

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 177 Prescription Drug Donation Repository Program

SPONSOR(S): Yarborough and Duran

TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	14 Y, 0 N	Morris	McElroy
2) Health Care Appropriations Subcommittee	10 Y, 0 N	Mielke	Clark
3) Health & Human Services Committee	17 Y, 0 N	Morris	Calamas

SUMMARY ANALYSIS

The United States spends approximately \$333.4 billion annually on prescription drugs. A significant amount of these prescription drugs go unused. Many states, including Florida, have drug reuse programs that allow unused prescription drugs to be donated and re-dispensed to patients. Florida's drug reuse program is limited to cancer drugs, and is not utilized.

CS/HB 177 creates a Prescription Drug Donation Repository Program (program) in the Department of Health (DOH) to facilitate donation and distribution of prescription drugs and supplies to indigent, underinsured, and uninsured patients in the state. The program uses a system of repositories to distribute donated prescription drugs throughout the state to eligible patients.

The bill establishes eligibility criteria for repositories, donors, donations, and donation recipients. To participate in the program, participants must follow the program's procedures for donating, inspecting, storing, and dispensing prescription drugs and supplies. Repositories must report on their program activities each month to DOH and DOH must publish registries on its website of participating repositories and available donations under the program. The bill requires DOH to adopt rules and forms necessary to implement the program. The bill also amends s. 252.36(5), to allow the Governor to waive the patient eligibility requirements of the program during a declared state of emergency.

The bill grants immunity for participating persons and entities that exercise reasonable care in donating, accepting, transferring, distributing, or dispensing prescription drugs under the program.

The bill has an insignificant, negative fiscal impact on DOH, which can be absorbed with existing resources. The bill has no fiscal impact on local governments.

The bill provides an effective date of July 1, 2020.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Pharmacy Regulation

The Florida Pharmacy Act (Act) regulates the practice of pharmacy and contains the minimum requirements for safe practice.¹ The Board of Pharmacy (Board) under the Department of Health (DOH) adopts rules to implement the provisions of the Act and sets the standards of practice within the state.² Any person or entity licensed, permitted, or registered pursuant to this chapter must practice pharmacy in accordance with the provisions of the Act and the Board rules.

Section 465.0276, F.S., prohibits persons from dispensing medicinal drugs unless they are licensed or authorized to do so under ch. 465, F.S., with the exception of the prescribing practitioner in the regular course of his or her practice.³

Prior to dispensing a prescription drug, a pharmacist is required to:⁴

- Determine that the individual has a valid prescription for the medicinal drug;⁵
- Interpret and assess the prescription order for potential adverse reactions, interactions, and dosage regimen she or he deems appropriate in the exercise of her or his professional judgment;
- Certify that the medicinal drug called for by the prescription is ready for dispensing; and
- Provide counseling on proper drug usage, either orally or in writing, if in the exercise of her or his professional judgment counseling is necessary.

Pharmacists cannot restock for re-dispensing any prescription drug returned by a patient unless the medication:⁶

- Has been maintained in a closed drug delivery system;⁷
- Is individually sealed in unit-dose⁸ or customized patient medication packaging⁹; and
- Clearly lists the name, dosage strength, manufacturer's control number, and expiration date on its packaging.

The practice of pharmacy is also subject to the requirements of ch. 499, F.S., the Florida Drug and Cosmetic Act, ch. 893, F.S., the Florida Comprehensive Drug Abuse Prevention and Control Act, the Federal Food, Drug, and Cosmetic Act, and the Federal Comprehensive Drug Abuse Prevention and Control Act. The Board can discipline a person or entity's license, permit, or registration for violation of any of these provisions, including suspension or revocation of the ability to practice pharmacy in the state.¹⁰

¹ Ch. 465, F.S.

² Ss. 465.005; 465.0155; and 465.022, F.S.

³ Only a pharmacist or a registered intern acting under direct supervision of a pharmacist may dispense drugs. The pharmacist maintains ultimate responsibility for the activities of the registered intern. Ss. 465.016(1)(c), 465.014(1), F.S.; Rule 64B16-27.1001, F.A.C.

