUTIVE APPOINTMENT

COMMITTEE: Appropriations Subcommittee on Health and Human Services
MEETING DATE: Wednesday, January 15, 2020
TIME: 4:00—6:00 p.m.
PLACE: Pat Thomas Committee Room, 412 Knott Building

TO: The Honorable Bill Galvano, President

FROM: Appropriations Subcommittee on Health and Human Services

The committee was referred the following executive appointment subject to confirmation by the Senate:

Office: State Surgeon General

Appointee: Rivkees, Scott A.

Term: 6/20/2019-Pleasure of Governor

After inquiry and due consideration, the committee recommends that the Senate **confirm** the aforesaid executive appointment made by the Governor.

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

1/15/20
Meeting Date

n/A
Bill Number (if applicable)

Topic State Surgeon General Scott A. Rivkees appointment

Amendment Barcode (if applicable)

Name Alan Abramowitz

Job Title Executive Director

Address 600 Calhoun St.
Street

Phone 850.241.3232

Tallahassee FL 32399
City *State* *Zip*

Email alan.abramowitz@gal.fl.gov

Speaking: ☐ For ☐ Against ☑ Information

Waive Speaking: ☑ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Guardian ad LItem Program

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

1/15/20
Meeting Date

Bill Number (if applicable)

Topic Surgeon General Confirmation

Amendment Barcode (if applicable)

Name Steve Winn

Job Title Executive Director

Address 2544 Blairstone Pines Dr. (*Street*)

Phone 850-878-7364

Tallahassee (*City*) FL (*State*) 32301 (*Zip*)

Email

Speaking: ☒ For ☐ Against ☐ Information

Waive Speaking: ☐ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Florida Osteopathic Medical Association

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

1/15/20
Meeting Date

Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic Appt of Surgeon General

Name Bob Asztalos

Job Title Chief Lobbyist

Address 307 W Park Ave
Street
Tallahassee FL 32301
City *State* *Zip*

Phone 850-284-1166

Email bAsztalos@fhca.org

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☑ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Florida HealthCare Assoc

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

1/15/00
Meeting Date

Bill Number (if applicable)

Topic Rivkees Confirmation

Amendment Barcode (if applicable)

Name Doug Bell

Job Title

Address 119 S. Monroe St.
Street

Phone 205-9000

TLH
City *State* *Zip*

Email doug.bell@mhdfirm.com

Speaking: [X] For [ ] Against [ ] Information

Waive Speaking: [ ] In Support [ ] Against
(The Chair will read this information into the record.)

Representing Florida Chapter, American Academy of Pediatrics

Appearing at request of Chair: [ ] Yes [ ] No

Lobbyist registered with Legislature: [X] Yes [ ] No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

1/15/20
Meeting Date

Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic Confirmation

Name Ebonni Chrispin

Job Title Legislative Affairs + Community Engagement

Address 700 SE 3rd Ave (*Street*) Phone

FtL (*City*) FL (*State*) 33316 (*Zip*) Email

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☑ In Support ☐ Against
(The Chair will read this information into the record.)

Representing AIDS Healthcare Foundation

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

1-15-20
Meeting Date

Bill Number (if applicable)

Topic Surg. Gen Confirmation

Amendment Barcode (if applicable)

Name Jon Conley

Job Title State Affairs Director

Address 325 John Knox Rd
Street

Phone 850 696 0826

Tallahassee FL 32301
City *State* *Zip*

Email jbconley@alz.org

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☒ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Alzheimer's Association

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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1/15/20
Meeting Date

Bill Number (if applicable)

Topic CONFIRMATION DR. RIVERS

Amendment Barcode (if applicable)

Name RAMON MANLY

Job Title

Address PO BOX 10245
Street

TALL FL 32301
City *State* *Zip*

Phone 850 222 1568

Email RAMON@MANLYBROWN

Speaking: [X] For [ ] Against [ ] Information

Waive Speaking: [X] In Support [ ] Against
(The Chair will read this information into the record.)

Representing MANLY BROWN

Appearing at request of Chair: [ ] Yes [X] No

Lobbyist registered with Legislature: [X] Yes [ ] No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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1-15-20
Meeting Date

Bill Number (if applicable)

Topic Confirmation Surgeon General

Amendment Barcode (if applicable)

Name Lisa Rawlins

Job Title Managing Partner, Maury Rawlins Brown

Address PO Box
Street
Tallahassee, FL
City *State* *Zip*

Phone 954.921.4592

Email Lisa@maryrawlinsbrown.com

Speaking: [X] For [ ] Against [ ] Information

Waive Speaking: [ ] In Support [ ] Against
(The Chair will read this information into the record.)

Representing

Appearing at request of Chair: [ ] Yes [ ] No

Lobbyist registered with Legislature: [✓] Yes [ ] No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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1/15/20
Meeting Date

Bill Number (if applicable)

Topic SSG Confirmation hearing

Amendment Barcode (if applicable)

Name Dr. Scott A. Rivkees

Job Title State Surgeon general

Address 4052 Bald Cypress Way
Street

Phone 850-245-4444

Tallahassee FL 32399
City *State* *Zip*

Email Scott.Rivkees@flhealth.gov

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☐ In Support ☐ Against
(The Chair will read this information into the record.)

