The Florida Senate

COMMITTEE MEETING EXPANDED AGENDA

HEALTH POLICY
Senator Harrell, Chair
Senator Berman, Vice Chair

MEETING DATE: Monday, March 25, 2019
TIME: 1:30—3:30 p.m.
PLACE: *Pat Thomas Committee Room,* 412 Knott Building

MEMBERS: Senator Harrell, Chair; Senator Berman, Vice Chair; Senators Baxley, Bean, Book, Cruz, Diaz, Hooper, Mayfield, and Rouson

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
1	**SB 1528** Bean (Compare H 19, S 1452)	Prescription Drug Importation Programs for Public Programs; Establishing the Canadian Prescription Drug Importation Program within the Agency for Health Care Administration for a specified purpose; requiring participating Canadian suppliers and importers to comply with specified federal requirements for distributing prescription drugs imported under the program; prohibiting Canadian suppliers and importers from distributing, dispensing, or selling prescription drugs imported under the program outside of the state, etc. HP 03/25/2019 Fav/CS AHS AP	Fav/CS Yeas 8 Nays 2
2	**SB 1526** Harrell (Compare CS/H 23, H 947)	Telehealth; Prohibiting Medicaid managed care plans from using providers who exclusively provide services through telehealth to achieve network adequacy; defining the terms “telehealth” and “telehealth provider”; prohibiting a telehealth provider from using telehealth to prescribe a controlled substance; prohibiting a health maintenance organization from requiring a subscriber to receive services via telehealth, etc. HP 03/25/2019 Favorable AHS AP	Favorable Yeas 10 Nays 0
3	**SB 1650** Albritton (Similar H 7099)	Child Welfare; Requiring that the order for placement of a child in shelter care contain a written finding specifying that the Department of Children and Families has placement and care responsibility for certain children; revising eligibility for the Relative Caregiver Program; revising when a court must return a child to the custody of his or her parents after making certain determinations; revising provisions related to the licensure of family foster homes and certain child-caring and child-placing agencies, etc. HP 03/25/2019 Fav/CS CF AP	Fav/CS Yeas 10 Nays 0

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
4	**SB 630** Perry (Compare CS/CS/H 451)	Nonopioid Directives; Requiring the Department of Health to establish a voluntary nonopioid directive form; authorizing a patient to appoint a duly authorized guardian or health care proxy who may revoke a voluntary nonopioid directive; providing that certain persons are not liable for damages or subject to criminal prosecution under certain circumstances, etc. HP 03/25/2019 Not Considered JU RC	Not Considered
5	**SB 1170** Brandes (Similar H 687)	Automated Pharmacy Systems; Authorizing a community pharmacy to use an automated pharmacy system under certain circumstances; providing that certain medicinal drugs stored in such system for outpatient dispensing are part of the inventory of the pharmacy providing services through such system, etc. HP 03/25/2019 Not Considered IT RC	Not Considered
6	**SB 1436** Gibson (Compare H 1045)	Closing the Gap Grant Proposals; Removing provisions related to Front Porch Florida Communities; adding a priority area that may be addressed in a Closing the Gap grant proposal, etc. HP 03/25/2019 Favorable AHS AP	Favorable Yeas 10 Nays 0
7	**SB 1618** Simmons (Similar H 1041, Compare H 1013, H 1125, S 734, S 1046, S 1574)	Tobacco Products; Citing this act as the "Tobacco 21 Act"; revising shipping documentation requirements for specified sales of tobacco products; deleting provisions requiring driver license penalties for certain persons who commit tobacco-related offenses; revising the age under which it is unlawful to smoke in, on, or near school property; revising the age limitation that applies to the sale, delivery, bartering, furnishing, or giving of tobacco products, etc. HP 03/25/2019 Favorable IT RC	Favorable Yeas 9 Nays 1

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
8	**SB 846** Pizzo (Similar CS/H 79)	HIV Prevention; Citing this act as the "HIV Prevention Justice Act"; providing an exception to allow the donation of human tissue by a person who has human immunodeficiency virus infection under certain circumstances; expanding the scope of unlawful acts by a person infected with a sexually transmissible disease; expanding the list of sexually transmissible diseases to include human immunodeficiency virus infection, etc. HP 03/25/2019 Temporarily Postponed ACJ AP	Temporarily Postponed
9	**SB 884** Baxley (Similar H 509, Compare CS/H 247, CS/H 7031, CS/CS/S 188, S 1042)	Clinical Social Workers, Marriage and Family Therapists, and Mental Health Counselors; Revising the licensure requirements for clinical social workers, marriage and family therapists, and mental health counselors; deleting a provision providing certified master social workers an exemption from continuing education requirements; requiring the Department of Health to license an applicant for designation as a certified master social worker under certain circumstances, etc. HP 03/25/2019 Not Considered AHS AP	Not Considered
	Other Related Meeting Documents		

