

## HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** CS/HB 59 Prescription Drug Donation Repository Program  
**SPONSOR(S):** Health Quality Subcommittee, Yarborough, Clay and others  
**TIED BILLS:** **IDEN./SIM. BILLS:** SB 104

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	15 Y, 0 N, As CS	Gilani	McElroy
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

### 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 which allow unused prescription drugs to be donated and re-dispensed to patients. Florida's drug reuse program is limited to cancer drugs.

HB 59 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 underinsured patients in the state. The Program uses a system of a centralized and local repositories to distribute donated prescription drugs throughout the state to eligible patients.

The bill establishes criteria for local repositories, prescription drug donors, donated prescription drug recipients, and which prescription drugs can be donated. Additionally, 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. DOH must approve a drug distributor to serve as the centralized repository for the program to oversee prescription drug donation and distribution, but local repositories are established as eligible entities elect to participate in the Program.

The bill authorizes DOH to establish a direct-support organization to provide assistance, funding, and promotional support to the Program, and requires DOH to adopt rules and forms necessary to implement the Program.

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 a significant, negative fiscal impact on DOH. The bill has no impact on local government.

The bill provides an effective date of July 1, 2019.

# FULL ANALYSIS

## I. SUBSTANTIVE ANALYSIS

### A. EFFECT OF PROPOSED CHANGES:

#### Background

##### Regulation of Pharmacy

The Florida Pharmacy Act (Act) regulates the practice of pharmacy and contains the minimum requirements for safe practice.<sup>1</sup> 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.<sup>2</sup> 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:<sup>3</sup>

- 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.<sup>4</sup>

Prior to dispensing a prescription drug, a pharmacist is required to:<sup>5</sup>

- Determine that the individual has a valid prescription for the medicinal drug;<sup>6</sup>
- 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.

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<sup>1</sup> Ch. 465, F.S.

<sup>2</sup> Ss. 465.005; 465.0155; and 465.022, F.S.

<sup>3</sup> 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.

<sup>4</sup> 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.

<sup>5</sup> S. 465.003(6), F.S.

<sup>6</sup> 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.

Pharmacists cannot restock for re-dispensing any prescription drug returned by a patient unless the medication.<sup>7</sup>

- Has been maintained in a closed drug delivery system;<sup>8</sup>
- Is individually sealed in unit-dose<sup>9</sup> or customized patient medication packaging<sup>10</sup>; 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.<sup>11</sup>

Federal law prohibits the return and re-dispensing of controlled substances to anyone other than the patient,<sup>12</sup> but the U.S. Food and Drug Administration (FDA) has no specific regulations with respect to 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.<sup>13</sup>

### Prescription Drug Reuse Programs

The United States spends approximately \$333.4 billion annually on prescription drugs,<sup>14</sup> with 14 percent (\$46.7 billion) paid out-of-pocket by consumers.<sup>15</sup> A significant number of these prescription drugs go unused, although the exact number is unknown.<sup>16</sup> Disposal methods of unused prescription drugs vary from flushing down the toilet to participating in local, state or federal drug take back days.

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<sup>7</sup> S. 465.016(1)(l), F.S.; Rule 64B16-28.118(2)(a), F.A.C.

<sup>8</sup> "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.

<sup>9</sup> "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.

<sup>10</sup> "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.

<sup>11</sup> S. 465.0465(1), F.S.

<sup>12</sup> 21 U.S.C. §§ 825(c), 841–844.

<sup>13</sup> 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 Feb. 15, 2019). See also 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 Feb. 15, 2019)(quoting FDA representative, "the redispensing of prescription drugs is entirely a state board of pharmacy matter"). See generally 21 U.S.C. § 903. <https://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/ensuringsafeuseofmedicine/safedisposalofmedicines/ucm186187.htm#7>

<sup>14</sup> *National Health Expenditures 2017 Highlights*, CENTERS FOR MEDICARE & MEDICAID SERVICES, Dec. 6, 2018, available at: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf> (last visited Feb. 15, 2019).