Representing

Appearing at request of Chair: ☑ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☐ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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1/15/20
Meeting Date

Bill Number (if applicable)

Topic State Surgeon General Confirmation Hearing

Amendment Barcode (if applicable)

Name Jeff Scott

Job Title

Address 1430 Piedmont Dr. E.
Street

Phone 850 224-6496

Tallahassee FL 32308
City *State* *Zip*

Email jscott@flmedical.org

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☑ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Florida Medical Association

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

Meeting Date

Bill Number (if applicable)

Topic Susan General appointment

Amendment Barcode (if applicable)

Name Ron Watson

Job Title Lobbyist

Address 3738 Mudon Way

Phone 850 567 1202

Street

Tallahassee FL 32309

Email watson.strategies

City State Zip

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☒ In Support ☐ Against

(The Chair will read this information into the record.)

Representing Florida Renal Assoc

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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S-001 (10/14/14)

CourtSmart Tag Report

Room: KN 412 **Case No.:** **Type:**
Caption: Senate Appropriations Subcommittee on Health and Human Services **Judge:**

Started: 1/15/2020 4:00:42 PM
Ends: 1/15/2020 4:56:32 PM **Length: 00:55:51**

4:00:42 PM Sen. Bean (Chair)
4:03:06 PM TAB 2 - Appointments to the State Surgeon General
4:03:31 PM Dr. Scott A Rivkees, State Surgeon General, Department of Health
4:07:34 PM Sen. Bean
4:08:30 PM S. Rivkees
4:08:59 PM Sen. Bean
4:09:21 PM Sen. Rouson
4:09:54 PM S. Rivkees
4:10:21 PM Sen. Rouson
4:10:23 PM S. Rivkees
4:13:18 PM Sen. Rouson
4:13:36 PM S. Rivkees
4:14:26 PM Sen. Rouson
4:14:39 PM S. Rivkees
4:15:01 PM Sen. Rouson
4:15:24 PM S. Rivkees
4:15:44 PM Sen. Rouson
4:15:46 PM Sen. Bean
4:15:52 PM Sen. Book
4:17:18 PM S. Rivkees
4:18:58 PM Sen. Book
4:20:01 PM S. Rivkees
4:20:32 PM S. Rivkees
4:20:44 PM Sen. Book
4:21:18 PM Sen. Harrell
4:22:17 PM S. Rivkees
4:23:26 PM Sen. Harrell
4:24:10 PM S. Rivkees
4:25:23 PM Sen. Harrell
4:26:03 PM S. Rivkees
4:26:43 PM Sen. Harrell
4:27:02 PM Sen. Bean
4:27:34 PM Sen. Farmer
4:27:56 PM Sen. Bean
4:28:14 PM Sen. Rader
4:28:50 PM Sen. Bean
4:28:57 PM Sen. Rader
4:29:14 PM S. Rivkees
4:29:33 PM Sen. Rader
4:29:49 PM S. Rivkees
4:30:07 PM Sen. Rader
4:30:13 PM S. Rivkees
4:30:26 PM Sen. Rader
4:30:57 PM S. Rivkees
4:31:27 PM Sen. Rader
4:31:29 PM S. Rivkees
4:31:45 PM Sen. Rader
4:31:50 PM S. Rivkees
4:32:06 PM Sen. Rader
4:32:08 PM Sen. Bean
4:33:14 PM Alan Abramowitz, Executive Director, Guardian ad Litem Program
4:34:46 PM Bob Asztalos, Chief Lobbyist, Florida Health Care Association (waives in support)

4:34:56 PM Ebonni Chrispin, Legislative Affairs and Community Engagement, AIDS Healthcare Foundation (waives in suppport)
4:35:09 PM Jeff Scott, Florida Medical Association (waives in support)
4:35:33 PM Steve Winn, Executive Director, Florida Osteopathic Medical Association
4:38:04 PM Doug Bell, Florida Chapter, American Academy of Peditrics
4:38:44 PM Jon Conley, State Affairs Director, Alzheimer's Association (waives in support)
4:39:05 PM Ron Watson, Lobbyist, Florida Renal Association (waives in support)
4:39:20 PM Ramon Maury, Representing Maury Rawlins Brown (waives in support)
4:39:35 PM Lisa Rawlins, Managing Partner, Maury Rawlins Brown (waives in support)
4:40:15 PM Sen. Rouson
4:40:23 PM Sen. Bean
4:40:56 PM Sen. Book
4:42:52 PM Sen. Bean
4:42:54 PM Sen. Rader
4:46:37 PM Sen. Harrell
4:49:02 PM S. Rivkees
4:53:16 PM Sen. Bean
4:54:09 PM Sen. Book
4:54:39 PM S 58 Prescription Drug Donation Repository Program
4:54:40 PM Carlos Cruz, Government Consultant, Polaris Pharmacy Services (waives in support)
4:55:22 PM Sen. Bean
4:56:01 PM
4:56:02 PM
4:56:03 PM
4:56:04 PM
4:56:05 PM
4:56:06 PM
4:56:07 PM
4:56:08 PM
4:56:09 PM
4:56:10 PM
4:56:11 PM
4:56:12 PM
4:56:13 PM