HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 291 Prescription Drug Donation Repository Program
SPONSOR(S): Health Quality Subcommittee; Yarborough and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 710

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	13 Y, 0 N, As CS	Gilani	McElroy
2) Health & Human Services Committee			

SUMMARY ANALYSIS

The United States spends approximately $328.6 billion annually on prescription drugs, a significant number of these prescription drugs go unused. Unused prescription drugs are commonly disposed through various manners ranging from flushing down the toilet to participating in local, state or federal drug take back days. However, 38 states, including Florida, have created drug reuse programs which allow unused prescription drugs to be donated and re-dispensed to patients. Florida's prescription drug reuse program is limited to cancer drugs.

CS/HB 291 creates a Prescription Drug Donation Repository Program (Program) in the Department of Health (DOH) to facilitate the donation and distribution of prescription drugs and supplies to eligible patients in the state. The Program:

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

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

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 will have a significant, negative fiscal impact on state government. The bill will have no impact on local government.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation:

Federal Regulation

The United States Food and Drug Administration (FDA) is the federal agency responsible for ensuring that foods, drugs, biological products, and medical devices are effective and safe for public consumption.[1] The FDA regulates these areas under the authority of the Federal Food, Drug, and Cosmetic Act (FDCA).[2] The FDCA prohibits any drug from being introduced or delivered for introduction into interstate commerce unless approved by the FDA. The FDCA further prohibits adulterated or misbranded drugs and devices from being introduced, delivered for introduction, or received in interstate commerce.

Federal law prohibits the return and re-dispensing of controlled substances,[3] but the FDA has no specific regulations with respect to reuse of non-controlled prescription drugs. The FDA defers to the state to regulate the re-dispensing of prescription drugs so long as the state enforces applicable laws relating to the medication.[4]

Risk Evaluation Mitigation Strategies

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.[5] 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 (REMS).[6] REMS may include medication guides[7], a communication plan[8], an implementation system,[9] or elements to assure safe use (ETASU).[10] ETASU 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.[11] Depending on the risk involved, ETASU 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.[12] The drug sponsor is responsible for dissemination of information and monitoring of the REMS implementation.[13] REMS may be modified or eliminated if an assessment of the measures shows that changes are needed or that the REMS has met its goals.[14]

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[1] U.S. FOOD & DRUG ADMINISTRATION, *What We Do,* https://www.fda.gov/AboutFDA/WhatWeDo/default.htm (last visited Jan. 26, 2018).
[2] 21 U.S.C. § 355(a).
[3] 21 U.S.C. §§ 825(c), 841–844.
[4] Fred Gebhart, *Medication Return, Reuse Gaining Ground in States,* DRUG TOPICS, MODERN MEDICINE NETWORK (June 16, 2003), http://drugtopics.modernmedicine.com/drug-topics/content/medication-return-reuse-gaining-ground-states (last visited Jan. 26, 2018)(quoting FDA representative, "the redispensing of prescription drugs is entirely a state board of pharmacy matter"). *See generally* 21 U.S.C. § 903.
[5] 21 U.S.C. § 355(r).
[6] 21 U.S.C. § 355–1. There are currently 72 FDA-approved REMS, U.S. FOOD & DRUG ADMINISTRATION, *Approved Risk Evaluation and Medication Strategies (REMS),* https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm (last visited Jan. 31, 2018).
[7] A "medication guide" gives the patient important information about the drug written in plain language, 21 C.F.R. § 208.
[8] A "communication plan" requires the drug sponsor to send letters and disseminate information to health care provider about REMS and explain safety protocols. 21 U.S. Code § 355–1(e)(3).
[9] An "implementation system" requires the drug sponsor to develop a system to monitor, evaluate, and improve implementation of REMS, 21 U.S.C. § 355–1(f)(4).
[10] 21 U.S.C. § 355–1(e)–(f).
[11] 21 U.S.C. § 355–1(f)(3).
[12] 21 U.S.C. § 355–1(f)(3).
[13] 21 U.S.C. § 355–1(f)(4).
[14] 21 U.S.C. § 355–1(g)(4).

State Regulation

Regulation of Pharmacy

The Florida Pharmacy Act (Act) regulates the practice of pharmacy and contains the minimum requirements for safe practice.[15] The Board of Pharmacy (Board) under the Department of Health adopts rules to implement the provisions of the Act and sets the standards of practice within the state.[16] 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.