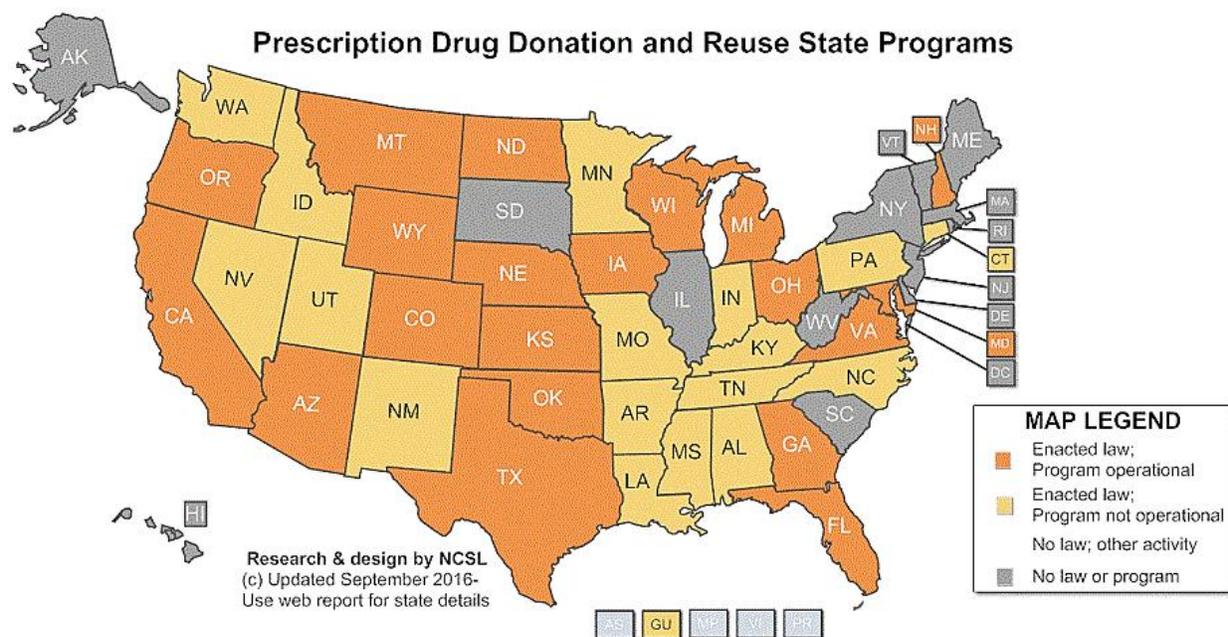
<sup>15</sup> *National Health Expenditures by Type of Service and Source of Funds, CY 1960-2017*, CENTERS FOR MEDICARE & MEDICAID SERVICES, available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html> (last visited Feb. 16, 2019).

<sup>16</sup> 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 visited Feb. 16, 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 Feb. 16, 2019).

Unused prescription drugs returned by a patient are not generally eligible for restocking or re-dispensing<sup>17</sup> 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.<sup>18</sup>

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.<sup>19</sup> However, more than a dozen of these states do not have functioning or operational programs,<sup>20</sup> 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.<sup>21</sup>

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.<sup>22</sup> Wyoming's program has filled over 150,000 prescriptions worth over \$12.5 million in the last 10 years,<sup>23</sup> and since 2004, Oklahoma's program has filled over 239,000 prescriptions worth over \$23.8 million.<sup>24</sup> Georgia formally launched its program in January 2018, and has served over 1,000 patients, dispensing prescription drugs worth over \$2 million.<sup>25</sup>



Note: New York enacted a drug recycling program in November 2016 but it is not operational.

<sup>17</sup> S. 465.016(1)(l), F.S.; Rule 64B16-28.118(2)(a), F.A.C.

<sup>18</sup> *Supra* note 8.

<sup>19</sup> *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 Feb. 16, 2019). Cancer-specific programs: CO, FL, KY, MI, MN, MT, NB, NV, OH, PA, UT, WA, and WI.

<sup>20</sup> "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.*

<sup>21</sup> *Supra* note 19.

<sup>22</sup> *Id.*

<sup>23</sup> WYOMING DEPARTMENT OF HEALTH, *Wyoming Medication Donation Program*, <https://health.wyo.gov/healthcarefin/medicationdonation/> (last visited Feb. 16, 2019).

<sup>24</sup> TULSA COUNTY MEDICAL SOCIETY, *Drug Recycling – Utilization of Unused Prescription Drugs Act*, <http://tcmsok.org/drug-recycling/> (last visited Feb. 16, 2019).

<sup>25</sup> Andy Miller, *Medicine Donation Program Helps Many Georgians Who Can't Afford What They Need*, GEORGIA HEALTH NEWS (Aug. 7, 2018), <http://www.georgiahealthnews.com/2018/08/medicine-donation-program-helps-georgians-afford/> (last visited Feb. 16, 2019).

