



Health & Human Services Committee

**Thursday, January 16, 2020
12:30 PM – 2:00 PM
Morris Hall (17 HOB)**

Meeting Packet

Committee Meeting Notice

HOUSE OF REPRESENTATIVES

Health & Human Services Committee

Start Date and Time: Thursday, January 16, 2020 12:30 pm

End Date and Time: Thursday, January 16, 2020 02:00 pm

Location: Morris Hall (17 HOB)

Duration: 1.50 hrs

Consideration of the following bill(s):

CS/HB 61 Adoption Benefits by Children, Families & Seniors Subcommittee, Roth, Daniels

CS/HB 177 Prescription Drug Donation Repository Program by Health Care Appropriations Subcommittee, Yarborough, Duran

CS/HB 197 Servicemembers Civil Relief Act by Local, Federal & Veterans Affairs Subcommittee, Payne

HB 1189 Genetic Information for Insurance Purposes by Sprowls, Williamson

Pursuant to rule 7.11, the deadline for amendments to bills on the agenda by non-appointed members shall be 6:00 p.m., Wednesday, January 15, 2020.

By request of the Chair, all committee members are asked to have amendments to bills on the agenda submitted to staff by 6:00 p.m., Wednesday, January 15, 2020.

NOTICE FINALIZED on 01/14/2020 4:02PM by Dewees.Cheryl

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 61 Adoption Benefits
SPONSOR(S): Children, Families & Seniors Subcommittee, Roth
TIED BILLS: **IDEN./SIM. BILLS:** SB 136

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Children, Families & Seniors Subcommittee	14 Y, 0 N, As CS	Woodruff	Brazzell
2) Health Care Appropriations Subcommittee	11 Y, 0 N	Fontaine	Clark
3) Health & Human Services Committee		Woodruff	Calamas

SUMMARY ANALYSIS

In Florida, the Department of Children and Families (DCF) provides child welfare services. Statute requires child welfare services, including adoption services, to be delivered through community-based care lead agencies contracted by DCF.

Adoption is a method of achieving permanency for children who have suffered abuse, neglect, or abandonment and who are unable to be reunified with their parents. In 2015, the Legislature reestablished an adoption benefit program within DCF for state employees who adopt children from the foster care system. Qualifying adoptive employees receive a one-time benefit of \$10,000 for the adoption of a child with special needs and \$5,000 for the adoption of a child who does not have such needs. The program currently has a \$2,750,000 recurring general revenue appropriation. Funding is accessed on a first come, first serve basis; 225 employees received the adoption benefit in FY 2018-19.

Eligible employees who may receive an adoption benefit include non-temporary employees, either full- or part-time, of a state agency, which is defined to also include school districts, state universities and colleges, and water management districts, among others.

CS/HB 61 allows state agencies to include certain other-personal-service (temporary) employees in the group of employees eligible for the adoption benefit.

Additionally, the bill allows a veteran or servicemember domiciled within Florida who adopts a child within the child welfare system to be eligible for the adoption benefit, regardless of whether he or she is a qualifying adoptive employee.

The bill has no fiscal impact on state or local governments. See fiscal comments.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Child Welfare System Adoptions

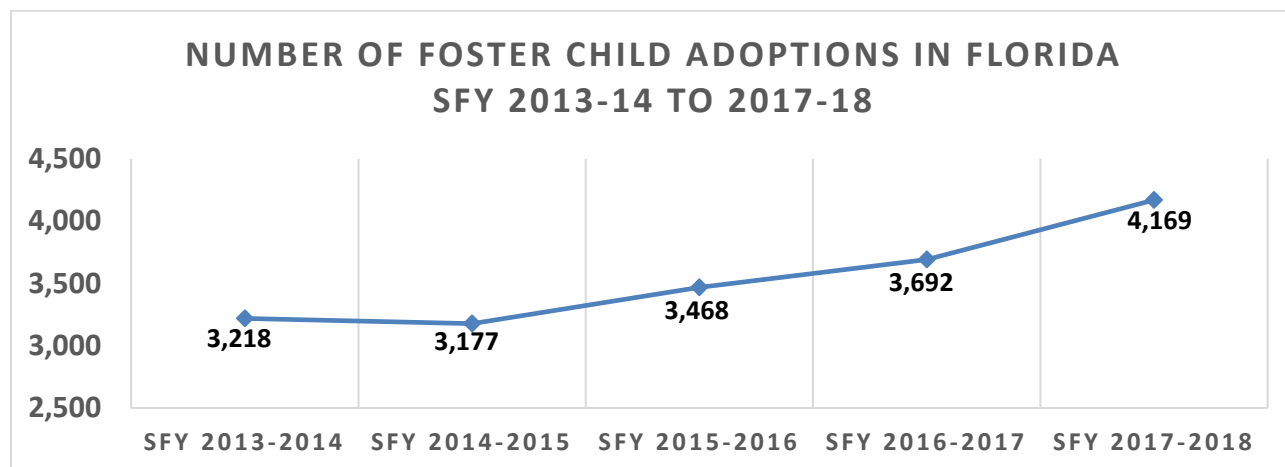
In Florida, the Department of Children and Families (DCF) provides child welfare services.¹ Statute requires child welfare services, including adoption services, to be delivered through community-based care (CBC) lead agencies contracted by DCF.² For example, CBCs provide pre- and post-adoption services and administer maintenance adoption subsidies which provide ongoing financial support for children adopted from the foster care system.

Adoption is a method of achieving permanency for children who have suffered abuse, neglect, or abandonment and who are unable to be reunited with their parents. Research indicates that children generally have better outcomes through adoption than through placement in long-term foster care.³

To become a licensed adoptive parent, an individual or couple must complete a licensing study class and complete a homestudy.⁴ The typical time frame is less than nine months for the entire process, and there is little to no cost to adopt a child from the child welfare system through a CBC.⁵

Statistics on Florida Foster Care Adoptions

During FY 2017-18, 4,169 adoptions of children within the child welfare system were finalized in Florida.⁶ Over the last five state fiscal years, the number of finalized adoptions in Florida has ranged from 3,218 to 4,169.⁷



¹ S. 20.19(4)(a)3, F.S.

² S. 409.986(1), F.S.

³ Evan B. Donaldson Adoption Institute, *Keeping the Promise: Critical Need for Post-Adoption Services to Enable Children and Families to Succeed*, Oct. 2010, p. 8.

⁴ Department of Children and Families, *How Do I Become a Foster Parent?*, <https://www.myflfamilies.com/service-programs/foster-care/how-do-i.shtml> (last visited Oct. 22, 2019).

⁵ Department of Children and Families, *Frequently Asked Questions*, <http://www.adoptflorida.org/faq.shtml> (last visited Oct. 22, 2019).

⁶ Department of Children and Families, *Adoption Incentive Annual Report*, <https://www.myflfamilies.com/service-programs/child-welfare/docs/2018LMRs/Adoption%20Incentive%20Annual%20Report%20with%20Appendices.pdf> (last visited Sept. 30, 2019).

⁷ *Id.*

Currently, in Florida, there are approximately 19,000 children in foster care.⁸ As of October 2019, DCF reported there were 8,417 children with a primary goal of adoption.⁹ Older children (especially teenagers) and sibling groups are likely to wait the longest for an adoptive family.

State Employee Adoption Benefit

From 2000 through 2010, Florida offered an adoption benefit to state employees. The program provided a one-time cash benefit to an employee of the state or a water management district who adopted a child. Qualifying employees adopting a child defined as “special-needs” under s. 409.166, F.S., were eligible to receive a monetary benefit of \$10,000 per child; qualifying employees adopting a child other than a “special-needs” child were eligible to receive a monetary benefit in the amount of \$5,000 per child.¹⁰ This program also authorized the benefit for private and foreign adoptions.

The law was amended in 2001 to restrict the program to state employees who adopted a child from the foster care system.¹¹ The benefit program was expanded in 2007 to include county school district employees, community college and university employees, and instructional personnel employed by the Florida School for the Deaf and the Blind as employees eligible to receive the benefit. The Legislature also transferred the program from the Department of Management Services (DMS) to DCF.¹² The program ended in 2010 when the statute was repealed and the funding ended.¹³

In 2015, the Legislature reestablished the adoption benefit program for state employees who adopt a child from the foster care system beginning on July 1, 2015. Adoptive employees may receive a one-time benefit of \$10,000 for a child with special needs and \$5,000 for the adoption of a child who does not have such needs.¹⁴

For purposes of the adoption benefit program, a “special-needs” child is defined in s. 409.166(2), F.S., as:

- A child whose permanent custody has been awarded to DCF or to a licensed child-placing agency; and
- Who has established significant emotional ties with his or her foster parents or is not likely to be adopted because he or she is:
 - Eight years of age or older;
 - Developmentally disabled;
 - Physically or emotionally handicapped;
 - Of black or racially mixed parentage; or
 - A member of a sibling group of any age, provided two or more members of a sibling group remain together for purposes of adoption; and
- For whom a reasonable but unsuccessful effort has been made to place the child without providing a maintenance subsidy, except when the child is being adopted by the child’s foster parents or relative caregivers.

⁸ AdoptUSKids, *Florida Foster Care and Adoption Guidelines*, <https://www.adoptuskids.org/adoption-and-foster-care/how-to-adopt-and-foster/state-information/florida#children> (last visited Sep. 30, 2018).

⁹ Email from John Paul Fiore, Legislative Specialist, Department of Children and Families, RE: Information request (Oct. 10, 2019), on file with Children, Families, and Seniors Subcommittee staff.

¹⁰ S. 110.152, F.S. (2000)

¹¹ S. 110.152, F.S. (2001)

¹² S. 409.1663, F.S. (2007)

¹³ Ch. 2010-152, L.O.F.

¹⁴ S. 409.1664, F.S.

In order for an adoptive parent to qualify for the adoption benefit program for state employees, he or she must meet the statutory requirements at the time the adoption takes place. A “qualifying adoptive employee” includes those individuals who are regular (not temporary) employees, either full- or part-time, of:

- A branch, department, or agency of state government for which the Chief Financial Officer processes payroll requisitions¹⁵;
- A state university or Florida College System institution as defined in s. 1000.21, F.S.;
- A school district unit as defined in s. 1001.30, F.S.;
- A water management district as defined in s. 373.019, F.S.;
- A charter school established under s. 1002.33, F.S.; or
- The Florida Virtual School established under s. 1002.37, F.S.

A “qualifying adoptive employee” also includes instructional personnel¹⁶ who are employed by the Florida School for the Deaf and Blind.