The practice of pharmacy includes:[17]

- Compounding, dispensing, and consulting concerning contents, therapeutic values, and uses of any medicinal drug;
- Consulting concerning therapeutic values and interactions of patent or proprietary preparations;
- Monitoring a patient's drug therapy and assisting the patient in the management of his or her drug therapy, including the review of the patient's drug therapy and communication with the patient's prescribing health care provider or the provider's agent or other persons specifically authorized by the patient, regarding drug therapy;
- Transmitting information from persons authorized to prescribe medicinal drugs to their patients; and
- Administering vaccines to adults.

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.[18]

Prior to dispensing a prescription drug, a pharmacist is required to: [19]

- Determine that the individual has a valid prescription for the medicinal drug;[20]
- 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:[21]

[15] Ch. 465, F.S.
[16] Ss. 465.005; 465.0155; and 465.022, F.S.
[17] S. 465.003(13), F.S. Pharmacists are expressly prohibited from altering a prescriber's directions, diagnosing or treating any disease, initiating drug therapies, or practicing medicine, unless otherwise permitted by law.
[18] 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.
[19] S. 465.003(6), F.S.
[20] S. 465.015(2)(c), F.S. A pharmacist may not dispense any medicinal drug even if there is a prescription if the pharmacists 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.

- Has been maintained in a closed drug delivery system;[22]
- Is individually sealed in unit-dose[23] or customized patient medication packaging[24]; 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 FDCA, 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.[25]

Prescription Drug Reuse Programs

The United States spends approximately $328.6 billion annually on prescription drugs,[26] with 14 percent ($45 billion) paid out-of-pocket by consumers.[27] A significant number of these prescription drugs go unused, although the exact number is unknown.[28] Disposal of these 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-dispensing[29] 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.[30]

Prescription drug reuse programs allow unused prescription drugs to be donated and re-dispensed to patients. At least 38 states have enacted prescription drug donation and reuse laws, 13 of which are limited to cancer drugs.[31] However, more than a dozen of these states do not have functioning or operational programs,[32] often due to a lack of awareness, no central agency or designated entity to operate the program, lack of funding, or added responsibilities for participating facilities.[33]