<sup>26</sup> *Id.*

Most of these programs exclude controlled substances, expired drugs, and drugs that show any physical signs of tampering, misbranding, deterioration, compromised integrity, or adulteration.<sup>27</sup> They also require that all drugs be inspected and dispensed by a licensed pharmacist.<sup>28</sup> 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.<sup>29</sup> 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.<sup>30</sup>

### *Iowa's Drug Donation Repository Program*

Iowa currently has one of the largest drug recycling programs 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.<sup>31</sup> Uninsured or underinsured Iowans with incomes at or below 200 percent of the federal poverty level with valid prescriptions are eligible to receive donated drugs under the program.<sup>32</sup>

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.<sup>33</sup>

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.<sup>34</sup>

### *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.<sup>35</sup> The Department of Business and Professional Regulation (DBPR) administers the CDDP.<sup>36</sup>

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<sup>27</sup> Id.

<sup>28</sup> Id.

<sup>29</sup> Id.

<sup>30</sup> 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.

<sup>31</sup> IOWA DEPARTMENT OF PUBLIC HEALTH, *SafeNetRx Program*, <https://idph.iowa.gov/ohds/rural-health-primary-care/repository> (last visited Feb. 16, 2019).

<sup>32</sup> IOWA ADMIN. CODE 641-109.

<sup>33</sup> Id.

<sup>34</sup> *Supra* note 19. 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 Feb. 16, 2019).

<sup>35</sup> 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.

<sup>36</sup> 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.

Only hospitals may accept or dispense donated cancer drugs or supplies under the CDDP.<sup>37</sup> DBPR maintains a participant facility registry on its website for potential donors and patients.<sup>38</sup> The CDDP allows only entities that are licensed, permitted, or otherwise maintain a closed drug delivery system,<sup>39</sup> to donate cancer drugs and supplies,<sup>40</sup> and excludes controlled substances<sup>41</sup> and drugs that will expire in less than 6 months, have been opened, tampered with, or mislabeled.<sup>42</sup>

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.<sup>43</sup> Only a licensed pharmacist may dispense cancer drugs to eligible patients under the CDDP.<sup>44</sup>

Participants are immune from civil and criminal liability, and from professional disciplinary action, relating to activities of the program if they exercise reasonable care.<sup>45</sup>

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 available for dispensing.<sup>46</sup> DBPR is aware of at least 40 cancer drug donations under this program historically since 2013 although there is no requirement for participating facilities to report this information to DBPR.<sup>47</sup>

### Direct-Support Organizations

A direct-support organization (DSO) is a non-profit organization authorized by statute to carry out specific tasks in support of a public entity or public cause. The function and purpose of a DSO is detailed in its enacting statute and the contract with the agency the DSO was created to support.<sup>48</sup>

### *DSO Transparency and Reporting Requirements*

In 2014, the Legislature created s. 20.058, F.S., establishing transparency and reporting requirements for DSOs.<sup>49</sup> Specifically, the law requires each DSO submit annually the following information to the agency it was created to support by August 1:<sup>50</sup>

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<sup>37</sup> 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.

<sup>38</sup> S. 499.029(10), F.S.

<sup>39</sup> "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.

<sup>40</sup> 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.

<sup>41</sup> S. 499.029(3)(a), F.S.

<sup>42</sup> S. 499.029(6), F.S.

<sup>43</sup> Rule 61N-1.026(3)(e)3., F.A.C.; S. 499.029(5), F.S.

<sup>44</sup> 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.

<sup>45</sup> 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.

<sup>46</sup> DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION, *Cancer Drug Donation Program Participation Report*, <http://www.myfloridalicense.com/dbpr/ddc/documents/ParticipatingHospital.pdf> (last visited Feb. 16, 2019).

<sup>47</sup> 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.

<sup>48</sup> 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, 2018), available at: [https://flauditor.gov/pages/pdf\\_files/10\\_700.pdf](https://flauditor.gov/pages/pdf_files/10_700.pdf) (last visited Feb. 16, 2019).

<sup>49</sup> S. 3, Ch. 2014-96, L.O.F

<sup>50</sup> S. 20.058(1), F.S.