In September 2019, the Chief Financial Officer processed payroll requisitions for 118,410 state employees (including all employees for the School of the Deaf and Blind).¹⁷ In addition, as of the Fall 2019 semester, there are approximately 48,855 State University System employees and approximately 46,326 Florida College System employees.¹⁸ As of FY 2018-19, there were approximately 337,792 full-time school district employees in Florida.¹⁹

Adoption benefits are awarded to qualifying adoptive employees on a first-come, first-served, basis, limited by the annual appropriation. Currently, the adoption benefit program has a \$2,750,000 recurring general revenue appropriation. Previously, the General Appropriations Act has authorized DCF to carry-forward any unspent funds at the end of the fiscal year to the next fiscal year. In FY 2018-19, the base appropriation for program was \$2,750,000; however, DCF had \$300,000 of unspent funds from the prior fiscal year. Therefore, \$3,050,000 was available to reward 225 qualifying adoptive employees with an adoption benefit.²⁰

¹⁵ These include the Legislature, Justice Administrative Commission, State Courts System, Governor’s Office, Department of Lottery, Department of Environmental Protection, Department of Economic Opportunity, Department of Legal Affairs, Department of Agriculture & Consumer Services, Department of Financial Services, Department of State, Department of Education, Florida School for the Deaf and Blind, Department of Veterans’ Affairs, Department of Transportation, Department of Citrus, Department of Children and Families, Public Service Commission, Department of Military Affairs, Department of Health, Department of Elder Affairs, Agency for Persons with Disabilities, Agency for Health Care Administration, Department of Corrections, Department of Law Enforcement, Department of Management Services, Division of Administrative Hearings, Department of Revenue, Department of Highway Safety and Motor Vehicles, Florida Fish & Wildlife Commission, Florida Commission on Offender Review, Department of Business & Professional Regulation, and Department of Juvenile Justice. This total includes 8,725 OPS employees. Email from Meredith Stanfield, Director of Legislative and Cabinet Affairs, Office of Chief Financial Officer, RE: Bill analysis and information request (Oct. 9, 2019), on file with Children, Families, and Seniors Subcommittee staff.

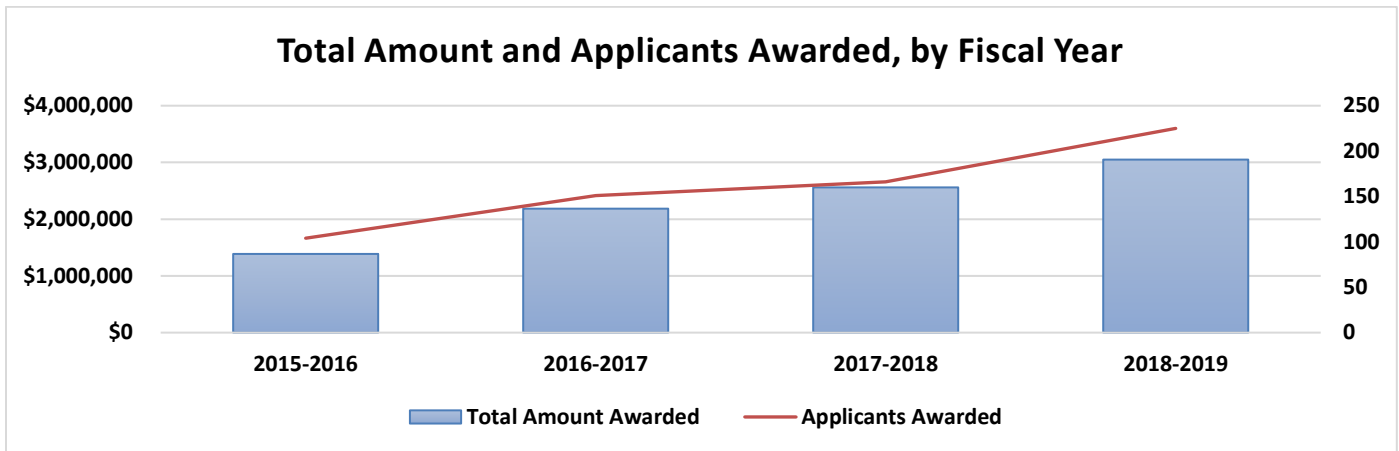
¹⁶ “Instructional personal,” as defined in s. 1012.01(1), F.S., means any K-12 staff member whose function includes the provision of direct instructional services to students and whose functions provide direct support in the learning process of students.

¹⁷ Email from Meredith Stanfield, Director of Legislative and Cabinet Affairs, Office of Chief Financial Officer, RE: Bill analysis and information request (Oct. 9, 2019), on file with Children, Families, and Seniors Subcommittee staff.

¹⁸ Florida Department of Education, *The Fact Book: Report for the Florida College System*, 2017, table 6.3T, <http://www.fldoe.org/accountability/data-sys/CCTCMIS/reports.shtml> (last visited Oct. 22, 2019). Note that this figure includes temporary employees.

¹⁹ Florida Department of Education, *Staff in Florida’s Public Schools*, <http://www.fldoe.org/accountability/data-sys/edu-info-accountability-services/pk-12-public-school-data-pubs-reports/staff.shtml> (last visited Oct. 22, 2019).

²⁰ *Supra*, note 9.



Other Personal Services Employees

Other Personal Services (OPS) employment is a temporary employment with the State of Florida used solely for accomplishing short term or intermittent tasks.²¹ Unless specifically provided by law, OPS employees are not eligible for any form of paid leave, paid holiday, a paid personal day or retirement benefits. Full-time OPS employees are eligible for state group health insurance.

An agency may employ any qualified individual in an OPS position; however, the agency must:

- Maintain employee records identifying the person employed, the hire date, and the type of OPS employment, and the number of hours worked;
- Determine the appropriate rate of pay and ensure the payments are in compliance with the federal Fair Labor Standards Act and state law; and
- Review, determine, and document by June 30 of each year whether the continuation of each OPS employment position is necessary to the mission of the agency.²²

As of September 2019, Department of Financial Services processed payroll for 8,725 OPS state employees.²³

Veterans and Servicemembers

Veterans

The term “veteran” includes a person who served in the active military, naval, or air service and who was discharged or released under honorable conditions only or who later received an upgraded discharge under honorable conditions, notwithstanding any action by the United States Department of Veteran Affairs (VA) on individuals discharged or released with other than honorable discharges.²⁴

As of 2017, the VA estimated there were 20 million veterans living in the United States.²⁵ During this period, Florida had the third largest veteran population in the nation with approximately 1,525,400 veterans living in the state.²⁶

²¹ R.60L-33.005, F.A.C.

²² S. 110.131(2), F.S.

²³ *Supra*, note 17.

²⁴ S. 1.01(14), F.S.

²⁵ Florida Department of Veterans Affairs, *Fast Facts*, <http://floridavets.org/our-veterans/profilefast-facts/> (last visited Oct. 22, 2019).

²⁶ *Id.*

Servicemembers

The term “servicemember” means any person serving as a member of the United States Armed forces²⁷ on active duty or state active duty²⁸ and all members of the Florida National Guard and United States Reserve Forces.²⁹

As of June 2019, there are 64,915 Floridians serving in the United States Armed Forces and 37,003 serving in Florida’s National Guard and United States Reserve Forces.³⁰

Adoption Benefits Available through the Military

Currently, the federal government reimburses eligible servicemembers on active duty a maximum of \$2,000 per child for qualifying expenses related to the adoption of children under age 18, up to a maximum of \$5,000 per calendar year for multiple adoptions. The adoption must be arranged by a qualified adoption agency. Qualifying expenses include:

- Public and private agency fees including fees charged by an agency in a foreign country.
- Placement fees, including fees charged adoptive parents for counseling.
- Legal fees, including court costs, for services that not available from military legal assistance or notary offices.
- Medical expenses, including:
 - Hospital expenses of the biological mother of the child to be adopted.
 - Hospital expenses of a newborn infant to be adopted.
 - Medical care given to the adopted child before the adoption.
 - Physical examinations of the biological mother of the child to be adopted
- Temporary foster care charges when payment of such charges is required to be made before the adoptive child's placement.³¹

Veterans with a service-connected disability that results in infertility are also eligible for similar adoption benefits.³²

However, as there is little to no cost³³ to adopt children through the DCF child welfare system,, servicemembers and veterans would likely incur minimal qualifying expenses, if any, for the adoption of a child within the child welfare system.

Effect of Proposed Changes

The bill amends current law to allow state agencies to include OPS employees in the group of employees eligible for the adoption benefit. Such OPS employees must have been employed full- or part-time by a state agency for one year. This will allow these employees to qualify to receive the adoption benefit for adopting a child from the child welfare system, provided funds are available and other requirements of rule

²⁷ The United States Armed Forces consists of the Army, Marine Corps, Navy, Air Force, and Coast Guard.

²⁸ “State active duty” means full-time duty in active military service of the State of Florida when ordered by the Governor or Adjutant General to preserve the public peace, execute the laws of the state, suppress insurrection, repel invasion, enhance security and respond to terrorist threats or attacks, respond to an emergency, enforce the law, carry out counter-drug operations, provide training, provide for the security of the rights or lives of the public, protect property, or conduct ceremonies. The term also includes the period during which a person in active military service is absent from duty as a result of illness, being wounded, being on leave, or other lawful cause.

²⁹ S. 250.01, F.S.

³⁰ Defense Manpower Data Center, *DOD Personnel, Workforce Reports & Publications*, https://www.dmdc.osd.mil/appj/dwp/dwp_reports.jsp (last visited Oct. 22, 2019).

³¹ U.S. Army, *My Army Benefits—Adoption Assistance*. <https://myarmybenefits.us.army.mil/Benefit-Library/Federal-Benefits/Adoption-Assistance?serv=122> (last visited Oct. 19, 2019).

³² U.S. Department of Veterans’ Affairs, *VAntage Point—VA Now Offers Adoption Reimbursement*. <https://www.blogs.va.gov/VAntage/47109/va-now-offers-adoption-reimbursement/> (last visited Oct. 19, 2019).

³³ The required adoptive parent training class and home study are provided to adoptive parents free of charge, and court costs and fees can be paid by DCF if the family cannot afford them. See Department of Children and Families, *Benefits of Adopting Florida’s Children*, <http://www.adoptflorida.org/benefits.shtml> (last visited Jan. 1, 2020).

and law are met. However, the bill gives discretion to state agencies to include or exclude their OPS employees from the adoption benefit. It is unclear whether this authorizes state agencies to exclude individual OPS employees or the entire class of OPS employees. As of September 2019, there were 8,725 OPS state employees.

Additionally, the bill allows veterans and servicemembers domiciled in the state who adopt a child within the child welfare system on or after July 1, 2020, to be eligible for an adoption benefit under s. 409.1664(2), F.S., regardless of whether the veteran or servicemember is a qualifying adoptive employee. Therefore, 1,627,318 persons may potentially apply for the adoption benefit.

Eligible OPS employees, veterans, and servicemembers meeting the requirements of the section will receive a monetary benefit of either \$5,000 or \$10,000 which they otherwise would not have been eligible to receive. Section 409.1664(2)(c), F.S., limits adoption benefit awards to those funds specifically designated for that purpose; therefore, while more individuals may be eligible, the number of actual recipients will be limited to the availability of funding.

B. SECTION DIRECTORY:

Section 1: Amending s. 409.1664, F.S., relating to adoption benefits for qualifying adoptive employees of state agencies.

Section 2: Providing an effective date of July 1, 2020.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

The payment of adoption benefits available under s. 409.1664, F.S., is subject to the availability of funds through a specific appropriation. While additional individuals are eligible to apply for benefits, the expenditure is capped. The FY 2020-21 base appropriation for this program is \$2,750,000.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

In FY 2018-19 the adoption benefit program received a base appropriation of \$2,750,000 plus \$300,000 in funding reappropriated from the prior fiscal year. Therefore, \$3,050,000 was available for DCF to award 225 individuals with an adoption benefit. Between FY 2015-16 and FY 2018-19, approximately 56 percent of the base appropriation was disbursed within the respective fiscal year, with authority in

the General Appropriations Act (GAA) that allowed for the carry-forward of unused funding to the subsequent fiscal year. For FY 2019-20, the program received a base appropriation of \$2,750,000; however, the GAA did not include the carry-forward authority. Therefore, any unspent funds on June 30, 2020, will revert back to General Revenue and will be available for any purpose.