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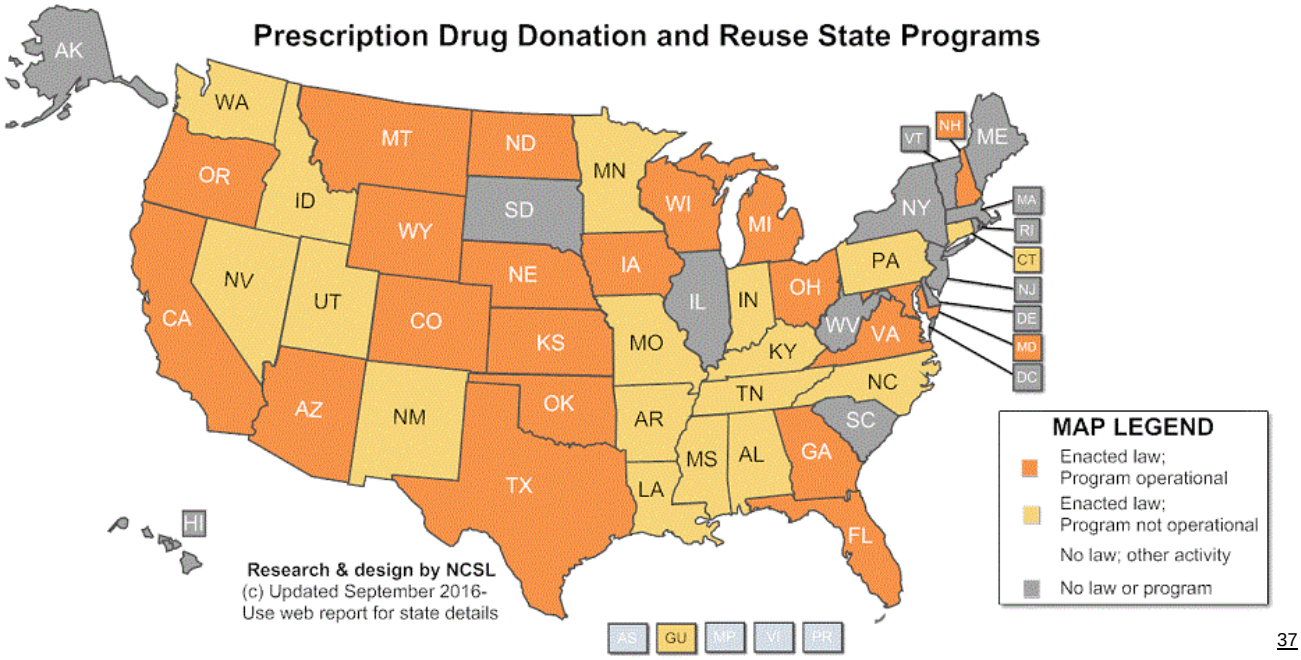
[21] S. 465.016(1)(l), F.S.; Rule 64B16-28.118(2)(a), F.A.C.
[22] "Closed drug delivery system" means a system in which the actual control of the unit dose or customized patient medication package is maintained by the facility rather than by the individual patient, Rule 64B16-28.118(1)(c), F.A.C.
[23] "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, manufacture's container is deemed to be a unit dose package. 64B16-28.118(1)(a), F.A.C.
[24] "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.
[25] S. 465.0465(1), F.S.
[26] *National Health Expenditures 2016 Highlights,* CENTERS FOR MEDICARE & MEDICAID SERVICES, *available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf (last visited Jan. 26, 2018).
[27] *National Health Expenditures by Type of Service and Source of Funds, CY 1960-2016,* 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 Jan. 26, 2018).
[28] 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://calpsc.org/mobius/cpsc-content/uploads/2015/08/Study-Taking-Stock-of-Medication-Wastage-Unused-Medicines-in-US-Households-2015.pdf (last viewed on January 27, 2018); From 2010 to 2017, the Drug Enforcement Administration collected 9,015,668 pounds (4,508 tons) of prescription drugs under its take back day program. *Drug Enforcement Administration Collects Record Number of Unused Pills as Part of its 14th Prescription Drug Take Back Day*, Department of Justice, Office of Public Affairs, November 7, 2017, available at https://www.justice.gov/opa/pr/drug-enforcement-administration-collects-record-number-unused-pills-part-its-14th-0 (last visited January 27, 2018).
[29] S. 465.016(1)(l), F.S.; Rule 64B16-28.118(2)(a), F.A.C.
[30] *Supra* note 22.
[31] *State Prescription Drug Return, Reuse and Recycling Laws*, NATIONAL CONFERENCE OF STATE LEGISLATURES (Mar. 31, 2017), http://www.ncsl.org/research/health/state-prescription-drug-return-reuse-and-recycling.aspx (last visited Jan. 26, 2018).
[32] "Operational" refers to programs where some level of donation and reuse transactions occurred during the 2015-2016 calendar year.
[33] *Supra* note 31.

Iowa, Wyoming, and Oklahoma have seen considerable success with their drug reuse programs. From 2008 to 2016, Iowa 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.[34] Wyoming's program has filled over 150,000 prescriptions worth over $12.5 million in the last 10 years,[35] and since 2004, Oklahoma's program has filled almost 1 million prescriptions worth over $19 million.[36]



37

Note: New York enacted a drug recycling program in November 2016.

Most of these programs exclude controlled substances, expired drugs, and drugs that show any physical signs of tampering, misbranding, deterioration, compromised integrity, or adulteration.[38] They also require that all drugs be inspected and dispensed by a licensed pharmacist.[39] The state programs tend to vary in which types of drugs are accepted for donation (*e.g.* prescription, cancer, or over-the-counter drugs), the entities that can donate or dispense drugs, and who can receive donated drugs under the program.[40] Most states only allow state or federally regulated professionals to donate, accept, inspect, or dispense donated drugs under their drug recycling programs in order to ensure safety of patients and integrity of donated drugs.[41]

Iowa's Drug Donation Repository Program[42]

[34] 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 Dec. 4, 2017).
[35] Wyoming Department of Health, *Wyoming Medication Donation Program,* https://health.wyo.gov/healthcarefin/medicationdonation/ (last visited Jan. 26, 2018).
[36] *Supra* note 31.
[37] Id.
[38] Id.
[39] Id.
[40] Id.
[41] Id. *See generally,* Ming Ren Toh and Lita Chew, *Turning Waste Medicines to Costs Savings: A Pilot Study on the Feasibility of Medication Recycling as a Solution to Drug Wastage,* 31(1) Palliative Medicine 35-41 (2016), a 2-month study of the feasibility of medication recycling found that medications donated by healthcare facilities are three times more likely to be reusable than those donated by individual patients.
[42] SAFENETRX, *Drug Donation Repository,* https://safenetrx.org/drug-donation/ (last visited Jan. 31, 2018).