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	CS/SB 1528
INTRODUCER:	Health Policy Committee and Senators Bean and Gruters
SUBJECT:	Prescription Drug Importation Programs for Public Programs
DATE:	March 29, 2019 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Lloyd	Brown	HP	**Fav/CS**
2.			AHS	
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1528 creates the Canadian Prescription Drug Importation Program (Program). The Agency for Health Care Administration (AHCA) is directed to establish the Program for the safe and effective importation of prescription drugs from Canada which will have the highest potential cost savings to the state.

The AHCA must contract with a vendor by December 1, 2019, to administer the Program, and develop a plan for federal approval of the Program to be submitted by July 1, 2020, to the federal Department of Health and Human Services. Once federal approval is granted, the AHCA must return to the Legislature and receive final approval before implementation. As part of that final approval process, the bill requires that the estimated cost savings to the state and the Program's success in meeting the required safety standards must be considered.

The bill contains numerous requirements for the vendor and for Program participants, designed to ensure the Program is safe and effective and results in cost-savings. The vendor, any participating supplier, and any participating importer must post two surety bonds of at least $1 million each; one bond is for administrative and performance-related actions and the other is to ensure participation in and payment of any civil and criminal causes of action.

An annual report is due every December 1st to the Governor, the President of the Senate, and the Speaker of the House of Representatives, and must include specified components. The AHCA may adopt rules to implement the Program.

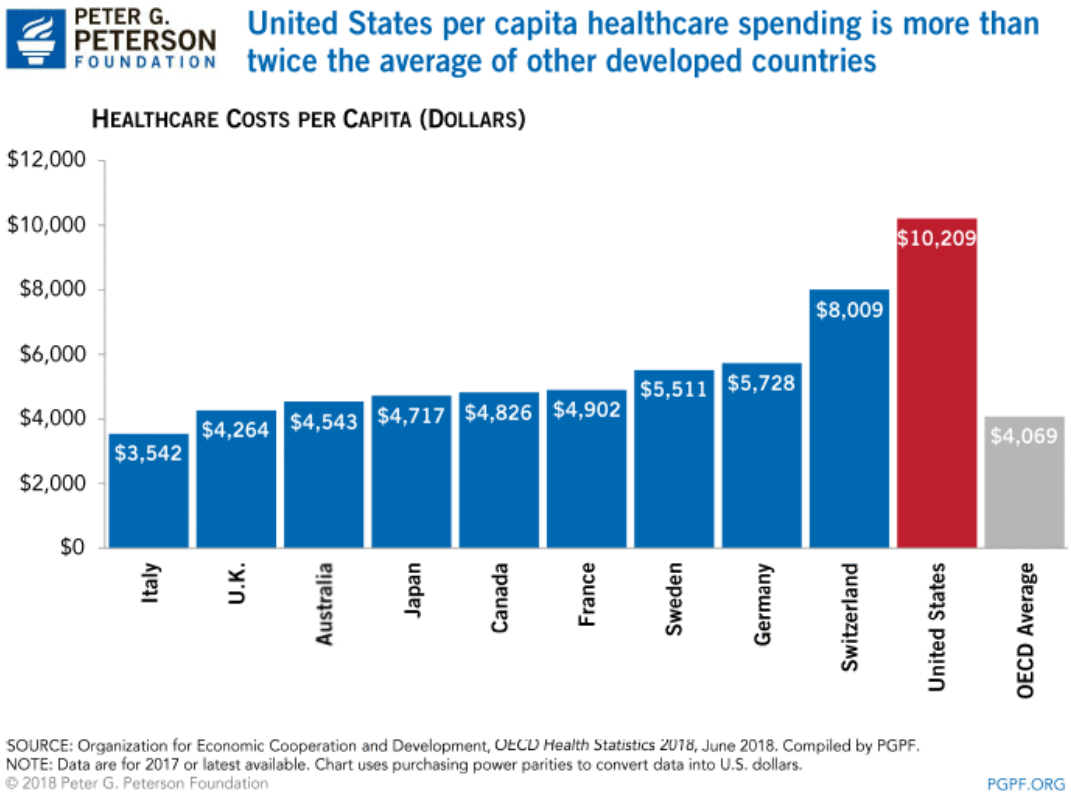
The bill has an incomplete fiscal impact analysis at this time with the expectation that there will be start-up costs associated with implementation prior to any achievement of potential savings under the Program.