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:

Not applicable.

B. RULE-MAKING AUTHORITY:

The agency has sufficient rulemaking authority to administer the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On October 24, 2019, the Children, Families and Seniors Subcommittee adopted an amendment that removed authority for DCF to adopt rules to administer the adoption benefits program when veterans and servicemembers apply for adoption benefits. Under s. 409.1664(6), F.S., DCF has rulemaking authority to adopt rules to administer the overall program. The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute as passed by the Children, Families and Seniors Subcommittee.

1 A bill to be entitled
 2 An act relating to adoption benefits; amending s.
 3 409.1664, F.S.; revising the definition of the term
 4 "qualifying adoptive employee"; providing that certain
 5 adoptive veterans and servicemembers are eligible to
 6 apply for certain monetary benefits; defining the
 7 terms "veteran" and "servicemember"; providing an
 8 effective date.

9
 10 Be It Enacted by the Legislature of the State of Florida:

11
 12 Section 1. Section 409.1664, Florida Statutes, is amended
 13 to read:

14 409.1664 Adoption benefits for qualifying adoptive
 15 employees of state agencies, veterans, and servicemembers.-

16 (1) As used in this section, the term:

17 (a) "Child within the child welfare system" has the same
 18 meaning as provided in s. 409.166.

19 (b) "Qualifying adoptive employee" means a full-time or
 20 part-time employee of a state agency, a charter school
 21 established under s. 1002.33, or the Florida Virtual School
 22 established under s. 1002.37 who is paid from regular salary
 23 appropriations, or otherwise meets his or her employer's
 24 definition of a regular rather than temporary employee, and who
 25 adopts a child within the child welfare system pursuant to

26 | chapter 63 on or after July 1, 2015. The term includes
27 | instructional personnel, as defined in s. 1012.01, who are
28 | employed by the Florida School for the Deaf and the Blind. For
29 | purposes of this paragraph, an employer's definition of a
30 | regular employee may include an other-personal-services employee
31 | who has been continuously employed full-time or part-time by the
32 | state agency for at least 1 year.

33 | (c) "State agency" means a branch, department, or agency
34 | of state government for which the Chief Financial Officer
35 | processes payroll requisitions, a state university or Florida
36 | College System institution as defined in s. 1000.21, a school
37 | district unit as defined in s. 1001.30, or a water management
38 | district as defined in s. 373.019.

39 | (2) A qualifying adoptive employee who adopts a child
40 | within the child welfare system who has special needs described
41 | in s. 409.166(2)(a)2. is eligible to receive a lump-sum monetary
42 | benefit in the amount of \$10,000 per such child, subject to
43 | applicable taxes. A qualifying adoptive employee who adopts a
44 | child within the child welfare system who does not have special
45 | needs described in s. 409.166(2)(a)2. is eligible to receive a
46 | lump-sum monetary benefit in the amount of \$5,000 per such
47 | child, subject to applicable taxes. A qualifying adoptive
48 | employee of a charter school or the Florida Virtual School may
49 | retroactively apply for the monetary benefit provided in this
50 | subsection if such employee was employed by a charter school or

51 the Florida Virtual School when he or she adopted a child within
52 the child welfare system pursuant to chapter 63 on or after July
53 1, 2015.

54 (a) Benefits paid to a qualifying adoptive employee who is
55 a part-time employee must be prorated based on the qualifying
56 adoptive employee's full-time equivalency at the time of
57 applying for the benefits.

58 (b) Monetary benefits awarded under this subsection are
59 limited to one award per adopted child within the child welfare
60 system.

61 (c) The payment of a lump-sum monetary benefit for
62 adopting a child within the child welfare system under this
63 section is subject to a specific appropriation to the department
64 for such purpose.

65 (3) A qualifying adoptive employee must apply to his or
66 her agency head, or to his or her school director in the case of
67 a qualifying adoptive employee of a charter school or the
68 Florida Virtual School, to obtain the monetary benefit provided
69 in subsection (2). Applications must be on forms approved by the
70 department and must include a certified copy of the final order
71 of adoption naming the applicant as the adoptive parent.

72 Monetary benefits shall be approved on a first-come, first-
73 served basis based upon the date that each fully completed
74 application is received by the department.

75 (4) This section does not preclude a qualifying adoptive

76 | employee from receiving adoption assistance for which he or she
77 | may qualify under s. 409.166 or any other statute that provides
78 | financial incentives for the adoption of children.

79 | (5) Parental leave for a qualifying adoptive employee must
80 | be provided in accordance with the personnel policies and
81 | procedures of his or her employer.

82 | (6) The department may adopt rules to administer this
83 | section. The rules may provide for an application process such
84 | as, but not limited to, an open enrollment period during which
85 | qualifying adoptive employees may apply for monetary benefits
86 | under this section.

87 | (7) The Chief Financial Officer shall disburse a monetary
88 | benefit to a qualifying adoptive employee upon the department's
89 | submission of a payroll requisition. The Chief Financial Officer
90 | shall transfer funds from the department to a state university,
91 | a Florida College System institution, a school district unit, a
92 | charter school, the Florida Virtual School, or a water
93 | management district, as appropriate, to enable payment to the
94 | qualifying adoptive employee through the payroll systems as long
95 | as funds are available for such purpose.

96 | (8) Each state agency shall develop a uniform procedure
97 | for informing employees about this benefit and for assisting the
98 | department in making eligibility determinations and processing
99 | applications. Any procedure adopted by a state agency is valid
100 | and enforceable if the procedure does not conflict with the

101 | express terms of this section.

102 | (9) A veteran or servicemember who is domiciled in this
103 | state and who adopts a child within the child welfare system
104 | pursuant to chapter 63 on or after July 1, 2020, is eligible to
105 | apply for the monetary benefits awarded under subsection (2),
106 | regardless of whether the veteran or servicemember is a
107 | qualifying adoptive employee. As used in this subsection, the
108 | term "veteran" has the same meaning as provided in s. 1.01(14)
109 | and the term "servicemember" has the same meaning as provided in
110 | s. 250.01(19).

111 | Section 2. This act shall take effect July 1, 2020.

Amendment No. 1

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED _____ (Y/N)
ADOPTED AS AMENDED _____ (Y/N)
ADOPTED W/O OBJECTION _____ (Y/N)
FAILED TO ADOPT _____ (Y/N)
WITHDRAWN _____ (Y/N)
OTHER

1 Committee/Subcommittee hearing bill: Health & Human Services
2 Committee

3 Representative Roth offered the following:

4
5 **Amendment (with title amendment)**

6 Remove everything after the enacting clause and insert:

7 Section 1. Section 409.1664, Florida Statutes, is amended
8 to read:

9 409.1664 Adoption benefits for qualifying adoptive
10 employees of state agencies, veterans, and servicemembers.—

11 (1) As used in this section, the term:

12 (a) "Child within the child welfare system" has the same
13 meaning as provided in s. 409.166.

14 (b) "Qualifying adoptive employee" means a full-time or
15 part-time employee of a state agency, a charter school
16 established under s. 1002.33, or the Florida Virtual School

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Amendment No. 1

17 established under s. 1002.37, who is not an independent
18 contractor ~~paid from regular salary appropriations, or otherwise~~
19 ~~meets his or her employer's definition of a regular rather than~~
20 ~~temporary employee,~~ and who adopts a child within the child
21 welfare system pursuant to chapter 63 on or after July 1, 2015.
22 The term includes instructional personnel, as defined in s.
23 1012.01, who are employed by the Florida School for the Deaf and
24 the Blind, and includes other-personal-services employees who
25 have been continuously employed full time or part time by a
26 state agency for at least 1 year.

27 (c) "Servicemember" has the same meaning as in s.
28 250.01(19).

29 (d) "State agency" means a branch, department, or agency
30 of state government for which the Chief Financial Officer
31 processes payroll requisitions, a state university or Florida
32 College System institution as defined in s. 1000.21, a school
33 district unit as defined in s. 1001.30, or a water management
34 district as defined in s. 373.019.

35 (e) "Veteran" has the same meaning as in s. 1.01(14).

36 (2) A qualifying adoptive employee, veteran, or
37 servicemember who adopts a child within the child welfare system
38 who has special needs described in s. 409.166(2)(a)2. is
39 eligible to receive a lump-sum monetary benefit in the amount of
40 \$10,000 per such child, subject to applicable taxes. A
41 qualifying adoptive employee, veteran, or servicemember who

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Amendment No. 1

42 adopts a child within the child welfare system who does not have
43 special needs described in s. 409.166(2)(a)2. is eligible to
44 receive a lump-sum monetary benefit in the amount of \$5,000 per
45 such child, subject to applicable taxes. A qualifying adoptive
46 employee of a charter school or the Florida Virtual School may
47 retroactively apply for the monetary benefit provided in this
48 subsection if such employee was employed by a charter school or
49 the Florida Virtual School when he or she adopted a child within
50 the child welfare system pursuant to chapter 63 on or after July
51 1, 2015. A veteran or servicemember may apply for the monetary
52 benefit provided in this subsection if he or she is domiciled in
53 this state and adopts a child within the child welfare system
54 pursuant to chapter 63 on or after July 1, 2020.

55 (a) Benefits paid to a qualifying adoptive employee who is
56 a part-time employee must be prorated based on the qualifying
57 adoptive employee's full-time equivalency at the time of
58 applying for the benefits.

59 (b) Monetary benefits awarded under this subsection are
60 limited to one award per adopted child within the child welfare
61 system.

62 (c) The payment of a lump-sum monetary benefit for
63 adopting a child within the child welfare system under this
64 section is subject to a specific appropriation to the department
65 for such purpose.

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Amendment No. 1

66 (3) A qualifying adoptive employee must apply to his or
67 her agency head, or to his or her school director in the case of
68 a qualifying adoptive employee of a charter school or the
69 Florida Virtual School, to obtain the monetary benefit provided
70 in subsection (2). A veteran or servicemember must apply to the
71 department to obtain the benefit. Applications must be on forms
72 approved by the department and must include a certified copy of
73 the final order of adoption naming the applicant as the adoptive
74 parent. Monetary benefits shall be approved on a first-come,
75 first-served basis based upon the date that each fully completed
76 application is received by the department.

77 (4) This section does not preclude a qualifying adoptive
78 employee, veteran, or servicemember from receiving adoption
79 assistance for which he or she may qualify under s. 409.166 or
80 any other statute that provides financial incentives for the
81 adoption of children.

82 (5) Parental leave for a qualifying adoptive employee must
83 be provided in accordance with the personnel policies and
84 procedures of his or her employer.

85 (6) The department may adopt rules to administer this
86 section. The rules may provide for an application process such
87 as, but not limited to, an open enrollment period during which
88 qualifying adoptive employees, veterans, or servicemembers may
89 apply for monetary benefits under this section.

Amendment No. 1

90 (7) The Chief Financial Officer shall disburse a monetary
91 benefit to a qualifying adoptive employee upon the department's
92 submission of a payroll requisition. The Chief Financial Officer
93 shall transfer funds from the department to a state university,
94 a Florida College System institution, a school district unit, a
95 charter school, the Florida Virtual School, or a water
96 management district, as appropriate, to enable payment to the
97 qualifying adoptive employee through the payroll systems as long
98 as funds are available for such purpose.