⁴ S. 465.003(6), F.S.

⁵ S. 465.015(2)(c), F.S. A pharmacist may not dispense any medicinal drug even if there is a prescription if the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship, s. 465.016(1)(s), F.S.

⁶ S. 465.016(1)(l), F.S.; Rule 64B16-28.118(2)(a), F.A.C.

⁷ "Closed drug delivery system" means a system in which the actual control of the unit dose or customized patient medication package is maintained by the facility rather than by the individual patient, Rule 64B16-28.118(1)(c), F.A.C.

⁸ "Unit dose system" means a system wherein all individually sealed unit doses are physically connected as a unit. For purpose of this rule, a product in an unopened, sealed, manufacturer's container is deemed to be a unit dose package. 64B16-28.118(1)(a), F.A.C.

⁹ "Customized patient medication package" means a system wherein all US Pharmacopeia approved multi-dose units are physically connected (also referred to as a "container"). However, these drugs should be separable and identifiable for individual patients. 64B16-28.118(1)(b), F.A.C.

¹⁰ S. 465.0465(1), F.S.

Federal law prohibits the return and re-dispensing of controlled substances to anyone other than the patient,¹¹ but the U.S. Food and Drug Administration (FDA) has no specific regulations with respect to the reuse of non-controlled prescription drugs. The FDA defers to the state to regulate re-dispensing prescription drugs so long as the state enforces applicable laws relating to the medication.¹²

Prescription Drug Reuse Programs

The United States spends approximately \$333.4 billion annually on prescription drugs,¹³ with 14 percent (\$46.7 billion) paid out-of-pocket by consumers.¹⁴ A significant number of these prescription drugs go unused, although the exact number is unknown.¹⁵ Disposal methods of unused prescription drugs vary from flushing down the toilet to participating in local, state, or federal drug take-back days.

Unused prescription drugs returned by a patient are not generally eligible for restocking or re-dispensing¹⁶ because the integrity of the drug cannot be confirmed. However, in facilities with closed drug delivery systems such as hospitals, nursing home facilities, or extended care facilities, unused and unopened unit-dose drugs could be re-dispensed to another patient because they have presumably been maintained in compliance with state and federal regulation.¹⁷

Prescription drug reuse programs allow unused prescription drugs to be donated and re-dispensed to patients. At least 39 states, including Florida, have enacted prescription drug donation and reuse laws, 13 of which are limited to cancer drugs.¹⁸ However, more than a dozen of these states do not have functioning or operational programs,¹⁹ often due to a lack of awareness, no central agency or designated entity to operate the program, lack of funding, or burdensomeness for participating facilities.²⁰

Iowa, Wyoming, and Oklahoma appear to have successful drug reuse programs. From its inception in 2007, Iowa's program has served over 71,000 uninsured or underinsured patients and provided 9.1 million units of free drugs and supplies. This has saved \$17.7 million in costs based on the value of donated medications.²¹ Wyoming's program has filled over 150,000 prescriptions worth over \$12.5 million in the last 10 years,²² and since 2004, Oklahoma's program has filled over 239,000 prescriptions

¹¹ 21 U.S.C. §§ 825(c), 841–844.

¹² U.S. Food & Drug Administration, *Disposal of Unused Medicines: What You Should Know*, <https://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/ensuringsafeuseofmedicine/safedisposalofmedicines/ucm186187.htm#7> (last visited Oct. 14, 2019).

¹³ *National Health Expenditures 2017 Highlights*, CENTERS FOR MEDICARE & MEDICAID SERVICES, Dec. 11, 2018, available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf> (last visited Oct. 14, 2019).

¹⁴ *National Health Expenditures by Type of Service and Source of Funds, CY 1960-2017*, CENTERS FOR MEDICARE & MEDICAID SERVICES, available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html> (last visited Oct. 14, 2019).