The effective date is July 1, 2019.

II. Present Situation:

U.S. Healthcare Marketplace

In 2017, health care spending in the United States increased 3.9 percent over the prior year to $3.5 trillion, or an average of $10,739 per person.[1] Health care spending represents over 17 percent of the nation's Gross Domestic Product.[2] In comparison to other countries, the United States' per capita health care costs can be double that of other counties of comparable size and wealth as the chart below shows.[3]



[1] Centers for Medicare and Medicaid Services, *National Health Expenditures 2017 Highlights*, p. 1, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf (last visited March 21, 2019).
[2] Centers for Medicare and Medicaid Services, *National Health Expenditure Data, Historical*, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html (last visited March 21, 2019).
[3] Peter J. Peterson Foundation, *Per Capita Healthcare Costs-International Comparison* (August 10, 2018), https://www.pgpf.org/chart-archive/0006_health-care-oecd (last visited March 21, 2019).

Retail prescription drug costs ranked third behind hospital care and physician and clinical services, representing 10 percent of health spending.[4] Prescription drugs posted a slower growth rate for 2017 of 0.4 percent compared to the prior year when the growth rate was 2.3 percent.

The 2017 growth rate in prescription drugs equated to an increase of $333.4 billion.[5] Of that amount, the vast majority, $285 million, is paid through health insurance coverage which includes private health insurance, Medicare, Medicaid, and other health insurance coverage.[6] The next highest category is private health insurance within with the health insurance coverage category ($100.9 million) followed by out-of-pocket costs ($46.7 million).[7]

The key drivers for prescription drug costs each year depend on the balance between consumers' usage of generic and brand drugs, the release of drugs from patent protection, and sales volumes of higher cost drugs.

Spending by different blocks of purchasers fluctuates each year. The federal government is the largest group purchaser of health care services, accounting for 28 percent of the health care market, with private business next at 20 percent, and then state and local governments with 17 percent for 2017.[8] Two out of three of these purchasing blocks experienced a deceleration in their health care spending rates: private households (decrease to 3.8 percent) and private business (decrease to 4.1 percent), and the third, state and local governments had an increase from 3.8 percent in 2016 to 4.1 percent in 2017.[9]

A majority of adults aged 18-64, nearly 60 percent, reported being prescribed a medication in the past 12 months in one study sponsored by the federal Centers for Disease Control and Prevention.[10] Approximately 70 percent of all prescriptions carry out-of-pocket costs, such as requirements for co-insurance, co-payments, or deductible, with generics having an average cost of $6 per prescription and brand names an average cost of $30 per prescription.[11]

Many adults who are prescribed drugs with higher out-of-pocket costs will forego their prescriptions or will take other measures, including considering other non-medication therapies, to avoid the out-of-pocket costs. Researchers found that while the number of adults who asked their health care provider for an alternative medical treatment option with a lower out-of-pocket

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[4] Centers for Medicare and Medicaid Services, *National Health Expenditures 2017 Highlights, supra* note 1.
[5] Centers for Medicare and Medicaid Services, *National Health Expenditures 2017 Highlights, supra* note 1.
[6] Centers for Medicare and Medicaid Services, *National Health Expenditures, Table 16 – Retail Prescription Drugs Expenditure; Levels, Percent Change, and Percent Distribution by Source of Funds: Selected Calendar Year 1970-2017,* https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html (last visited March 21, 2019).
[7] U.S. Department of Health and Human Services, *National Health Expenditures, Table 16 – Retail Prescription Drugs Expenditure; Levels, Percent Change, and Percent Distribution by Source of Funds: Selected Calendar Year 1970-2017, Id.*
[8] U.S. Department of Health and Human Services, *National Health Expenditures 2017 Highlights, Id* at 2.
[9] *Id.*
[10] Robin A. Cohen, et al, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, *Strategies Used by Adults Aged 18-64 to Reduce Their Prescription Drug Costs, 2017, NCHS Data Brief* (March 2019), p. 1, https://www.cdc.gov/nchs/data/databriefs/db333-h.pdf (last visited March 21, 2019).
[11] Robin A. Cohen, *supra* note 10.