99 (8) To receive an approved monetary benefit under this
100 section, a veteran or servicemember must be registered as a
101 vendor with the state.

102 (9) Each state agency shall develop a uniform procedure
103 for informing employees about this benefit and for assisting the
104 department in making eligibility determinations and processing
105 applications. Any procedure adopted by a state agency is valid
106 and enforceable if the procedure does not conflict with the
107 express terms of this section.

108 Section 2. This act shall take effect July 1, 2020.

109 -----
110
111 **T I T L E A M E N D M E N T**

112 Remove everything before the enacting clause and insert:

113 A bill to be entitled

Amendment No. 1

114 An act relating to adoption benefits; amending s.
115 409.1664, F.S.; revising the definition of the term
116 "qualifying adoptive employee" and providing for
117 retroactive application; defining the terms
118 "servicemember" and "veteran"; providing that adoptive
119 servicemembers and veterans are eligible to receive
120 certain monetary benefits; specifying eligibility
121 criteria; requiring servicemembers and veterans
122 seeking a benefit to apply to the Department of
123 Children and Families; revising construction;
124 providing for applicability of certain department
125 rules to servicemembers and veterans; requiring
126 servicemembers and veterans seeking a benefit to be
127 registered as a vendor with the state; providing an
128 effective date.

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		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

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.

any of these provisions, including suspension or revocation of the ability to practice pharmacy in the state.¹⁰

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

¹⁰ S. 465.0465(1), F.S.

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_564353d3d3dede4b2295cd8be515c865be.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.

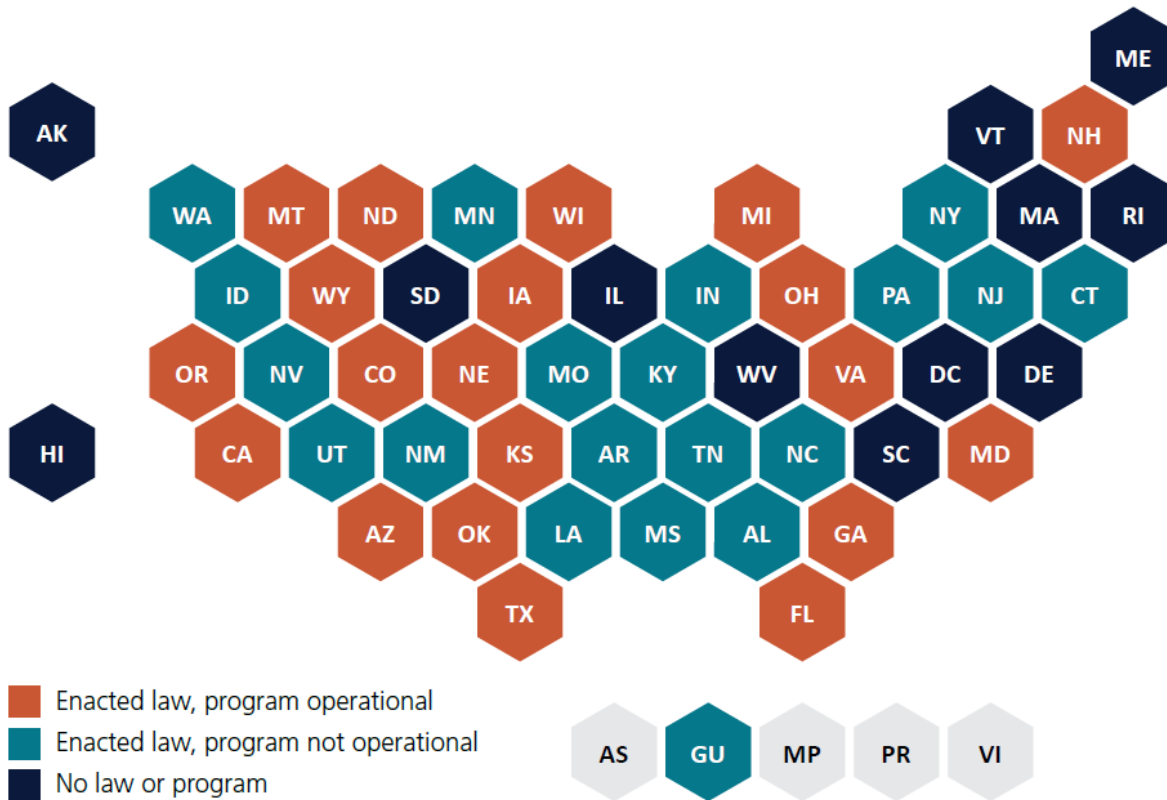
¹⁹ "Operational" are those states that have participating pharmacies, charitable clinics, and/or hospitals collecting and redistributing donated drugs to eligible patients, and have had some level of donation and reuse transactions during 2017-2018. Id.

²⁰ *Supra* note 18.

²¹ Id.

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

Prescription Drug Donation and Reuse Programs²⁵



Source: NCSL, 2018

Most of these programs exclude controlled substances, expired drugs, and drugs that show any physical signs of tampering, misbranding, deterioration, compromised integrity, or adulteration.²⁶ They also require that all drugs be inspected and dispensed by a licensed pharmacist.²⁷ 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.²⁸ 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 the safety of patients and the integrity of donated drugs.²⁹

Iowa’s Drug Donation Repository Program

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

²³ TULSA COUNTY MEDICAL SOCIETY, *Drug Recycling – Utilization of Unused Prescription Drugs Act*, <http://tcmsok.org/drug-recycling/> (last visited Oct. 14, 2019).

²⁴ 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 Oct. 14, 2019).

²⁵ NATIONAL CONFERENCE OF STATE LEGISLATURES, *Prescription Drug Donation and Reuse Programs*, LegisBrief Vol. 26, No. 43 (Nov. 2018), available at: http://www.ncsl.org/Portals/1/Documents/legisbriefs/2018/November/DrugDonations_Nov2018_43_FINAL.pdf (last visited Oct. 14, 2019).

²⁶ *Supra* note 18.

²⁷ *Id.*

²⁸ *Id.*

²⁹ *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.

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.³⁰ 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.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

³⁰ IOWA DEPARTMENT OF PUBLIC HEALTH, *SafeNetRx Program*, <https://idph.iowa.gov/ohds/rural-health-primary-care/repository> (last visited Oct. 14, 2019).

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.

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

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

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.

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.

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 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 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.

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

- 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.

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:

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.

- 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.

B. RULE-MAKING AUTHORITY:

⁵⁴ Department of Health, *HB 177 Department Bill Analysis*. On file with Health Care Appropriations Subcommittee staff.
STORAGE NAME: h0177d.HHS
DATE: 1/15/2020

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.

1 A bill to be entitled
2 An act relating to the Prescription Drug Donation
3 Repository Program; creating s. 465.1902, F.S.;
4 providing a short title; defining terms; creating the
5 Prescription Drug Donation Repository Program within
6 the Department of Health; specifying the purpose of
7 the program; specifying entities that may participate
8 as repositories; requiring a repository to notify the
9 department of its intent to participate in the
10 program; providing notification requirements;
11 providing a procedure for a repository to withdraw
12 from participation in the program; requiring the
13 department to adopt rules regarding the disposition of
14 prescription drugs and supplies of a withdrawing
15 repository; specifying entities that may donate
16 prescription drugs or supplies under the program;
17 providing criteria and procedures for eligible
18 donations; prohibiting donations to specific patients;
19 providing inspection, inventory, and storage
20 requirements for repositories; requiring inspection of
21 donated prescription drugs and supplies by a licensed
22 pharmacist; requiring a repository to submit its
23 inventory records to the department monthly;
24 authorizing the department to facilitate the
25 redistribution of donated prescription drugs and

26 supplies; authorizing a repository to transfer
27 prescription drugs and supplies to another repository
28 after notifying the department; specifying patients
29 eligible to receive donated prescription drugs and
30 supplies; specifying conditions for dispensing donated
31 prescription drugs and supplies to eligible patients;
32 providing intake collection form requirements;
33 requiring that such form provide certain notice to
34 patients; prohibiting the sale of donated prescription
35 drugs and supplies under the program; requiring
36 repositories to establish a protocol for notifying
37 recipients of a prescription drug recall; providing
38 for destruction of donated prescription drugs under
39 certain circumstances; providing recordkeeping
40 requirements; requiring the department to establish,
41 maintain, and publish a registry of participating
42 repositories and available donated prescription drugs
43 and supplies; requiring the department to publish
44 certain information and forms on its website;
45 providing immunity from civil and criminal liability
46 and professional disciplinary action for program
47 donors and participants under certain circumstances;
48 providing specified immunity to pharmaceutical
49 manufacturers under certain circumstances; requiring
50 the department to adopt rules; amending s. 252.36,

51 F.S.; authorizing the Governor to waive program
52 patient eligibility requirements during a declared
53 state of emergency; providing an effective date.
54

55 Be It Enacted by the Legislature of the State of Florida:
56

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

59 465.1902 Prescription Drug Donation Repository Program.—

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

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

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

67 (b) "Controlled substance" means any substance listed in
68 Schedule II, Schedule III, Schedule IV, or Schedule V of s.
69 893.03.

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

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

76 (e) "Health care practitioner" or "practitioner" means a
77 practitioner licensed under this chapter, chapter 458, chapter
78 459, chapter 461, chapter 463, chapter 464, or chapter 466.

79 (f) "Indigent" means having a family income during the 12
80 months preceding the determination of income that is below 200
81 percent of the federal poverty level as defined by the most
82 recently revised poverty income guidelines published by the
83 United States Department of Health and Human Services.

84 (g) "Nonprofit health clinic" means a nonprofit legal
85 entity that provides medical care to patients who are indigent,
86 uninsured, or underinsured. The term includes, but is not
87 limited to, a federally qualified health center as defined in 42
88 U.S.C. s. 1396d(1)(2)(B) and a rural health clinic as defined in
89 42 U.S.C. s. 1396d(1)(1).

90 (h) "Nursing home facility" has the same meaning as in s.
91 400.021.

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

95 (j) "Prescription drug" has the same meaning as the term
96 "medicinal drugs" or "drugs," as those terms are defined in s.
97 465.003(8), but does not include controlled substances, cancer
98 drugs donated under s. 499.029, or drugs with an approved United
99 States Food and Drug Administration risk evaluation and
100 mitigation strategy that includes elements to assure safe use.

101 (k) "Program" means the Prescription Drug Donation
 102 Repository Program created by this section.

103 (l) "Supply" means a material or an instrument used to
 104 administer a prescription drug.

105 (m) "Tamper-evident packaging" means a package that has
 106 one or more indicators or barriers to access which, if breached
 107 or missing, can reasonably be expected to provide visible
 108 evidence to consumers that tampering has occurred. The term
 109 includes, but is not limited to, unopened unit-dose packaging,
 110 multiple-dose packaging, and medications with a seal on their
 111 immediate, outer, secondary, or tertiary packaging.

112 (n) "Underinsured" means having health care coverage or
 113 prescription drug coverage, but having exhausted these benefits
 114 or not having prescription drug coverage for the drug
 115 prescribed.

116 (o) "Uninsured" means not having health care coverage and
 117 being ineligible for prescription drug coverage under a program
 118 funded in whole or in part by the Federal Government.