¹⁵ One study found that 2 out of 3 medications in U.S. households were unused. *Taking Stock of Medication Wastage: Unused Medications in U.S. Households*, Research in Social and Administrative Pharmacy, Oct. 2014, Vol. 11; Issue 4, available at https://docs.wixstatic.com/ugd/ad724e_564353d3dede4b2295cd8be515c865be.pdf (last visited Oct. 14, 2019); From 2010 to 2018, the Drug Enforcement Administration collected 10,878,950 pounds (5,440 tons) of expired, unused, or unwanted prescription drugs under its take back day program; DEA DIVERSION CONTROL DIVISION, *16th National Take Back Day (Oct. 27, 2018)*, <https://takebackday.dea.gov/sites/default/files/NTBI%20XVI%20Totals.pdf> (last visited Oct. 14, 2019).

¹⁶ S. 465.016(1)(l), F.S.; Rule 64B16-28.118(2)(a), F.A.C.

¹⁷ *Supra* note 7.

¹⁸ *State Prescription Drug Return, Reuse and Recycling Laws*, NATIONAL CONFERENCE OF STATE LEGISLATURES (Oct. 1, 2018), <http://www.ncsl.org/research/health/state-prescription-drug-return-reuse-and-recycling.aspx> (last visited Oct. 14, 2019). Cancer-specific programs: CO, FL, KY, MI, MN, MT, NB, NV, OH, PA, UT, WA, and WI.

¹⁹ "Operational" are those states that have participating pharmacies, charitable clinics, and/or hospitals collecting and redistributing donated drugs to eligible patients, and have had some level of donation and reuse transactions during 2017-2018. Id.

²⁰ *Supra* note 18.

²¹ Id.

²² WYOMING DEPARTMENT OF HEALTH, *Wyoming Medication Donation Program*, <https://health.wyo.gov/healthcarefin/medicationdonation/> (last visited Oct. 14, 2019).

incomes at or below 200 percent of the federal poverty level with valid prescriptions are eligible to receive donated drugs under the program.³¹

Iowa's program uses a system of central and local repositories to intake and dispense drugs and supplies throughout the state. The central repository is a permitted drug distributor responsible for intake, inspection, storage, and inventory of all donated drugs and supplies. Local repositories are pharmacies and medical facilities that elect to participate in the program and agree to accept and re-dispense drugs and supplies on behalf of the central repository. These entities must already be authorized by Iowa law to dispense prescription drugs in order to participate. The program only allows a licensed pharmacist, physician or nurse practitioner to dispense prescription drugs and supplies to an eligible patient.³²

Since 2007, the Iowa program has served over 71,000 uninsured or underinsured patients, provided 9.1 million units of free drugs and supplies, and based on the value of donated medications, has saved \$17.7 million in costs.³³

Florida's Cancer Drug Donation Program

In 2006, the Legislature created the Cancer Drug Donation Program (CDDP) to facilitate the donation of cancer drugs and supplies to uninsured and underinsured Floridians who are diagnosed with cancer.³⁴ The Department of Business and Professional Regulation (DBPR) administers the CDDP.³⁵

Only hospitals may accept or dispense donated cancer drugs or supplies under the CDDP.³⁶ DBPR maintains a participant facility registry on its website for potential donors and patients.³⁷ The CDDP allows only entities that are licensed, permitted, or otherwise maintain a closed drug delivery system, to donate cancer drugs and supplies,³⁸ and excludes controlled substances⁴⁰ and drugs that will expire in less than 6 months, have been opened, tampered with, or mislabeled.⁴¹

An eligible cancer patient with a valid prescription may contact a participating facility directly, sign a form certifying they qualify under the CDDP, and request an available donated cancer drug or supply.⁴² Only a licensed pharmacist may dispense cancer drugs to eligible patients under the CDDP.⁴³

³¹ IOWA ADMIN. CODE 641-109.