cost had dropped from the prior study, the percentage was still 19.8 percent.[12] Other strategies that adults used included not taking the medication as prescribed, which could mean skipping doses, taking less than the prescribed dose, delaying a refill; or using alternative therapies instead of the prescribed medication.[13]

As with the comparison of general health care costs, the United States' prescription drug spending on its own also stands in stark contrast to other industrialized nations. By 2015, the United States' spending on prescription drugs had exceeded $1,000 per person per year and was 30 to 190 percent higher than nine other western countries.[14]

Role of Price Controls

Reasons given for the price differentials among the countries primarily are related to the fact that most of these nations have some type of price control over drug pricing. In the United States, only two federal entities, the Department of Defense and the Department of Veterans Affairs, negotiate directly with drug manufacturers for drug prices, and they pay approximately 50 percent of what is paid at a retail pharmacy.[15] The discount is equal to 24 percent off of a drug's average price or the lowest price paid by other non-federal buyers, as well as other discounts if a drug's price outstrips inflation.[16]

The United States typically uses drug price controls in one of two ways. First, in the manner described above with the Department of Defense and the Department of Veterans' Affairs with price controls in the form of a required discount of the average price paid by other purchasers of the same product. The other manner is through negotiated pricing when the government wields its market power as a large purchaser of health care services to bargain for more favorable rates from pharmaceutical suppliers.[17]

Medicaid is also the recipient of manufacturer discounts and rebates, receiving whichever is lower: typically 23.1 percent less than the average price paid for the drug by other buyers, or the lowest price at which the drug is sold to other buyers.[18] Medicaid can also negotiate additional rebates and will receive additional discounts if the price of the drug rises faster than inflation.[19]

Medicare Part D, the prescription drug benefit for Medicare, differs with Medicaid in the prices paid for prescription drugs and in the measures used to control prescription drug spending. These differences are often a function of the different options that are statutorily available relating to

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[12] Robin A. Cohen, s*upra* note 10.
[13] Robin A. Cohen, *supra* note 10, at 2 - 4.
[14] Dana O. Sarnak, et al, *Paying for Prescription Drugs Around the World: Why is the U.S. an Outlier?*, The Commonwealth Fund, www.commonwealthfund.org, https://www.commonwealthfund.org/publications/issue-briefs/2017/oct/paying-prescription-drugs-around-world-why-us-outlier (last visited March 21, 2019). The nine western countries being used in comparison are Switzerland, Germany, Canada, France, United Kingdom, Australia, Netherlands, Norway, and Sweden.
[15] Dana O. Sarnak, et al, *supra* note 14.
[16] David Blumenthal, M.D. and David Squires, *Drug Price Control: How Some Government Programs Do It*, The Commonwealth Fund, (May 10, 2016) www.commonwealthfund.org, https://www.commonwealthfund.org/blog/2016/drug-price-control-how-some-government-programs-do-it?redirect_source=/~/media/2aca550e3b1446fd91b0f5d0b16eb87c.ashx (last visited March 21, 2019).
[17] David Blumenthal, M.D. and David Squires, *supra* note 16.
[18] David Blumenthal, M.D. and David Squires, *supra* note 16.
[19] David Blumenthal, M.D. and David Squires, *supra* note 16.