119 (3) PRESCRIPTION DRUG DONATION REPOSITORY PROGRAM;
 120 CREATION; PURPOSE.—The Prescription Drug Donation Repository
 121 Program is created within the department to facilitate the
 122 donation of prescription drugs and supplies to eligible
 123 patients.

124 (4) REPOSITORIES.—

125 (a) A repository may accept and dispense eligible

126 donations to eligible patients under the program. The repository
 127 must inspect, store, and dispense donations and report to the
 128 department in accordance with this section.

129 (b) The following entities may participate as a
 130 repository:

- 131 1. A health care practitioner's office.
- 132 2. A pharmacy.
- 133 3. A hospital with a closed drug delivery system.
- 134 4. A nursing home facility with a closed drug delivery
 135 system.
- 136 5. A free clinic or nonprofit health clinic that is
 137 licensed or permitted to dispense medicinal drugs in the state.

138 (c) An eligible entity must notify the department of its
 139 intent to participate in the program as a repository before
 140 accepting or dispensing any donations under the program. The
 141 notification must be made on a physical or an electronic form
 142 prescribed by the department in rule and must, at a minimum,
 143 include:

144 1. The name, street address, website, and telephone number
 145 of the intended repository and any license or registration
 146 number issued by the state to the intended repository, including
 147 the name of the issuing agency.

148 2. The name and telephone number of the pharmacist
 149 employed by or under contract with the intended repository who

150 is responsible for the inspection of donated prescription drugs
151 and supplies.

152 3. A signed and dated statement by the responsible
153 pharmacist affirming that the intended repository meets the
154 eligibility requirements of this subsection.

155 (d) A repository may withdraw from participation in the
156 program at any time by providing written notice to the
157 department, as appropriate, on a physical or an electronic form
158 prescribed by the department in rule. The department shall adopt
159 rules addressing the disposition of prescription drugs and
160 supplies in the possession of the withdrawing repository.

161 (5) ELIGIBLE DONORS.—The following entities may donate
162 prescription drugs or supplies to a repository under the
163 program:

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

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

168 (c) Hospitals with closed drug delivery systems.

169 (d) Pharmacies.

170 (e) Drug manufacturers or wholesale distributors.

171 (f) Medical device manufacturers or suppliers.

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

175 (6) ELIGIBLE DONATIONS; DONATION REQUIREMENTS; PROHIBITED
176 DONATIONS.—

177 (a) An eligible donor may only donate a prescription drug
178 to a repository if:

179 1. The drug is approved for medical use in the United
180 States.

181 2. The drug is in unopened, tamper-evident packaging.

182 3. The drug requires storage at normal room temperature
183 per the manufacturer or federal storage requirements.

184 4. The drug has been stored according to manufacturer or
185 federal storage requirements.

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

189 6. The packaging does not have any physical signs of
190 tampering, misbranding, deterioration, compromised integrity, or
191 adulteration.

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

195 8. The drug has an expiration date that is more than 3
196 months after the date on which the drug was donated.

197 (b) An eligible donor may donate a prescription drug or
198 supply to a repository only if it is in unopened, tamper-evident
199 packaging.

200 (c) Donations must be made on the premises of a repository
201 to a person designated by the repository. A drop box may not be
202 used to accept donations.

203 (d) A prescription drug or supply may not be donated to a
204 specific patient.

205 (7) INSPECTION AND STORAGE.—

206 (a) Upon receipt of a proposed donation, a licensed
207 pharmacist employed by or under contract with a repository shall
208 inspect the donation to determine whether it meets the
209 requirements of subsections (5) and (6). The repository shall
210 quarantine a donation until such inspection is complete and the
211 donation is approved for dispensing.

212 (b) The inspecting pharmacist must sign an inspection
213 record on a physical or an electronic form prescribed by the
214 department in rule which verifies that the prescription drug or
215 supply meets the criteria of subsections (5) and (6) and must
216 attach the record to the inventory required in paragraph (d). A
217 repository that receives prescription drugs and supplies from
218 another repository is not required to reinspect such drugs and
219 supplies.

220 (c) A repository shall store donations in a secure storage
221 area under the environmental conditions specified by the
222 manufacturer or federal storage requirements. Donations may not
223 be stored with other inventory.

224 (d) A repository shall maintain an inventory of the name,

225 strength, available quantity, and expiration date of donations;
226 the transaction date; and the name, street address, and
227 telephone number of the donor. The repository shall record such
228 inventory on a physical or an electronic form prescribed by the
229 department in rule.

230 (e) By the 5th day of each month, a repository shall
231 submit to the department its inventory records of donations
232 received during the previous month.

233 (f) The department may facilitate the redistribution of
234 donations between repositories. A repository that receives
235 donations may, after notifying the department, distribute the
236 donations to another repository.

237 (8) ELIGIBLE PATIENTS; DISPENSING REQUIREMENTS; PATIENT
238 NOTICE; PROHIBITIONS.—

239 (a) A repository may dispense an eligible donation to a
240 state resident who is indigent, uninsured, or underinsured, and
241 who has a valid prescription for such donation, as applicable.

242 (b) Each new eligible patient must submit an intake
243 collection form to a repository to receive a donation using a
244 physical or an electronic form prescribed by the department in
245 rule. Such form shall, at a minimum, include:

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

248 2. The basis for the patient's eligibility, which must
249 specify that the patient is indigent, uninsured, or

250 underinsured.

251 3. A statement physically or electronically signed and
252 dated by the patient affirming that the patient meets the
253 eligibility requirements of this section and will inform the
254 repository if the patient's eligibility changes.

255 4. Notice that the prescription drug or supply was donated
256 to the program, that the donors and participants in the program
257 are immune from civil or criminal liability or disciplinary
258 action, and that the eligible patient is not required to pay for
259 the prescription drug or supply.

260 5. A statement physically or electronically signed and
261 dated by the eligible patient acknowledging receipt of notice
262 required under this paragraph.

263 (c) By the 5th day of each month, a repository shall
264 submit to the department a summary of each intake collection
265 form obtained during the previous month.

266 (d) A dispenser may dispense donations, if available, only
267 to an eligible patient who has submitted a completed intake
268 collection form.

269 (e) A dispenser may provide dispensing and consulting
270 services to an eligible patient.

271 (f) Donations may not be sold or resold.

272 (g) A dispenser may not submit a claim or otherwise seek
273 reimbursement from any public or private third-party payor for
274 donations.

275 (9) RECALLED PRESCRIPTION DRUGS.—

276 (a) Each repository shall establish and follow a protocol
277 for notifying recipients in the event that a prescription drug
278 donated under the program is recalled.

279 (b) A repository shall destroy all donated prescription
280 drugs that are recalled, expired, or unsuitable for dispensing.
281 A repository must complete a destruction form for all such drugs
282 using a physical or an electronic form prescribed by the
283 department in rule.

284 (10) RECORDKEEPING.—

285 (a) A repository shall maintain records of prescription
286 drugs and supplies that are accepted, donated, dispensed,
287 distributed, or destroyed under the program using a physical or
288 an electronic form prescribed by the department in rule.

289 (b) All required records must be maintained in accordance
290 with any applicable practice act. A repository shall submit
291 these records monthly to the department for data collection.

292 (11) REGISTRIES; PUBLICATION OF FORMS.—

293 (a) The department shall establish and maintain registries
294 of all repositories and prescription drugs and supplies
295 available under the program. The registry of repositories must
296 include each repository's name, street address, website, and
297 telephone number. The registry of available prescription drugs
298 and supplies must include the name, strength, available
299 quantity, and expiration date of the prescription drugs or

300 supplies and the name and contact information of each repository
301 where such drugs or supplies are available. The department shall
302 publish the registries on its website.

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

305 (12) IMMUNITY FROM LIABILITY; DISCIPLINARY ACTION.—

306 (a) Any donor of prescription drugs or supplies and any
307 participant in the program who exercises reasonable care in
308 donating, accepting, distributing, or dispensing prescription
309 drugs or supplies under the program is immune from civil or
310 criminal liability and professional disciplinary action by the
311 state for any injury, death, or loss to person or property
312 relating to such activities.

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

320 (13) RULEMAKING.—The department shall adopt rules
321 necessary to administer this section.

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

324 252.36 Emergency management powers of the Governor.—

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325 (5) In addition to any other powers conferred upon the
326 Governor by law, she or he may:

327 (o) Waive the patient eligibility requirements of s.
328 465.1902.

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

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 197 The Servicemembers Civil Relief Act
SPONSOR(S): Local, Federal & Veterans Affairs Subcommittee, Payne
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Children, Families & Seniors Subcommittee	14 Y, 0 N	Woodruff	Brazzell
2) Local, Federal & Veterans Affairs Subcommittee	10 Y, 0 N, As CS	Renner	Miller
3) Health & Human Services Committee		Woodruff	Calamas

SUMMARY ANALYSIS

Chapter 39, F.S., creates the child welfare system charged with protecting child welfare. The child welfare system identifies families whose children are in danger of suffering or have suffered abuse, abandonment, or neglect and works with those families to address the problems that are endangering children, if possible.

Abandonment of a child occurs when a parent, legal custodian, or caregiver has made no significant contribution to the child's care and maintenance or has failed to establish or maintain a substantial relationship with the child even when being able to do so.

The Servicemembers Civil Relief Act (SCRA) is a federal law that applies to civil proceedings. The act protects active duty servicemembers by allowing for the temporary suspension of judicial and administrative proceedings and transactions that may adversely affect the civil rights of servicemembers during their military service.

The bill amends the definition of "abandoned" or "abandonment" in s. 39.01(1), F.S., to prohibit the absence of a parent, legal custodian, or caregiver responsible for a child's welfare, who is a servicemember, by reason of deployment or anticipated deployment from being considered or used as a factor in determining abandonment.

Additionally, the bill amends s. 39.0137, F.S., to include the SCRA as one of the specific federal laws which ch. 39, F.S., does not supersede and requires the Department of Children and Families (DCF) to ensure that the SCRA is observed in cases where a parent, legal custodian, or caregiver is unable to take custody of his or her child or appear at a court proceeding in person because of his or her military service.

The bill does not have a fiscal impact on state or local governments.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Florida's Child Welfare System

Chapter 39, F.S., creates the dependency system that is charged with protecting child welfare. The child welfare system identifies families whose children are in danger of suffering or have suffered abuse, abandonment, or neglect and works with those families to address the problems that are endangering children, if possible. If the problems cannot be addressed, the child welfare system finds safe out-of-home placements for these children.

To serve families and children, the Department of Children and Families (DCF) contracts for foster care and related services with lead agencies, also known as community-based care organizations (CBCs). The outsourced provision of child welfare services was intended to increase local community ownership of service delivery and design.¹ DCF, through the CBCs, administers a system of care for children² to:

- Prevent children's separation from their families;
- Intervene to allow children to remain safely in their own homes;
- Reunify families who have had children removed from their care, if possible and appropriate;
- Ensure safety and normalcy for children who are separated from their families;
- Enhance the well-being of children through educational stability and timely health care;
- Provide permanency; and
- Develop their independence and self-sufficiency.

Abandonment

A child is considered abandoned if the parent, legal custodian, or caregiver, while being able, has made no significant contribution to the child's care and maintenance or has failed to establish or maintain a substantial and positive relationship³ with the child.⁴ The incarceration, repeated incarceration, or extended incarceration of a parent, legal custodian, or caregiver responsible for a child's welfare may support a finding of abandonment. A surrendered newborn, a "child in need of services,"⁵ or a "family in

¹ Department of Children and Families, *Community-Based Care*, <http://www.dcf.state.fl.us/service-programs/community-based-care/> (last visited Nov. 1, 2019).