³² *Id.*

³³ *Supra* note 18. See also SAFENETRX, *Iowa Drug Donation Repository 2016 Performance Update*, available at <https://safenetrx.org/wp-content/uploads/2017/04/2016-Performance-Update-Drug-Donation-Repository-brochure.pdf> (last visited Oct. 14, 2019).

³⁴ Ch. 06-310, sec. 1, Laws of Fla.; Ss. 499.029(2) and (9), F.S.; Rule 61N-1.026(1)(a), F.A.C. An eligible cancer patient must be a Florida resident and not receive prescription coverage through the Medicaid program, a third-party insurer, or any other prescription drug program funded in whole or in part by the Federal Government. People may still be eligible if they have exhausted all of these benefits or the cancer drug or supply needed is not included in their coverage. Cancer drugs or supplies cannot be donated to a specific patient or resold by the program, S. 499.029(4), F.S.

³⁵ In 2010, the Legislature shifted responsibility from the Department of Health to DBPR to administer chapter 499, F.S., including the CDDP. Ch. 10-161, sec. 27, Laws of Fla.

³⁶ Ss. 499.029(3)(e), 499.029(7), F.S. Participating hospitals cannot accept donated drugs that are eligible for return to the Medicaid program for restocking. Additionally, they cannot submit claims or otherwise seek reimbursement from any public or private third-party payor for donated drugs or supplies dispensed under the program. However, participating facilities may charge a handling fee as established in rule by DBPR. Currently, handling fees are limited to 300 percent of the Medicaid dispensing fee or \$15, whichever is less. Ss. 499.029(4), and (6)(d), F.S.; Rule 61N-1.026(5), F.A.C.

³⁷ S. 499.029(10), F.S.

³⁸ "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. S. 499.029(3)(b), F.S.

³⁹ S. 499.029(3)(c), F.S., eligible donors include: A patient or a patient representative, donated through a closed drug delivery system; Health care facilities, nursing homes, hospices, or hospitals with a closed drug delivery system; Pharmacies, drug manufacturers, medical device manufacturers or suppliers, or wholesalers of drugs or supplies; A Florida-licensed allopathic or osteopathic physician who receives cancer drugs or supplies directly from a drug manufacturer, drug wholesaler, or pharmacy.

⁴⁰ S. 499.029(3)(a), F.S.

⁴¹ S. 499.029(6), F.S.

⁴² Rule 61N-1.026(3)(e)3., F.A.C.; S. 499.029(5), F.S.

⁴³ S. 499.029(5), F.S. Prior to dispensing, the pharmacist must inspect the donated drug or supply to confirm that it has not been tampered with or mislabeled, and has not expired, S. 499.029(6)(c), F.S., Rule 61N-1.026(3)(e)2., F.A.C.

Participants are immune from civil and criminal liability, and from professional disciplinary action, relating to activities of the program if they exercise reasonable care.⁴⁴

Currently, there are 15 participating facilities registered with DBPR, all of which registered with DBPR in or prior to 2012, and no donated cancer drugs are currently available for dispensing, although there is no requirement for participating facilities to report this information to DBPR.⁴⁵ DBPR is aware of at least 40 cancer drug donations under this program historically since 2013.⁴⁶

Governor's Executive Powers

The Governor has broad authority to act as he or she deems necessary during a declared state of emergency. Section 252.36(1), F.S., authorizes the Governor, in part, to assume or delegate direct operational control over all or any part of the emergency management functions in the state in the event of an emergency that is beyond local control. During this time, the Governor is authorized to use all resources of the state government and each political subdivision of the state, as reasonably necessary, to cope with the emergency.⁴⁷ Additionally, the Governor may issue executive orders, proclamations, and rules which have the force and effect of law. A declared state of emergency is limited to 60 days, unless renewed by the Governor or terminated by the Legislature.⁴⁸

Effect of the Bill

CS/HB 177 creates s. 465.1902, F.S, establishing a Prescription Drug Donation Repository Program (Program) within the Department of Health (DOH) to authorize and facilitate donation and distribution of prescription drugs and supplies to indigent, uninsured, and underinsured Floridians through a system of repositories.