- 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 code of ethics; and
- A copy of the organization's most recent Internal Revenue Service (IRS) Form 990.<sup>51</sup>

Additionally, the information submitted annually by a DSO must be available on the agency's website and include a link to the DSO's website, if one exists.<sup>52</sup> A contract between an agency and a DSO must be contingent upon the DSO submitting the required information to the agency and posting the information on the agency's website.<sup>53</sup> The contract must include a provision for ending operations and returning state-issued funds if the authorizing statute is repealed, the contract is terminated, or the organization is dissolved.<sup>54</sup> If a DSO fails to submit the required information to the agency for two consecutive years, the agency head must terminate its contract with the DSO.<sup>55</sup>

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 the information submitted by each DSO, along with the agency's recommendation and supporting rationale to continue, terminate, or modify the agency's association with the DSO.<sup>56</sup>

Any law creating or authorizing a DSO must provide that the authorization is repealed on October 1 of the 5th year after enactment, unless reviewed and reenacted by the Legislature. Current law requires all DSOs in existence prior to July 1, 2014 to be reviewed by the Legislature by July 1, 2019.<sup>57</sup>

#### *DSO Audit Requirements*

Section 215.981, F.S., requires each DSO with annual expenditures in excess of \$100,000 to conduct an annual financial audit of its accounts and records.<sup>58</sup> The audit must be conducted by an independent certified public accountant in accordance with rules adopted by the Auditor General and the state agency that created, approved, or administers the DSO. The audit report must be submitted within nine months after the end of the fiscal year to the Auditor General and to the state agency the DSO supports. 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 DSO accounts and records.<sup>59</sup>

#### *DSO Code of Ethics Requirements*

Section 112.3251, F.S., requires a 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.<sup>60</sup> A DSO may adopt additional or more stringent standards of conduct and disclosure requirements and must post its code of ethics on its website.<sup>61</sup>

<sup>51</sup> 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.

<sup>52</sup> S. 20.058(2), F.S.

<sup>53</sup> S. 20.058(4), F.S.

<sup>54</sup> Ch. 2017-75, L.O.F.

<sup>55</sup> S. 20.058(4), F.S.

<sup>56</sup> S. 20.058(3), F.S.

<sup>57</sup> S. 20.058(5), F.S.

<sup>58</sup> The independent audit requirement does not apply to a 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 DSO for the Department of Environmental Protection and the Department of Agriculture and Consumer Services.

<sup>59</sup> S. 11.45(3), F.S.

<sup>60</sup> Examples of standards of conducts and disclosures in ss. 112.313 and 112.3143(2), F.S., include misuse of a public position, solicitation or acceptance of gifts, unauthorized compensation, and voting conflicts.

<sup>61</sup> S. 112.3251, F.S.

## 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.<sup>62</sup> 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.<sup>63</sup>

## **Effect of the Bill**

HB 59 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 a centralized and local repositories. DOH may contract with a third-party vendor to implement the program. The bill requires a DOH-approved permitted drug distributor to serve as the centralized repository that will oversee prescription drug donation and distribution. DOH has indicated that its Bureau of Public Health Pharmacy, which distributes prescription drugs from its central pharmacy to its county health departments and other public health programs, would function as the centralized repository for the Program.<sup>64</sup>

Local 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. Once the donations are inspected by a pharmacist and approved for dispensing, they are reported to the centralized repository and added to a public registry of available donations under the Program. Patients can contact the local repository where a donated drug or supply is located, present there with 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 local repositories to address demand, and makes more information available to the public.

## Centralized and Local Repositories

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

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<sup>62</sup> S. 252.36(5), F.S

<sup>63</sup> S. 252.36(2), F.S.

<sup>64</sup> DOH's central pharmacy has a restricted drug distributor permit for government programs under ch. 499, F.S. This permit allows a state agency to distribute prescription drugs to its contract providers and subcontractors for dispensing to patients under a state program. DOH has indicated that if local repositories have their own restricted drug distributor permits, DOH will be able to distribute prescription drugs under the Program using its restricted drug distributor permit for government programs. The entities that will be participating as local repositories often already have this permit in the regular course of their business (i.e., pharmacies, hospitals, clinics, dispensing physicians). Telephone call with Darren Evans, PharmD, MPH, Chief of Bureau of Public Health Pharmacy, Department of Health, on Feb. 20, 2019.

central repository may only accept, inspect, inventory, and distribute donations to local repositories but cannot dispense them to eligible patients, leaving that to the local repositories. The centralized repository is also responsible for maintaining record of all activities under the Program and reports them to DOH annually. The bill requires DOH to approve a drug distributor permitted under ch. 499, F.S., to serve as the centralized repository but does not state how DOH shall select such a drug distributor.

Local repositories will accept, inspect, inventory, and dispense prescription drugs and supplies donated under the Program. Participation as local repository is voluntary. The bill allows only certain entities licensed or permitted to dispense medicinal drugs in Florida to be 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 deliver only medical diagnostic services or nonsurgical medical treatment free of charge to 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).