² S. 409.145(1), F.S.

³ "Establish or maintain a substantial positive relationship," includes, but is not limited to, frequent and regular contact with the child through frequent and regular visitation or frequent and regular communication to or with the child, and the exercise of parental rights and responsibilities. Marginal efforts and incidental or token visits or communications are not sufficient to establish a substantial and positive relationship with the child. See s. 39.01(1), F.S.

⁴ S. 39.01(1), F.S.

⁵ A "child in need of services" is defined in s. 984.03(9), F.S., as a child for whom there is no pending investigation into an allegation or suspicion of abuse, neglect, or abandonment; no pending referral alleging the child is delinquent; or no current supervision by the Department of Juvenile Justice or the Department of Children and Families for an adjudication of dependency or delinquency. The child must also be found by the court to have persistently run away from home despite reasonable efforts to remedy the child's behavior; to be habitually truant from school despite reasonable efforts to remedy the situation; or to have persistently disobeyed the reasonable and lawful demands of the child's parents or legal custodians, and to be beyond their control, despite efforts to remedy the behavior.

need of services”⁶ is not considered abandonment and will not meet the statutory definition required for a child protective investigation.⁷

If DCF verifies a child has been abandoned, then it may file a dependency petition and require the parents to engage in services to ameliorate the state’s concerns and protect the child.⁸ During the delivery of services and with the court’s supervision, DCF may place the child in out-of-home care until reunification with the parent is in the child’s best interest. Because a verified finding of abandonment establishes grounds for termination of parental rights, DCF has the option to petition the court to terminate parental rights at any time.⁹

From September 2018 through September 2019, there were 2,984 children alleged¹⁰ to be abandoned, with 865 verified as abandoned after a child protective investigation.¹¹

Currently, Florida’s statutory definition of abandonment does not explicitly exclude deployment or anticipated deployment¹² of a parent or caregiver from being considered when determining whether a child has been abandoned.

Federal Law

While states bear primary responsibility for child welfare, numerous federal laws have been enacted that affect how states operate their child welfare systems. Section 39.0137, F.S., specifically states that ch. 39, F.S., does not supersede the requirements of two of them: the Indian Child Welfare Act¹³ and the Multi-Ethnic Placement Act.¹⁴

Servicemembers in Florida

Florida statutes define “servicemember” as any person serving as a member of the United States Armed Forces¹⁵ on active duty or state active duty¹⁶ and all members of the Florida National Guard and United States Reserve Forces.¹⁷

As of June 2019, 64,915 Floridians were serving in the United States Armed Forces and 37,003 serving in Florida’s National Guard and United States Reserve Forces.¹⁸

⁶ A “family in need of services” is defined in s. 984.03(25), F.S., as a family that has a child who is running away; who is persistently disobeying reasonable and lawful demands of the parent or legal custodian and is beyond the control of the parent or legal custodian; or who is habitually truant from school or engaging in serious behaviors that places the child at risk of future abuse, neglect, or abandonment or at risk of entering the juvenile justice system. The child must be referred to a law enforcement agency, the Department of Juvenile Justice, or an agency contracted to provide services to children in need of services.

⁷ *Supra* note 4.

⁸ S. 39.501(1), F.S.

⁹ S. 39.806(1)(b), F.S.

¹⁰ These allegations included situations where there were no indicators of abandonment, the allegation was not substantiated, or the allegation was verified.

¹¹ Department of Children and Families, *Child Welfare Dashboard, Alleged Maltreatments – Statewide*, <https://www.myflfamilies.com/programs/childwelfare/dashboard/alleged-maltreatments.shtml> (last visited Nov. 1, 2019).

¹² 50 U.S.C. s. 3938(e) defines “deployment” as the movement or mobilization of a servicemember to a location for a period of longer than 60 days and not longer than 540 days pursuant to temporary or permanent official orders that are designated as unaccompanied for which dependent travel is not authorized or that otherwise do not permit the movement of family members to that location.

¹³ 25 U.S.C. ss. 1901, et seq.

¹⁴ Pub. L. No. 103-382.

¹⁵ The United States Armed Forces consists of the Army, Marine Corps, Navy, Air Force, and Coast Guard. See 10 U.S.C. s. 101.

¹⁶ “State active duty” means full-time duty in active military service of the State of Florida when ordered by the Governor or Adjutant General to preserve the public peace, execute the laws of the state, suppress insurrection, repel invasion, enhance security and respond to terrorist threats or attacks, respond to an emergency, enforce the law, carry out counter-drug operations, provide training, provide for the security of the rights or lives of the public, protect property, or conduct ceremonies. The term also includes the period during which a person in active military service is absent from duty as a result of illness, being wounded, being on leave, or other lawful cause.

¹⁷ S. 250.01, F.S.

¹⁸ Defense Manpower Data Center, *DOD Personnel, Workforce Reports & Publications*, https://www.dmdc.osd.mil/appj/dwp/dwp_reports.jsp (last visited Oct. 22, 2019).

Legal Protections for Servicemembers

The Servicemembers Civil Relief Act

The Servicemembers Civil Relief Act (SCRA) is a federal law that applies to civil proceedings. The act protects servicemembers¹⁹ by allowing for the temporary suspension of judicial and administrative proceedings and transactions that may adversely affect the civil rights of servicemembers during their military service.²⁰ The purpose is to enable servicemembers to “devote their entire energy to the defense needs of the Nation.”²¹ The SCRA allows a servicemember to request a delay in court or agency proceeding that may affect his or her rights if harm would result if the case were not delayed.²²

While the SCRA applies to all civil proceedings, the SCRA was amended in 2014 and 2016 to provide servicemembers with additional protections, beyond the stay provisions, in child custody proceedings. Child custody may become an issue in a child welfare proceeding if the court is determining which parent should have custody over the child when the other parent cannot protect the child’s safety and well-being. The act protects servicemembers from losing custody of their children due to military deployment and prohibits state courts from considering current or future deployments as the sole factor in determining the best interest of the child when contemplating a permanent change in child custody.²³ Additionally, servicemembers must receive notice both annually and prior to deployment of the child custody protections under the SCRA.²⁴

Courts are to construe the SCRA liberally in favor of servicemembers but retain discretion to deny relief in certain cases.²⁵

State Protections for Servicemembers

States may provide more protections to servicemembers than what is provided under the SCRA, and Florida law does so. For example, because the SCRA only applies to National Guard call-ups by the President, Florida law expands SCRA protections to governor-ordered National Guard call-ups if the service exceeds 17 days.²⁶ In these situations, the court may stay any civil action or proceeding up to 30 days on its own motion, and must stay the proceeding upon motions of either party, unless it finds the ability to prosecute or defend the action is not materially affected by reason of the active duty status.²⁷ Florida law also allows active duty servicemembers to terminate real estate contracts if certain requirements are met.²⁸

Interplay of the SCRA and State Law

As a federal law, the SCRA supersedes state law even if not explicitly listed in state law. However, several Florida statutes explicitly reference the SCRA. For example, under s. 61.076(2)(b), F.S., if one of the parties to a divorce has performed at least 10 years of credible service in the military and the division of marital property includes division of military retirement benefits, then the final judgement must include certification that the SCRA was observed if the decree was issued while the member was

¹⁹ Servicemembers Civil Relief Act, 50 U.S.C. §3911 defines a servicemember as a member of the uniformed services, which includes the Armed Forces and the commissioned corps of the National Oceanic and Atmospheric Administration and the Public Health Service. The SCRA only applies to a member of the National Guard if that member has been called to active service authorized by the President or Secretary of Defense for a period of more than 30 consecutive days for purposes of responding to a national emergency.

²⁰ 50 U.S.C. §3902.

²¹ *Id.*

²² *Id.*

²³ 50 U.S.C. § 3938.

²⁴ Pub. L. No. 114-328, div. A § 573, 130 Stat. 2141 (2016).

²⁵ *Boone v. Lightner*, 319 U.S. 561, 575 (1943).

²⁶ S. 250.5201, F.S.

²⁷ *Id.*

²⁸ S. 689.27(2), F.S.

on active duty and was not represented in court. Additionally, under s. 61.733(1), F.S., unless prohibited by the SCRA, the court may issue a temporary order granting custodial responsibility after a deploying parent receives notice of deployment; however, the temporary custody may only last until the deployment terminates. Further, under s. 61.749(1), F.S., a court may modify or terminate a temporary grant of custodial responsibility on motion of a deploying parent if modification or termination is consistent with the SCRA and is in child's best interest.

Florida statutes also provide a monetary penalty if a person violates any provision of state law that protects members of the United States Armed Forces, the United States Reserve Forces, or the National Guard or any provision of federal law affording protections to such servicemembers over which a state court has concurrent jurisdiction.²⁹

Additionally, s. 250.83, F.S., explicitly states that if any other provision of law conflicts with the SCRA or the provisions of Florida law related to military affairs, the SCRA or the provisions of Florida law related to military affairs, whichever is applicable, shall control.

Currently, Florida's child welfare statutes, ch. 39, F.S., do not explicitly state that the SCRA prevails over state law. However, because the SCRA is a federal law, it will supersede state law even if it is not explicitly stated in Florida's child welfare law.

Effect of Proposed Changes

The bill amends the definition of "abandoned" or "abandonment" in s. 39.01(1), F.S., to add that the absence of a parent, legal custodian, or caregiver responsible for a child's welfare, who is a servicemember, by reason of deployment or anticipated deployment as defined in 50 U.S.C. s. 39.28(e),³⁰ may not be considered or used as a factor in determining abandonment of a child.

The bill also amends s. 39.0137, F.S., to include the SCRA as one of the specific federal laws which Ch. 39, F.S., does not supersede and requires DCF to ensure that the SCRA is observed in cases where a parent, legal custodian, or caregiver is unable to take custody of his or her child or appear at a court proceeding in person because of his or her military service. While dependency attorneys and judges are currently obligated to abide by the SCRA, including this language in statute may ensure that compliance with the SCRA happens sooner or to a greater degree.

The bill is effective July 1, 2020.

B. SECTION DIRECTORY:

Section 1. Amends s. 39.01, F.S., relating to definitions.

Section 2. Amends s. 39.0137, F.S., relating to federal law; rulemaking authority.

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:

None.

²⁹ S. 250.905, F.S.

³⁰ *Supra* note 12.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

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:

Rulemaking authority is not required to implement this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On December 11, 2019, the Local, Federal & Veterans Affairs Subcommittee adopted a strike-all amendment and reported the bill favorably as a committee substitute. The strike-all amendment corrects punctuation in the definition of “abandonment” to clarify that the absence of the parent, legal custodian, or caregiver is due to the deployment or anticipated deployment as defined in the U.S. Code. The strike-all amendment also adds “legal custodians” and “caregivers” to section 2 of the bill to be consistent with other provisions of the bill.

This analysis is drafted to the committee substitute as approved by the Local, Federal & Veterans Affairs Subcommittee.

1 A bill to be entitled
2 An act relating to the Servicemembers Civil Relief
3 Act; amending s. 39.01, F.S.; revising the definition
4 of "abandoned" or "abandonment"; amending s. 39.0137,
5 F.S.; providing that certain state laws relating to
6 children do not supersede the Servicemembers Civil
7 Relief Act; requiring the Department of Children and
8 Families to ensure that the act is observed in certain
9 cases; providing an effective date.