Repositories will be established on a voluntary basis by health care entities in the state. While participation in the Program is voluntary, the bill requires registration with DOH to participate and establishes criteria for the types of entities that can participate as a local repository, the types of entities that can donate prescription drugs and supplies, who can receive donated prescription drugs, and which prescription drugs can be donated.

Donations are made at repositories. After the donations are inspected by a pharmacist and approved for dispensing, they are reported to DOH each month and added to a public registry of available donations under the Program. Patients can contact the repository where a donated drug or supply is located, present a valid prescription for it, certify their eligibility under the program, and receive the donated drug or supply.

The Program imposes procedures for inventorying, storing, dispensing, recalling, and destroying prescription drugs donated under the Program. Unlike the CDDP, the Program requires participating entities to maintain records and report their activities to DOH, allows distribution of donations between repositories to address demand, and makes more information available to the public.

Repositories

The bill requires DOH to facilitate donation and distribution of prescription drugs and supplies to eligible patients throughout the state. Specifically, repositories are required to report to DOH any donations they receive or dispense under the Program. When an eligible patient requests a donated prescription drug under the Program, DOH may facilitate the distribution of donations between the repositories in

⁴⁴ S. 499.029(11), F.S. Additionally, a pharmaceutical manufacturer is not liable for any claim or injury arising from the transfer of any cancer drug under the program. S. 499.029(12), F.S.

⁴⁵ DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION, *Cancer Drug Donation Program Participation Report*, <http://www.myfloridalicenses.com/dbpr/ddc/documents/ParticipatingHospital.pdf> (last visited Oct. 14, 2019).

⁴⁶ Email from Colton Madill, Deputy Legislative Affairs Director, Department of Business and Professional Regulation, RE: Information request (Nov. 21, 2017)(on file with Health Quality Subcommittee staff). All 40 of these donations were reported by Moffitt Cancer Center and the cancer drugs donated varied in brand, quantity, and strength.

⁴⁷ S. 252.36(5), F.S.

⁴⁸ S. 252.36(2), F.S.

the state to address the need or repositories may redistribute donations on their own after notifying DOH.

Repositories will accept, inspect, inventory, and dispense prescription drugs and supplies donated under the Program. Participation as a repository is voluntary. The bill allows only certain entities licensed or permitted to dispense medicinal drugs in Florida to be repositories:

- The offices of any allopathic, osteopathic, or podiatric physician, dentist, or any other practitioner licensed to practice pharmacy, nursing, or optometry.
- Pharmacies.
- Hospitals with closed drug delivery systems.
- Nursing home facilities with closed drug delivery systems.
- Free clinics that deliver only medical diagnostic services or nonsurgical medical treatment free of charge to low-income recipients.
- Nonprofit health clinics that provide medical care to indigent, uninsured, or underinsured patients (i.e., federally qualified health centers, rural health clinics).

While participation is voluntary, an eligible entity must register with DOH as a repository before accepting or dispensing any prescription drugs or supplies under the Program. The bill requires DOH to establish in rule a form for such registration, to include, at a minimum:

- The name, street address, and telephone number of the intended repository, any state-issued license or registration number issued to the intended repository, including the name of the issuing agency;
- The name and telephone number of the pharmacist employed by or under contract with the intended repository who will be responsible for the inspection of donated prescription drugs and supplies; and
- A statement signed and dated by the responsible pharmacist affirming that the intended repository meets the eligibility requirements of this section.

A repository may withdraw from participation in the Program but must notify DOH on a form adopted by DOH in rule. The bill requires DOH to adopt rules establishing a procedure for disposition of any donated prescription drugs still in possession of the withdrawing repository.

The bill prohibits the repositories from reselling drugs, submitting claims, or otherwise seeking reimbursement from any public or private third-party payor for donated drugs or supplies dispensed under the Program.

Repositories: Inspection and Storage

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 meet the donation criteria under the Program. The pharmacist must sign an inspection record affirming this, and attach it to the inventory record. Re-inspection is not required if inspected drugs are redistributed to another repository under the Program. Repositories must destroy any donated drug not eligible for dispensing and make a record of the destruction on a form to be developed by DOH in rule.