Iowa currently has the largest drug recycling program in the nation. Iowa established its Drug Donation Repository Program in 2007, making prescription and over-the-counter medications and medical supplies available to Iowans in need of assistance.[43] Iowans that are at or below 200 percent of the federal poverty level, uninsured, or underinsured, and have a valid prescription, are eligible to receive donated drugs under the program.[44]

Iowa's program uses a system of central and local repositories to intake and dispense drugs and supplies throughout the state.[45] The centralized repository is a permitted drug wholesale distributor that is responsible for the intake, inspection, storage, and inventory of all donated drugs and supplies.[46] 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 centralized repository.[47] These entities must already be authorized by Iowa law to dispense prescription drugs in order to participate.[48] The program only allows a licensed pharmacist, physician or nurse practitioner to dispense prescription drugs and supplies to an eligible patient.[49]

While there is insufficient analysis to determine the overall impact of drug recycling programs in offsetting costs to emergency rooms or clinics, Iowa's program has measured its progress since its inception in 2007. From 2008 to 2016, 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.[50]

Florida's Cancer Drug Donation Program

In 2006, the Legislature created the Cancer Drug Donation Program (CDDP or program) to facilitate the donation of cancer drugs and supplies to eligible patients.[51] DBPR administers the CDDP.[52] Currently, there are 14 participating facilities registered with DBPR and no donated cancer drugs available for dispensing. DBPR is aware of at least 40 drugs that have been donated under this program historically since 2013 although there is no requirement for participating facilities to report this information to DBPR.[53]

Eligible Donors

The following individuals or entitles may donate cancer drugs and supplies:[54]

- A patient or a patient representative, donated through a closed drug delivery system.[55]
- 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.

[43] IOWA DEPARTMENT OF PUBLIC HEALTH, *SafeNetRx Program*, https://idph.iowa.gov/ohds/rural-health-primary-care/repository (last visited Jan. 31, 2018).
[44] IOWA ADMIN. CODE 641-109.7.
[45] IOWA ADMIN. CODE 641-109.4.
[46] IOWA ADMIN. CODE 641-109.1.
[47] IOWA ADMIN. CODE 641-109.1.
[48] IOWA ADMIN. CODE 641-109.6.
[49] IOWA ADMIN. CODE 641-109.6(1).
[50] 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 Jan. 31, 2018).
[51] Ch. 06-310, sec. 1, Laws of Fla.; S. 499.029(2), F.S.
[52] 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.
[53] Email from Colton Madill, Deputy Legislatives Affairs Director, Department of Business and Professional Regulation, RE: Information request (Nov. 21, 2017)(on file with Health Quality Subcommittee staff).
[54] S. 499.029(3)(c), F.S.
[55] "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.

- A Florida-licensed allopathic or osteopathic physician who receives cancer drugs or supplies directly from a drug manufacturer, drug wholesaler, or pharmacy.

A donor of cancer drugs or supplies or a program participant who exercises reasonable care in donating, accepting, distributing, or dispensing cancer drugs or supplies under the program is immune from civil or criminal liability and from professional disciplinary action relating to activities of the program.[56] Additionally, a pharmaceutical manufacturer is not liable for any claim or injury arising from the transfer of any cancer drug under the program.[57]

Eligible Donations

A cancer drug is only eligible for donation and dispensing if the drug:[58]

- Does not include a substance listed in Schedule II, Schedule III, Schedule IV, or Schedule V of s. 893.03, F.S.;[59]
- Is in its original, unopened, sealed container, or in a tamper-evident unit-dose packaging. Single-unit dose drugs may be accepted if the single-unit dose packaging is unopened;
- Will not expire until at least six months after the donation is made; and
- Has been inspected by a pharmacist to determine that the drug and supplies do not appear to have been tampered with or mislabeled.