10
11 Be It Enacted by the Legislature of the State of Florida:

12
13 Section 1. Subsection (1) of section 39.01, Florida
14 Statutes, is amended to read:

15 39.01 Definitions.—When used in this chapter, unless the
16 context otherwise requires:

17 (1) "Abandoned" or "abandonment" means a situation in
18 which the parent or legal custodian of a child or, in the
19 absence of a parent or legal custodian, the caregiver, while
20 being able, has made no significant contribution to the child's
21 care and maintenance or has failed to establish or maintain a
22 substantial and positive relationship with the child, or both.
23 For purposes of this subsection, "establish or maintain a
24 substantial and positive relationship" includes, but is not
25 limited to, frequent and regular contact with the child through

26 frequent and regular visitation or frequent and regular
27 communication to or with the child, and the exercise of parental
28 rights and responsibilities. Marginal efforts and incidental or
29 token visits or communications are not sufficient to establish
30 or maintain a substantial and positive relationship with a
31 child. A man's acknowledgment of paternity of the child does not
32 limit the period of time considered in determining whether the
33 child was abandoned. The term does not include a surrendered
34 newborn infant as described in s. 383.50, a "child in need of
35 services" as defined in chapter 984, or a "family in need of
36 services" as defined in chapter 984. The absence of a parent,
37 legal custodian, or caregiver responsible for a child's welfare,
38 who is a servicemember, by reason of deployment or anticipated
39 deployment as defined in 50 U.S.C. s. 3938(e), may not be
40 considered or used as a factor in determining abandonment. The
41 incarceration, repeated incarceration, or extended incarceration
42 of a parent, legal custodian, or caregiver responsible for a
43 child's welfare may support a finding of abandonment.

44 Section 2. Subsection (1) of section 39.0137, Florida
45 Statutes, is amended, and a new subsection (3) is added to that
46 section to read:

47 39.0137 Federal law; rulemaking authority.—

48 (1) This chapter does not supersede the requirements of
49 the Indian Child Welfare Act, 25 U.S.C. ss. 1901 et seq., ~~or~~ the
50 Multi-Ethnic Placement Act of 1994, Pub. L. No. 103-382, as

51 amended, the Servicemembers Civil Relief Act, 50 U.S.C. ss. 3901
52 et seq., or the implementing regulations for such acts.

53 (3) The department shall ensure that the Servicemembers
54 Civil Relief Act is observed in cases where a parent, legal
55 custodian, or caregiver responsible for a child's welfare, by
56 virtue of his or her service, is unable to take custody of the
57 child or appear before the court in person.

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

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1189 Genetic Information for Insurance Purposes

SPONSOR(S): Sprowls

TIED BILLS: **IDEN./SIM. BILLS:** SB 1564

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health & Human Services Committee		Grabowski	Calamas
2) Commerce Committee			

SUMMARY ANALYSIS

The availability and use of genetic tests has increased dramatically in recent years. The resulting genetic information is generally used by individuals or their physicians to determine whether any action should be taken to improve long-term wellbeing.

Since the advent of genetic testing, there have been concerns about the use of personal genetic information by third parties. In particular, there is a concern that insurers may discriminate against individuals who have genetic markers indicating a heightened risk of developing certain diseases or health conditions.

The federal Health Insurance Portability and Accountability Act of 1996 prohibits health insurers from making coverage decisions solely based on personal genetic information. The federal Genetic Information Nondiscrimination Act of 2008 extended this concept by prohibiting health insurers from using genetic information in the underwriting process, and in the setting of premiums.

Florida law also prohibits health insurers from considering genetic information, both when issuing insurance policies and when setting applicable premium rates. This prohibition, however, does not extend to issuers of life insurance, disability income insurance, and long-term care insurance policies.

The bill expands existing prohibitions on the use of genetic information by insurers to include entities that issue policies for life insurance and long-term care insurance. Specifically, the bill prohibits issuers of life insurance and long-term care insurance from canceling, limiting, or denying coverage, and from setting different premium rates, based on personal genetic information without a specific diagnosis related to the genetic information. The bill also prohibits life insurers and long-term care insurers from requiring or soliciting genetic information, using genetic test results, or considering a person's decisions or actions relating to genetic testing for any insurance purpose.

The bill has no fiscal impact on state or local government.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Regulation of Insurance in Florida

The Office of Insurance Regulation (OIR) regulates insurers, including life, health, and long-term care insurers, under the Florida Insurance Code.¹ Parts III and V of ch. 627, F.S., specifically address life insurers. Part VI of ch. 627, F.S. specifically addresses health insurers. The Agency for Healthcare Administration (AHCA) regulates the quality of care provided by health maintenance organizations (HMOs) under part III of ch. 641, F.S., and part I of ch. 641, F.S., focuses on OIR's regulatory role of HMOs. Before receiving a certificate of authority from OIR, an HMO must receive a health care provider certificate from AHCA.² Part XVIII of ch. 627, F.S., specifically addresses long-term care insurance, which is coverage for medical and personal care services provided in a setting other than an acute care unit of a hospital.³

Genetic Testing

The availability and use of genetic tests has increased dramatically in recent years. As of March 2017, there were nearly 70,000 genetic testing products on the market, with an average of 10.6 new testing products entering the market *a day* since 2015.⁴ A 2016 survey indicated that 5.5 percent of adults in the U.S. had had genetic testing. Over half of those tested did so based on a concern about future health problems for them or their children, while 18 percent were tested to learn more about family heritage.⁵ The U.S. Centers for Disease Control and Prevention (CDC) recognizes the development of genomic tests for thousands of diseases and health conditions, while also acknowledging that such tests are not necessarily a conclusive indication that an individual will develop a particular disease or condition.⁶

A wide range of health-related DNA screenings are available. The National Institutes for Health (NIH) categorizes these tests as follows.

- **Diagnostic testing** - identifies a genetic condition or disease that is making or in the future will make a person ill. The results of diagnostic testing can help in treating and managing the disorder.
- **Predictive and pre-symptomatic genetic testing** - identifies genetic variations that increase a person's chance of developing specific diseases. This type of genetic testing may help provide information about a person's risk of developing a disease, and can help in decisions about lifestyle and health care.
- **Carrier testing** – identifies whether a person “carries” a genetic change that can cause a disease. Carriers usually show no signs of the disorder; however, they can pass on the genetic variation to their children, who may develop the disorder or become carriers themselves.

¹ Chapters 624–632, 634–636, 641, 642, 648, and 651, F.S. constitute the Florida Insurance Code.

² Ss. 641.21(1) and 641.48, F.S.

³ S. 627.9404, F.S. Long-term care services may encompass a wide array of medical, social, and personal care services required by an individual with a chronic disability. American Academy of Actuaries, *The Use of Genetic Information in Disability Income and Long-Term Care Insurance*, Issue Brief, Spring 2002, available at https://www.actuary.org/files/publications/genetic_25apr02.pdf (last accessed January 10, 2020).

⁴ *The Current Landscape of Genetic Testing*, Concert Genetics, March 2017, available at https://www.concertgenetics.com/wp-content/uploads/2017/05/10_ConcertGenetics_CurrentLandscapeofGeneticTesting_2017Update.pdf (last accessed January 10, 2020).

⁵ Harvard University T.H. Chan School of Public Health, *The Public and Genetic Editing, Testing, and Therapy*, Jan. 2016, available at <https://cdn1.sph.harvard.edu/wp-content/uploads/sites/94/2016/01/STAT-Harvard-Poll-Jan-2016-Genetic-Technology.pdf> (last accessed January 10, 2020). Genetic testing has also given rise to a novel industry aimed at providing individuals with customized data related to family ancestry, including companies like 23andMe, Ancestry.com, FamilyTree DNA, and Living DNA.

⁶ U.S. Centers for Disease Control and Prevention, *Genomic Testing*, last updated July 19, 2017, available at <https://www.cdc.gov/genomics/gtesting/> (last accessed January 10, 2020).

- **Prenatal testing** - identifies fetuses that have certain diseases.
- **Pre-implantation genetic testing** – identifies whether embryos for implantation carry genes that could cause disease. This is often done in conjunction with *in vitro* fertilization.
- **Newborn screening** - is used to test babies one or two days after birth to determine if those newborns have certain diseases known to cause problems with health and development.
- **Pharmacogenetic testing** - provides information about how certain medicines are processed in a person's body. This type of testing can help a healthcare provider choose the medicines that work best with a person's genetic makeup. For example, genetic testing is now available to guide treatments for certain cancers.
- **Research genetic testing** – helps scientists learn more about how genes contribute to health and disease, as well as develop gene-based treatments. Sometimes the results do not directly help the research participant, but they may benefit others in the future by helping researchers expand their understanding of the human body.⁷

One often-cited use of genetic testing involves screening of female patients for a gene mutation that can be an early predictor of breast cancer. *BRCA 1* and *BRCA 2* gene mutations are relatively rare, but women having these mutations develop breast cancer at much higher rates than those without.⁸ *BRCA* testing has become increasingly prevalent among women in families with histories of breast cancer.⁹

Use of Personal Genetic Information in Insurance Markets

The now-widespread availability of genetic tests has given rise to questions and concerns over the appropriate use of genetic information. While an individual may voluntarily submit to genetic testing in an effort to gain insights into his or her own genetic history, third parties may seek to obtain this same information for other purposes, such as for use in insurance markets.

For example, insurers might use genetic information to exclude high-risk individuals from established risk pools. Insurers might also charge higher premium rates to an individual whose genetic information indicates that the individual is at an increased risk of developing a degenerative health condition.¹⁰ Conversely, exclusion of higher-risk insureds could reduce premium inflation for those left in the risk pool.

Similarly, consumers could use personal genetic information to the detriment of insurers. For example, an individual may discover through genetic testing that he or she is likely to develop a serious health condition, and only then purchase life insurance. An insurer is at a disadvantage and cannot accurately gauge the risk posed by covering an individual in this situation.¹¹ Adverse selection¹² of this nature could destabilize insurance markets if access to personal genetic information leads to widespread changes in consumer behavior.¹³ Specifically, the risk-spreading ability of insurance could be compromised if only those who are likely to become ill purchase insurance.¹⁴

While the specific information provided by the genetic testing industry regarding medical conditions and their associated risks is limited at present, it is rapidly evolving. In 2013, the United States Food and

⁷ U.S. Department of Health and Human Services, National Institutes for Health, *Genetic Testing: How it is Used for Healthcare*, available at <https://report.nih.gov/nihfactsheets/ViewFactSheet.aspx?csid=43> (last accessed January 10, 2020).

⁸ McCarthy, Anne Marie and Armstrong, Katrina, "The Role of Testing for *BRCA1* and *BRCA2* Mutations in Cancer Prevention." *JAMA Intern Med.* 2014;174(7):1023–1024. doi:10.1001/jamainternmed.2014.1322, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4169670/> (last accessed January 10, 2020).

⁹ *Id.*

¹⁰ Klitzman, Robert, Appelbaum, Paul S., Chung, Wendy K, "Should Life Insurers Have Access to Genetic Test Results?" *JAMA.* 2014;312(18):1855–1856. doi:10.1001/jama.2014.13301, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4259574/> (last accessed January 10, 2020).