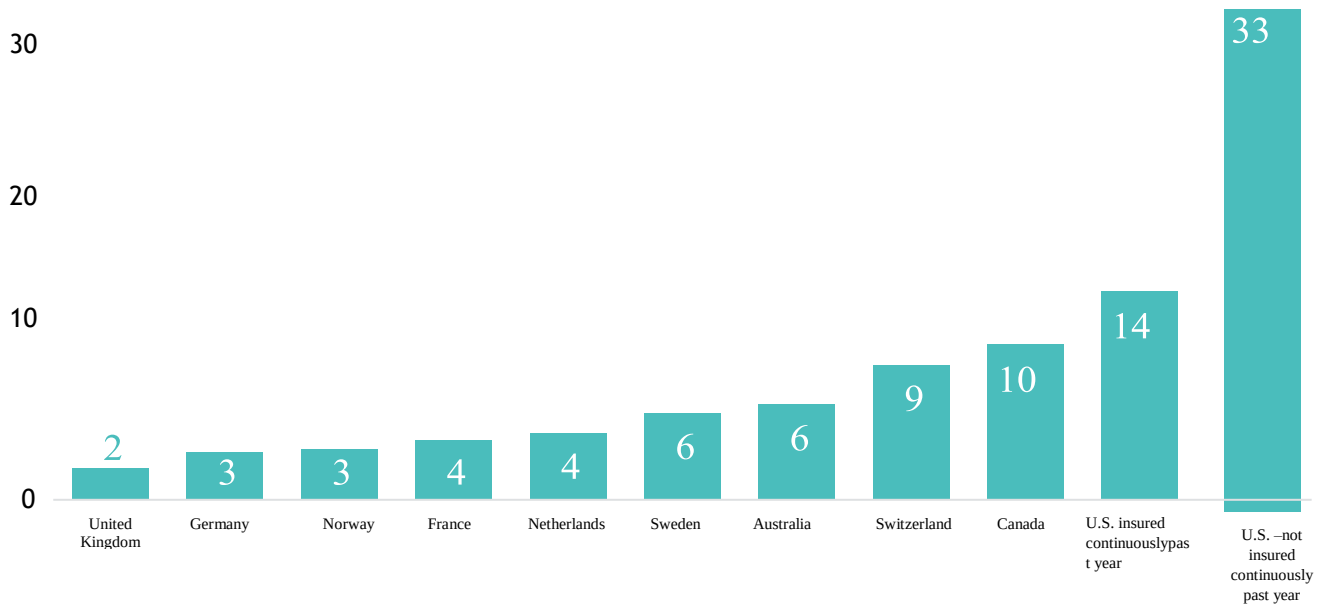
copayment restrictions, rebate levels, and the fact that the two programs do not serve the same constituencies, and therefore, the drug usage between the programs do not match up.[20]

Programmatic Differences – Prescription Drugs – Federal Programs[21]		
	Medicare Part D	Medicaid Fee for Service
Average Rebate	15 percent of retail price (2010) *Top 53 therapeutic classes*	54 percent of retail price - Brand *Top 53 Therapeutic Classes* Average Rebate – 56 percent
Use of Generics	75 percent	70 percent
Use of Drugs Within Therapeutic Class Average Price	$49	$36

Out of Pocket Costs

Out of pocket prescription drug spending per capita varies widely, country by country, from a low in $0 in France and the United Kingdom for certain individuals or in certain areas of the United Kingdom (Scotland, Wales, or Northern Ireland) to a high of $221 in Switzerland.[22] Many of these national drug plans come with further protections for lower income individuals such as reduced copayments or spending caps, and exemptions for the chronically ill.

Adults Who Cited Cost as a Reason for Skipping Prescriptions or Doses, 2016[23]



[20] Congressional Budget Office, Competition and the Cost of Medicare's Prescription Drug Program (July 2014), p. 30, https://www.cbo.gov/sites/default/files/113th-congress-2013-2014/reports/45552-PartD.pdf (last visited March 21, 2019).
[21] Congressional Budget Office, *supra* note 20, at 31-32.
[22] Dana O. Sarnak, et al, *supra* note 14, Appendix – Patient Exposure to Out of Pocket Prescription Drug Costs.
[23] Dana O. Sarnak, *supra* note 14. Credit for chart specifically: R. Langreth, B. Migliozzi, and K. Gokhale, (Bloomberg, December 18, 2015) (last visited March 22, 2019).

From a cost perspective, 58 percent of respondents to a survey reported spending $100 or more a month on prescriptions and those who were in fair or poor health said they were taking four or more prescriptions a month (49 percent).[24] The public also viewed the profits made by the pharmaceutical companies as the largest contributor to prescription drug prices (80 percent) followed by the cost of research and development (69 percent), profits made by pharmacy benefit managers or PBMs (63 percent), and the cost of marketing and advertising (52 percent).[25]When the survey asked the public how prescription drug costs could be kept down, the top five answers were:

- Requiring drug companies to include list prices in ads (88 percent).
- Making it easier for generic drugs to come to market (88 percent).
- Allowing the government to negotiate with drug companies to get a lower price for people with Medicare (86 percent).
- Allowing Americans to buy drugs imported from Canada. (80 percent)
- Planning an annual limit on out-of-pocket drug costs for people with Medicare (76 percent).[26]