Cancer drugs or supplies cannot be donated to a specific patient or resold by the program.[60] Additionally, the program cannot accept donated drugs that are eligible for return to the Medicaid program for restocking.[61] Dispensing facilities cannot submit claims or otherwise seek reimbursement from any public or private third-party payor for donated drugs or supplies dispensed under the program.[62] 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.[63]

Only hospitals operating a Class II institutional pharmacy[64] may accept or dispense donated cancer drugs or supplies under this program.[65] Hospitals wanting to participate in the program must first register with DBPR, identifying appropriate permitting and the pharmacist that will be responsible for the oversight of the donated drugs and supplies.[66] DBPR is required to maintain a participant facility registry on its website for potential donors and patients.[67] Currently, there are 14 participating facilities statewide, all of which registered with DBPR in or prior to 2012.[68]
Florida residents who are diagnosed with cancer are eligible to receive drugs or supplies under the CDDP,[69] unless they are eligible to receive them through the Medicaid program, a third-party insurer, or

[56] S. 499.029(11), F.S.
[57] S. 499.029(12), F.S.
[58] S. 499.029(6), F.S.
[59] S. 499.029(3)(a), F.S.
[60] S. 499.029(4), F.S.
[61] S. 499.029(4), F.S.
[62] S. 499.029(6)(d), F.S.
[63] 61N-1.026(5), F.A.C.
[64] "Class II institutional pharmacies" are those institutional pharmacies which employ the services of a registered pharmacist or pharmacists who … shall provide dispensing and consulting services on the premises to patients of that institution, for use on the premises of that institution. Medicinal drugs may be dispensed in a Class II institutional pharmacy, but only in accordance with the provisions of this section. S. 465.019(2)(b), F.S. However, s. 499.029(4), F.S., allows the participant facilities to provide dispensing and consulting services to individuals who are not a patient of the hospital.
[65] Ss. 499.029(3)(e), 499.029(7), F.S.
[66] Rule 61N-1.026(2)(b), F.A.C.
[67] S. 499.029(10), F.S.
[68] DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION, *Cancer Drug Donation Program Participation Report*, http://www.myfloridalicense.com/dbpr/ddc/documents/ParicipatingHospital.pdf (last visited Dec. 1, 2017).
[69] Rule 61N-1.026(1)(a), F.A.C.

any other prescription drug program funded in whole or in part by the Federal Government.[70] 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.[71]

An eligible cancer patient may contact a participating facility directly, sign a form certifying they qualify under the CDDP, and request an available donated cancer drug or supply.[72] The eligible patient must have a valid prescription for a cancer drug in order to receive drugs or supplies from a participating facility.[73]

Only a licensed pharmacist may dispense cancer drugs and supplies to an eligible patient.[74] 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.[75]

Effect of the Bill:

The Prescription Drug Donation Repository Program

CS/HB 291 creates s. 465.1902, F.S, establishing a Prescription Drug Donation Repository Program (Program) within the Department of Health (DOH) to authorize and facilitate the donation and distribution of prescription drugs and supplies to eligible patients through a system of local and centralized repositories. DOH may contract with a third party to implement and administer the Program.

Eligible Donors

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

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

The bill 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 and the rules adopted pursuant to. Additionally, a pharmaceutical manufacturer, who exercises reasonable care, is not liable for any claim or injury arising from the transfer of any prescription drug under the Program.

Eligible Donations

The bill authorizes prescription drugs to be donated if the drug:

[70] S. 499.029(9), F.S.
[71] S. 499.029(9), F.S.
[72] Rule 61N-1.026(3)(e)3., F.A.C.
[73] S. 499.029(5), F.S.
[74] S .499.029(5), F.S.
[75] S. 499.029(6)(c), F.S., Rule 61N-1.026(3)(e)2., F.A.C.

- 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; single-unit dose drugs may be accepted if the single-unit dose packaging is unopened;
- Requires storage at normal room temperature per the manufacturer or the United States Pharmacopeia;
- Has been stored according to the manufacturer or United States Pharmacopeia storage requirements;
- Does not have any physical signs of tampering or adulteration, and there is no reason to believe that the drug is adulterated;
- Packaging contains a lot number and expiration date of the drug;
- Will not expire until at least three months after the donation is made;
- Is not eligible for return to the Medicaid program for restocking; and
- Is not subject to a FDA REMS with ETASU.

The bill requires that prescription drugs or supplies be donated at a repository and prohibits the use of a dropbox and donation to a specific patient. Repositories are not required to accept a donation of drug or supply, and may refuse to do so. 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.