The bill requires repositories to maintain an inventory of all donated prescription drugs and supplies they receive. The inventory record must include the following information for each donation:⁴⁹

- Name, strength, available quantity, and expiration date of the donated prescription drug or supply.
- Transaction date and name, address, and phone number of the donor.

By the fifth day of each month, the repository must submit to DOH inventory records of all donations it received in the previous month. DOH maintains an inventory of all prescription drugs and supplies

⁴⁹ The bill requires DOH to establish this notification form in rule.

donated to the Program. DOH may redistribute drugs and supplies between repositories to facilitate dispensing as needed throughout the state or repositories may redistribute donations on their own after notifying DOH.

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 federal requirements. Repositories must quarantine donated drugs and supplies from dispensing inventory until they have been inspected and approved for dispensing by the pharmacist.

Repositories: Drug Recall and Destruction

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

- Establish and follow a protocol for notifying recipients of the drug;
- Destroy all recalled prescription drugs in the repository; and
- Complete a destruction information form for all donated prescription drugs that were destroyed.

If a donated drug does not indicate a lot number on its packaging or the lot number is not otherwise retrievable, all such drugs must be destroyed in the event of a recall.

Additionally, each repository shall destroy any donated prescription drugs which are expired or otherwise not suitable for dispensing, and complete a destruction information form for all such prescription drugs that are destroyed.

Repositories: Recordkeeping

The bill requires all repositories to maintain records of all prescription drugs and supplies that were accepted, donated, dispensed, distributed, or destroyed under the Program. These records shall be maintained by the repositories in accordance with any applicable practice acts. However, repositories must submit these records each month to DOH for data collection.

Eligible Donors

The bill limits who can donate prescription drugs and supplies under the Program to only those who can ensure the drugs are maintained entirely by licensed or permitted professionals and not the patients. Specifically, the bill only allows the following individuals or entities to donate prescription drugs and supplies:

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

Eligible donors may only make donations to a designated person at a repository and may not use a dropbox to do so. The bill prohibits the donation of a prescription drug or supply to a specific patient.

Eligible Donations

The bill authorizes eligible donors to donate prescription drugs only if the drug:

- Is approved for medical use in the United States;

- Does not include a substance listed in Schedule II, III, IV, or V of the Florida Controlled Substance Act;⁵⁰
- Is in unopened tamper-evident packaging;⁵¹
- Requires storage at normal room temperature per the manufacturer or the federal storage requirements;
- Has been stored according to the manufacturer or federal storage requirements;
- Has no physical signs of tampering or adulteration, and there is no reason to believe that the drug is adulterated;
- Packaging indicates the expiration date of the drug;
- Will not expire until at least three months after the donation is made; and
- Is not subject to a FDA Risk Evaluation Mitigation Strategy with Elements to Assure Safe Use.⁵²

Similarly, eligible donors may only donate prescription drug supplies that are in unopened tamper-evident packaging.

Eligible Patients

The bill authorizes Florida residents to receive donated prescription drugs or supplies under the Program if they have a valid prescription for a drug or supply provided under the Program, and meet at least one of the following criteria:

- Family income below 200 percent of the federal poverty level.⁵³
- Uninsured and ineligible for prescription drug coverage under any program funded in whole or in part by the Federal Government.
- Insured or have prescription drug coverage, but have exhausted these benefits or do not have prescription drug coverage for the drug prescribed.

⁵⁰ s. 893.03, F.S. The Federal Controlled Substance Act prohibits the transfer of a controlled substance to anyone other than the patient except to authorized entities for disposal or destruction. 21 U.S.C. §§ 825 and 822a.

⁵¹ The bill defines “tamper-evident packaging” as a package that has one or more indicators or barriers to access which, if breached or missing, can reasonably be expected to provide visible evidence to consumers that tampering has occurred. The term includes, but is not limited to, unopened unit-dose packaging, multiple-dose packaging, and medications with a seal on their immediate, outer, secondary, or tertiary packaging.