Blame for prescription costs in the U.S. can likely be attributed to a number of different causes if the number of newspaper articles, blog posts, and magazine stories about the issue are anything to go by in the past several years. Representatives from the PBMs will argue that the country cannot be responsible for subsidizing the research and development costs for the world.[27] Drug makers often insist that comparing prices country to country or even payor to payor is not a true comparison of prices since comparisons do not include all of the discounts drug makers may provide.[28] In remarks to stakeholders and the news media, the current Secretary of the federal Department of Health and Human Services Alex Azar remarked that "the problem has multiple parts: high list prices, overpaying in government programs, high out-of-pocket costs, foreign government free-loading. They are connected in a way that attempting to squeeze one end of the balloon won't lead to lasting change."[29]

Federal Regulation of Prescription Drugs

The United States Food and Drug Administration (FDA) is the federal agency responsible for ensuring that food, drugs, biological products, and medical devices are effective and safe for public consumption. The FDA regulates these areas under the authority of the Food, Drug, and Cosmetic Act (FDCA).[30] Generally, the state boards of pharmacy have primary responsibility for

[24] Jay Hancock, Kaiser Health News, *Id.*
[25] Jay Hancock, Kaiser Health News, *Id.*
[26] Jay Hancock, Kaiser Health News, *Id.*
[27] Robert Langreth, et al, *The U.S. Pays a Lot More for Top Drugs Than Other Countries,* Bloomberg News (December 18, 2015), https://www.bloomberg.com/graphics/2015-drug-prices/ (last visited March 21, 2019). "We can no longer sustain a system where 300 million Americans subsidize drug development for the entire world," said Steve Miller, chief medical officer for Express Scripts Holding Co.
[28] Robert Langreth, et al, Bloomberg News. "The difference in prices here in the U.S. compared to other countries is often vastly overstated," said Robert Zirkelbach, spokesman for the Pharmaceutical Research Manufacturers of America trade group.
[29] Alex M. Azar, II, *Remarks on Drug Pricing Blueprint (May 14, 2018) as prepared for delivery,* delivered in Washington, D.C., https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html (last visited March 21, 2019).
[30] Food, Drug, and Cosmetic Act, 21 U.S.C. ss. 301 et seq. 52 Stat. 1040 et. seq. as amended by the Drug Quality and Security Act, 21 U.S.C. 351 et seq.

oversight and regulation of pharmacy; however, the FDA regulates, and in some cases preempts state action, through the FDCA and the Drug Quality and Security Act (DQSA). The DQSA created a national uniform standard and an electronic system for the tracing of drugs at the package level, preempting pedigree laws that previously existed in Florida and 28 other states. In the 2016 Legislative Session, Florida conformed its statutes to the revised federal standards.[31]

The FDCA prohibits any drug from being introduced or delivered for introduction or delivered for introduction into interstate commerce unless approved by the FDA. The FDCA further prohibits adulterated[32] or misbranded drugs[33] and devices from being introduced, delivered for introduction, or received in interstate commerce.[34] In a warning letter dated February 26, 2019, to CanaRx, the FDA cited this statutory reference and at least five others it believed had been violated by a foreign pharmacy and its business associates in the delivery of prescription drugs from Canada to recipients in the United States.[35] CanaRx serves as a broker between foreign pharmacies and public and private employer sponsored health plans to provide employees with prescription drugs, according to the FDA. The letter identified issues with dispensing unapproved new drugs, substitution of FDA approved drugs with recalled or unapproved drugs, misbranded drugs, and drugs subject to the Risk Evaluation and Mitigation Strategy program.[36] More than 150 websites were included in the letter as affiliated with CanaRx. The FDA gave CanaRx 10 days to respond to the warning letter.

[31] *See* ch. 2016-212 Laws of Florida (CS/CS/HB 1211)

[32] An "adulterated drug or device" is defined, in part, under 21 U.S.C. 351, as a drug or device that consists "in whole or in part of any filthy, putrid, or decomposed substance; or if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or if it is a drug and the methods used in or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess…"

[33] A "misbranded drug or device" is defined, in part, under 21 U.S.C. 352, as a drug or device whose "labeling is false or misleading in any particular. Health care economic information provided to a payor, formulary committee, or other similar entity with knowledge and expertise in the area of health care economic analysis, carrying out its responsibilities for the selection of drugs for coverage or reimbursement, shall not be considered to false or misleading under this paragraph if the health care economic information related to an indication approved under section 505 or under section 351 of the Public Health Service Act for such drug, is based on competent and reliable scientific evidence, and includes, where applicable, a conspicuous and prominent statement describing any material differences between the health care economic information and the labeling approved for the drug under section 505 or under section 351 of the Public Health Service Act…

[34] *See* 21 U.S.C. 331 (as amendment through P.L. 115-271, enacted October 24, 2018).