While participation is voluntary, an eligible entity must register with DOH as a local 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 local repository, any state-issued license or registration number issued to the intended local repository, including the name of the issuing agency;
- The name and telephone number of the pharmacist employed by or under contract with the intended local 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 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 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 local repository.

The bill prohibits the centralized and local 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 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.

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.<sup>65</sup> 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 between repositories 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. Local 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 the centralized repository or a local 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.

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 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.

#### 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 the centralized repository or a local repository and may not use a drop box to do so. The bill prohibits the donation of a prescription drug or supply to a specific patient.

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<sup>65</sup> The bill requires DOH to establish this notification form in rule.

## 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;<sup>66</sup>
- Is in its original sealed and tamper-evident packaging or in unopened single-unit dose packaging;
- Requires storage at normal room temperature per the manufacturer or the United States Pharmacopeia storage requirements;
- Has been stored according to the manufacturer or United States Pharmacopeia storage requirements;
- Has no physical signs of tampering or adulteration, and there is no reason to believe that the drug is adulterated;
- Packaging indicates 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 Risk Evaluation Mitigation Strategy with Elements to Assure Safe Use.<sup>67</sup>

Similarly, eligible donors may only donate prescription drug supplies that are in their original, unopened, sealed packaging, and have not been tampered with or misbranded.

## 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.<sup>68</sup>
- Uninsured and ineligible 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.
- Insured or 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:

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<sup>66</sup> 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.

<sup>67</sup> 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.

<sup>68</sup> 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.

- 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;
- Inspect the donated prescription drug or supply to confirm it is still eligible for dispensing under the Program; and
- Provide written notification to the eligible patient or his or her legal representative, and have him or her acknowledge receipt in writing, that the prescription drug they are receiving was donated to the program, that donors and participants are immune from liability, and the eligible patient is not required to pay for the prescription drug.

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. The DSO is repealed on October 1, 2024, unless reviewed and saved from repeal by the Legislature.

### 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 local 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.

### Direct-Support Organization

The bill authorizes DOH to establish a direct-support organization, in accordance with s. 20.58, F.S., to provide assistance, funding, and promotional support for the activities authorized under the Program. Should DOH establish a DSO, the bill requires DOH to adopt rules prescribe governing procedures for the DSO.

The bill requires DOH to adopt rules and forms necessary to administer the program and when applicable, provide for the use of electronic forms, recordkeeping, and meeting by teleconference.

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, 2019.

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, 2019.

**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. The bill authorizes DOH to create a DSO to provide assistance, funding, and promotional support for the Program's authorized activities. However, without sufficient funding support from the DSO, DOH will experience a significant increase in workload, a need for additional facility space, and require updated technology resources to administer the Program. DOH assumes that the Program will be administered by DOH's Bureau of Public Health Pharmacy. Based on costs the Bureau of Public Health Pharmacy incurs for similar activities under its central pharmacy, DOH estimates the fiscal impact of the bill will be \$406,603 in the first year and \$331,603 thereafter as follows:<sup>69</sup>

<b>DOH Fiscal Analysis</b>	
<b>Space and Housing</b>	<b>\$19,000</b>
Current market lease at \$11.73/sq. ft.	\$14,000 annually
Estimated utilities	\$5,000 annually
<b>Staffing</b>	<b>\$282,603 (6 FTEs)</b>
1 Senior Pharmacist	
1 Administrator	
3 Pharmacy Technicians	
1 Administrative Support	
<b>System Enhancements</b>	<b>\$70,000 (nonrecurring)</b>
Dispensing System (estimated 300 hours at \$75-\$95/hr)	\$35,000
Pharmaceutical Forms System (estimated 300 hours at \$75-\$95/hr)	\$35,000
<b>Prescription Drug Shipping Costs</b>	<b>\$35,000</b>
<b>Total First Year Costs</b>	<b>\$406,603</b>
<b>Total Recurring Costs</b>	<b>\$331,603</b>

<sup>69</sup> Florida Department of Health, Agency Analysis of 2019 HB 59, p. 6-7 (Dec. 20, 2018)(on file with House Health Quality Subcommittee staff).

**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 local 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.

**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:**

The bill requires a DOH-approved drug distributor permitted under ch. 499, F.S., to serve as the centralized repository, but does not state how DOH will select the drug distributor. The bill authorizes DOH to contract with a third-party vendor to implement the Program but does not state whether such vendor shall serve as the centralized repository.

**IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES**

On February 20, 2019, the Health Quality Subcommittee adopted an amendment that removed authorization for DOH to establish a nominal handling fee that local repositories could charge an eligible patient receiving a donated prescription drug or supply under the Program, and made a conforming change.

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