¹¹ *Id.*

¹² Adverse selection is defined as an imbalance in an exposure group created when persons who perceive a high probability of loss for themselves seek to buy insurance to a much greater degree than those who perceive a low probability of loss. IRMI, <https://www.irmi.com/term/insurance-definitions/adverse-selection> (last accessed January 10, 2020).

¹³ American Academy of Actuaries, *The Use of Genetic Information in Disability Income and Long-Term Care Insurance*, Issue Brief, Spring 2002, available at https://www.actuary.org/files/publications/genetic_25apr02.pdf (last accessed January 10, 2020).

¹⁴ *Id.*

Drug Administration (FDA) instructed *23andMe* to stop giving health information to consumers.¹⁵ However, by 2018, *23andMe* received approval from the FDA to provide reports regarding certain health conditions or risks, including the genetic variants in the *BRCA 1* and *BRCA 2* genes.¹⁶ Other vendors also provide lists of genetic variants, available to consumers, with information regarding the scientific significance of each variant.¹⁷ In the future, consumers may be able to take the ever-evolving information provided by genetic testing, compare it to the information provided by these vendors, and determine they have a genetic condition or disease, or are likely to develop a health condition. Based upon this determination, they may decide to purchase insurance they otherwise would not, without disclosing the results of their genetic testing, and thereby receive the insurance at a rate that is actuarially unsound for their true risk class.

Federal Laws

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) includes the first federal regulations on the use of personal genetic information.¹⁸ HIPAA prohibits health insurers from using “preexisting condition” exclusions based solely on an individual’s genetic information. Under HIPAA, insurers can make coverage decisions using information reflecting diagnosed health conditions, but not based on genetic indicators alone.¹⁹

The Genetic Information Nondiscrimination Act of 2008 (GINA) extended federal patient protections by preventing health insurers from using genetic information in the underwriting of health insurance products.²⁰ Health insurers may not charge higher premiums or make coverage decisions based solely on an individual’s genetic information. However, the prohibitions outlined in GINA do not extend to other types of insurance, such as life insurance and long-term care insurance. There are currently no federal limitations on the use of genetic information by these insurers.

The federal Patient Protection and Affordable Care Act²¹ (PPACA) prohibits most individual and group health insurers from excluding coverage to or otherwise discriminating against persons with pre-existing or complex health conditions. Moreover, the law prohibits plans from using most forms of medical underwriting, which had previously been used to link personal health status to the cost and availability of health insurance.²²

State Laws

States have adopted various regulations related to the use of genetic information by insurers. In general, states address patient privacy for personal genetic information by:²³

1. Requiring informed consent before performing genetic testing;
2. Restricting the use of genetic data by health insurance, employers or providers of long-term life care or insurance; and,
3. Limiting disclosure of the personal genetic information without the consent of the individual or defining genetic data as the ‘property’ of the individual.

¹⁵ Tina Hesman Saey, *What consumer DNA data can and can't tell you about your risk for certain diseases*, ScienceNews (Jun. 3, 2018), <https://www.sciencenews.org/article/health-dna-genetic-testing-disease> (last accessed January 10, 2020).

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ Hall, Mark A. and Rich, Stephen S., “Laws Restricting Health Insurers' Use of Genetic Information: Impact on Genetic Discrimination.” *AJHG* 2000: 66(1): 293-307, available at <https://doi.org/10.1086/302714> (last accessed January 10, 2020).

¹⁹ *Id.*

²⁰ U.S. Equal Employment Opportunity Commission, *The Genetic Information Nondiscrimination Act of 2008*, available at <https://www.eeoc.gov/laws/statutes/gina.cfm> (last accessed January 10, 2020).

²¹ Patient Protection and Affordable Care Act (PPACA), Pub. L. No. 111-148. On March 30, 2010, PPACA was amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152.

²² 42 U.S.C. 300gg. The law allows insurers to consider an individual’s age and tobacco use in the development of applicable rates. However, virtually all other underwriting is prohibited.

²³ Miller, Amalia R. and Tucker, Catherine E., “Privacy Protection, Personalized Medicine and Genetic Testing” (July 31, 2014), available at <https://ssrn.com/abstract=2411230> (last accessed January 10, 2020).

Most states have enacted laws that prohibit genetic discrimination by health insurers.²⁴ A number of states have taken actions to limit or prohibit the use of genetic information in other lines of insurance as well.²⁵ For example, Arizona, California, Massachusetts and New Jersey restrict use of genetic information by life insurers, and Kansas, Maryland and Massachusetts restrict use by long-term care insurers. Similarly, Arizona, California, Idaho, Kansas, Massachusetts and New Jersey restrict use by disability²⁶ insurers.²⁷

Florida Law

Section 760.40, F.S., makes the results of genetic testing the exclusive personal property of the person tested, and makes it a first degree misdemeanor to sharing test results without the informed consent of the person tested.

Section 627.4301, F.S., prohibits health insurers from considering genetic information, both when issuing insurance policies and when setting applicable premium rates.²⁸ Insurers cannot require or solicit genetic information, or employ underwriting based on the results of any genetic testing that an individual may choose to complete, and cannot use such results for any purpose. This prohibition is currently limited to self-insured health plans, fully-insured health plans, HMOs, prepaid limited health service organizations, prepaid health clinics, fraternal benefit societies, or any other health care arrangement where risk is assumed. This section of law expressly exempts several forms of insurance from the prohibition: life insurance, disability income, long-term care, accident-only, hospital indemnity or fixed indemnity, dental, and vision.

Effect of Proposed Changes

The bill amends s. 627.4301, F.S., existing prohibitions on the use of genetic information by insurers to include entities that issue policies for life insurance and long-term care insurance. Specifically, the bill prohibits issuers of life insurance and long-term care insurance from canceling, limiting, or denying coverage, and from setting different premium rates, based on personal genetic information without a specific diagnosis²⁹ related to the genetic information. The bill also prohibits life insurers and long-term care insurers from requiring or soliciting genetic information, using genetic test results, or considering a person's decisions or actions relating to genetic testing for any insurance purpose.

The bill has an effective date of July 1, 2020, and applies to insurance policies entered into or renewed on or after January 1, 2021.

B. SECTION DIRECTORY:

- Section 1:** Amends s. 627.4301, F.S., relating to genetic information for insurance purposes.
- Section 2:** Establishes that the bill's requirements are applicable to insurance policies entered into or renewed on or after January 1, 2021.
- Section 3:** Provides an effective date of July 1, 2020.

²⁴ Rothstein, Mark A., "Putting the Genetic Nondiscrimination Act in context." *Genetics in Medicine* 2008: 10: 655-656, available at <https://www.nature.com/articles/gim200899> (last accessed January 10, 2020).

²⁵ The National Human Genome Human Research Institute maintains a searchable database of legislation related to genetic information that has either been enacted or considered by state legislatures. U.S. Department of Health and Human Services, National Institutes of Health – National Human Genome Human Research Institute, *Genome Statute and Legislation Database*, available at <https://www.genome.gov/policyethics/legdatabase/pubsearch.cfm?CFID=22285441&CFTOKEN=7fc536f1b99bbd21-2342A48B-03C6-03BE-03FEEF39A8695C0F> (last accessed January 10, 2020).

²⁶ Disability income insurance protects earned income against potential loss due to disabling injury or illness. American Academy of Actuaries, *The Use of Genetic Information in Disability Income and Long-Term Care Insurance*, Issue Brief, Spring 2002, available at https://www.actuary.org/files/publications/genetic_25apr02.pdf (last accessed January 10, 2020).

²⁷ *Supra* note 19.

²⁸ See also s. 626.9706, F.S., which prohibits insurers from refusing coverage or charging higher premiums to individuals determined to carry the sickle-cell trait.

²⁹ Florida law does not define "diagnosis." However, "diagnosis" is generally defined as the "art or act of identifying a disease from its signs and symptoms." Merriam-Webster, <https://www.merriam-webster.com/dictionary/diagnosis> (last accessed January 10, 2020).

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

It is unclear whether or how, issuers of life insurance and long-term care insurance are currently using personal genetic information, so the economic impact of the bill's prohibition on its use is unknown. As genetic testing evolves and provides additional information that indicates a consumer has an increased risk of developing a certain health conditions, but that consumer has not yet received a diagnosis, the consumer may be more likely to purchase additional life or long-term care insurance coverage at a rate that is not actuarially sound. Such purchases, if done in significant quantities, could have a negative impact on the financial solvency of insurers.

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 neither authorizes nor requires administrative rulemaking.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

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A bill to be entitled
 An act relating to genetic information for insurance purposes; amending s. 627.4301, F.S.; providing definitions; prohibiting life insurers and long-term care insurers from canceling, limiting, or denying coverage, or establishing differentials in premium rates based on genetic information under certain circumstances; prohibiting such insurers from taking certain actions relating to genetic information for any insurance purpose; providing applicability; providing an effective date.

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

Section 1. Section 627.4301, Florida Statutes, is amended to read:

627.4301 Genetic information for insurance purposes.—

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

(a) "Genetic information" means information derived from genetic testing to determine the presence or absence of variations or mutations, including carrier status, in an individual's genetic material or genes that are scientifically or medically believed to cause a disease, disorder, or syndrome, or are associated with a statistically increased risk of developing a disease, disorder, or syndrome, which is

26 asymptomatic at the time of testing. Such testing does not
 27 include routine physical examinations or chemical, blood, or
 28 urine analysis, unless conducted purposefully to obtain genetic
 29 information, or questions regarding family history.

30 (b) "Health insurer" means an authorized insurer offering
 31 health insurance as defined in s. 624.603, a self-insured plan
 32 as defined in s. 624.031, a multiple-employer welfare
 33 arrangement as defined in s. 624.437, a prepaid limited health
 34 service organization as defined in s. 636.003, a health
 35 maintenance organization as defined in s. 641.19, a prepaid
 36 health clinic as defined in s. 641.402, a fraternal benefit
 37 society as defined in s. 632.601, or any health care arrangement
 38 whereby risk is assumed.

39 (c) "Life insurer" has the same meaning as in s. 624.602
 40 and includes an insurer issuing life insurance contracts that
 41 grant additional benefits in the event of the insured's
 42 disability.

43 (d) "Long-term care insurer" means an insurer that issues
 44 long-term care insurance policies as described in s. 627.9404.

45 (2) USE OF GENETIC INFORMATION.—

46 (a) In the absence of a diagnosis of a condition related
 47 to genetic information, ~~no~~ health insurers, life insurers, and
 48 long-term care insurers ~~insurer~~ authorized to transact insurance
 49 in this state may not cancel, limit, or deny coverage, or
 50 establish differentials in premium rates, based on such

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51 information.

52 (b) Health insurers, life insurers, and long-term care
53 insurers may not require or solicit genetic information, use
54 genetic test results, or consider a person's decisions or
55 actions relating to genetic testing in any manner for any
56 insurance purpose.

57 (c) This section does not apply to the underwriting or
58 issuance of an ~~a life insurance policy, disability income~~
59 ~~policy, long-term care policy,~~ accident-only policy, hospital
60 indemnity or fixed indemnity policy, dental policy, or vision
61 policy or any other actions of an insurer directly related to an
62 ~~a life insurance policy, disability income policy, long-term~~
63 ~~care policy,~~ accident-only policy, hospital indemnity or fixed
64 indemnity policy, dental policy, or vision policy.

65 Section 2. This act applies to policies entered into or
66 renewed on or after January 1, 2021.

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