⁵² Newly approved drugs are subject to post-market safety surveillance and evaluation by the FDA for 18 months after approval or after its use by 10,000 individuals, whichever is later. If the FDA determines that a drug requires safety measures beyond the professional labeling, it requires the drug sponsors to create risk management plans, or Risk Evaluation Mitigation Strategies, which can include Elements to Assure Safe Use. These are required medical interventions or other actions healthcare professions need to execute before the drug can be prescribed or dispensed to a patient, which can be ongoing requirements for treatment. Depending on the risk involved, elements can include special certification or training from healthcare practitioners to prescribe or dispense the drug, enrolling the patient in a registry, or limiting the setting and manner in which the drug can be dispensed. The drug sponsor is responsible for dissemination of information and monitoring of the REMS implementation, which can be modified or ultimately eliminated when the FDA determines the goals are met. 21 U.S.C. § 355–1.

⁵³ In 2019, the federal poverty guideline for a 5-person household is \$30,170; 200% of this would be \$60,340. To qualify, a person must have such income for the 12 months preceding the determination of income.

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

- The name, street address, and telephone number of the eligible patient;
- The specific basis for eligibility, which must be indigent, uninsured, or underinsured, as defined in the Program;
- A statement signed and dated by the patient affirming that he or she meets the eligibility requirements of the Program and will inform the repository if the patient's eligibility change; and
- Notice, and a statement signed and dated by the patient acknowledging receipt of such notice, that the prescription drug was donated to the Program, the donors and participants in the Program are immune from civil or criminal liability or disciplinary action, and the eligible patient is not required to pay for the prescription drug.

The bill requires repositories to collect an executed intake form from each new eligible patient receiving drugs or supplies under the Program. By the fifth day of each month, repositories must send to DOH a summary of each intake collection form it received in the previous month.

Dispensing Donations

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 through a duly executed intake collection form. The bill allows a dispenser to provide dispensing and consulting services to an eligible patient. The repository must maintain a record of all prescription drugs and supplies dispensed under the Program.

Registries

The bill requires DOH to maintain a registry on its website of all available prescription 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. DOH is also required to maintain a registry on its website of all participating repositories, to include each repository's name, address, website, and telephone number.

Immunity

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

The bill requires DOH to adopt rules and forms necessary to administer the program and provides for the use of electronic forms throughout the bill.

Emergency Management Powers of the Governor

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

The bill provides an effective date of July 1, 2020.

B. SECTION DIRECTORY:

- Section 1:** Creates s. 465.1902, F.S., relating to the Prescription Drug Donation Repository Program.
- Section 2:** Amends s. 252.36(5), F.S., relating to emergency management powers of the Governor.
- Section 3:** Provides an effective date of July 1, 2020.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

DOH will incur insignificant costs related to rulemaking, recordkeeping, and publishing of required information under the bill. Current resources are adequate to absorb these costs.⁵⁴

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Participation in the Program is voluntary. Entities that participate as repositories in the Program will incur costs associated with processing, storage, dispensing, and disposal of donated prescription drugs and supplies. Entities that donate prescription drugs or supplies that would otherwise go unused will save the costs of destroying or disposing of them. Program patients will experience a reduction in drug costs.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not Applicable. This bill does not appear to affect county or municipal governments.

2. Other:

None.

⁵⁴ Department of Health, *HB 177 Department Bill Analysis*. On file with Health Care Appropriations Subcommittee staff.
STORAGE NAME: h0177e.HHS
DATE: 1/16/2020

B. RULE-MAKING AUTHORITY:

The bill provides sufficient rulemaking authority for DOH to adopt rules to implement the requirements of the Program.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On November 6, 2019, the Health Care Appropriations Subcommittee adopted one amendment that removed the section of the bill authorizing two FTEs and an appropriation. The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute as passed by the Health Care Appropriations Subcommittee.