Repositories

The bill permits the following entities that are licensed or permitted to dispense medicinal drugs in Florida to participate in the Program as local 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 delivers only medical diagnostic services or nonsurgical medical treatment free of charge to all low-income recipients.
- Nonprofit health clinics that provides medical care to indigent, uninsured, or underinsured patients (i.e. federally qualified health centers, rural health clinics).

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

- The name, street address, and telephone number of the local repository, 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 of this section.

A local repository may withdraw from participation in the Program, but must notify DOH on a form prescribed by DOH and adopted in rule.
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 this, and attach it to the inventory record. Re-inspection is not required if inspected drugs are redistributed to another repository under the Program.

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 5 days of receipt.[76] The centralized repository maintains an inventory of all prescription drugs and supplies donated to the Program, including donations made at local repositories. The centralized repository may redistribute drugs and supplies to facilitate dispensing as needed throughout the state.

The bill 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 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 local repositories in accordance with any applicable practice acts. However, local repositories must 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 DOH.

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

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

Eligible Patients

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

- Have an income that 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.
- Have no third-party insurance and are 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.
- Have third-party insurance or are 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 have exhausted these benefits or do not have prescription drug coverage for the drug prescribed.

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

[76] The bill requires DOH to establish this notification form in rule.

- 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; and
- A statement signed and dated by the eligible patient affirming that he or she meets the eligibility requirements of the Program.

The bill requires local repositories to collect an executed intake form from each eligible patient receiving drugs or supplies under the Program. Upon receiving a duly executed intake form, the local repository shall issue the eligible patient an identification card that the patient can use to verify eligibility for up to one year after it is issued. Local repositories must send a summary of the intake collection form data to the centralized repository within 5 days of receipt.

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, 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 allows a dispenser to provide dispensing and consulting services to an eligible patient. The local repository shall maintain a record of all prescription drugs and supplies dispensed under the Program.

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 prescription drugs in the repository; and
- Complete a destruction information form for all donated prescription drugs that were destroyed.

The bill requires DOH to adopt rules and forms necessary to implement the requirements of the Program, incorporate any forms in rule by reference, and publish them on its website.

<u>Emergency Management Powers of the Governor</u>

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, 2018.

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.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The bill has a significant, negative fiscal impact on DOH. DOH developed a range of cost estimates to operate the program based upon costs and utilization rates for Iowa's program. [77] DOH based its estimates on two utilization rates 1% (Iowa's actual rate) and 2.5% (assumed highest plausible rate) and two per person costs estimates, $45.05 per person (Iowa's 2017-2018 appropriation) and $101.93 per person (Iowa's 3rd party vendor costs).[78] DOH estimates that there will be approximately 6.5 million patients eligible to receive prescription drugs under the Program which translates to approximately $3 million - $6.7 million at 1% utilization and approximately $7.4 million to $16.7 million at 2.5% utilization.[79]

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. To the extent that hospitals and nursing home facilities elect to participate in the Program, there will be costs associated with the processing, storage, dispensing, and disposal of donated prescription drugs and supplies; however, these costs may be recovered fully, or in part, by the authorized handling fee.

Participating entities that donate prescription drugs or supplies that would otherwise go unused will save the associated costs of destroying or disposing of the drugs and supplies. To the extent that eligible patients use the Program, there may be a reduction in healthcare expenses associated with nonadherence to medical regimens, such as emergency visits to hospitals or clinics.

D. FISCAL COMMENTS:

None.

III. COMMENTS

[77] Email from Paul Runk, Legislative Affairs Director, Department of Health, RE: Fiscal Impact for Prescription Drug Donation Program (Jan. 18, 2018)(on file with the Health Quality Subcommittee staff).
[78] Id.
[79] Id.

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.

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 January 29, 2018, the Health Quality Subcommittee adopted an amendment that:

- Eliminates the expansion of the Cancer Drug Donation Program and creates a Prescription Drug Donation Program in the Department of Health.
- Creates a system of centralized and local repositories to facilitate distribution of donated prescription drugs and supplies throughout the state.
- Establishes eligibility criteria to donate, dispense and receive prescription drugs under the program.
- Revises the definition of prescription drug to align with the Florida Pharmacy Act and exclude controlled substances and cancer drugs.
- Provides inspection and storage requirements for donated prescription drugs.
- Authorizes the Governor to waive patient eligibility requirements during a declared state of emergency.

The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute as passed by the Health Quality Subcommittee.