[35] Letter to Gregory Anthony Howard, CanaRx Services, Inc. (Feb. 26, 2019), U.S. Food and Drug Administration Warning Letter, https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm632061.htm (last visited March 21, 2019).

[36] The FDA's Risk Evaluation and Mitigation Strategy (REMS) program is a drug safety program for drugs that have a narrow therapeutic index, and/or is the drug is indicated to treat a serious condition such as HIV, cancer, or hepatitis. A strategy is designed specific to a particular drug to address the safety and risk concerns unique to that drug, such as requiring that a drug only be administered in a health care facility or by a provider. Another strategy may be a special patient information pamphlet insert included with the prescription. All of the strategies are aimed at reducing the frequency or severity of an adverse event.

Drug Approval Process

The FDA process for new and innovative drugs is rigorous and requires an exhaustive and extensive series of clinical trials, first on animals and then on humans, before a new drug application (NDA) can even be formally filed with the FDA.[37] The NDA process has three goals:

- Whether the drug is safe and effective in its proposed uses(s), and whether the benefits of the drug outweigh the risks.
- Whether the drugs proposed labeling (package insert) is appropriate and what it should contain.
- Whether the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity.[38]

The first step in the process is for a sponsor, such as a company, research institution, or other organization, to take responsibility for developing the drug by showing the FDA results of preclinical lab testing on animals and how they propose to conduct human testing. The FDA must decide at that point whether it is reasonably safe for the sponsor to move forward with the proposed plan. Clinical trials only move forward after an investigation of a new drug application (IND) has been reviewed by the FDA and a local institutional review board (IRB). The IRB includes scientists and non-scientists in hospitals and research institutions who will oversee the clinical research.[39]

In Phase One of the clinical trials, usually health volunteers are used to determine what the drug's most frequent side effects are, and how the drug is metabolized and excreted. The size of the clinical trial is between 20 and 80 people.[40] If unacceptable levels of toxicity in the drug are not revealed, then the clinical trial will usually move on to Phase II where the emphasis is on effectiveness of the drug. Patients receiving the drug will be compared against those who will not be receiving the drug, usually a placebo or a different drug. The number of participants in this phase ranges from a few dozen to about 300.[41]

At the end of Phase Two, the sponsors and the FDA will try to reach a consensus on how large of scale the study should be in Phase Three. Phase Three will occur only if the drug showed signs of effectiveness in Phase Two. Different strengths and doses may be tried in this phase and the drug may be used in combination with other drugs. The size of the participant pool may range from several hundred to upwards of 3,000.[42]

The NDA is the formal step that the drug sponsor will decide to take to seek formal approval from the FDA at the end of Phase Three trials. An NDA application will incorporate all of the data from the clinical trials, animal and human, as well as how the drug behaves and will be manufactured. Once received by the FDA, the FDA has 60 days to decide whether to file it for

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[37] U.S. Food and Drug Administration, *New Drug Application*, https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm (last visited March 21, 2019).
[38] U.S. Food and Drug Administration, *supra* note 37
[39] U.S. Food and Drug Administration, *The FDA's Drug Review Process: Ensuring Drugs are Safe an Effective,* https://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143534.htm (last visited March 21, 2019).
[40] U.S. Food and Drug Administration, *The FDA's Drug Review Process: Ensuring Drugs are Safe an Effective, supra* note 39.
[41] U.S. Food and Drug Administration, *The FDA's Drug Review Process: Ensuring Drugs are Safe an Effective, supra* note 39.
[42] U.S. Food and Drug Administration, *The FDA's Drug Review Process: Ensuring Drugs are Safe an Effective, supra* note 39.

review. The goal once the NDA is received is 10 months to review and act or 6 months for priority drugs.[43]

When new drugs are approved, the sponsoring entities may apply for and receive a patent for the drug which gives the sponsor the right to exclude others from making, using, offering to sell, or selling the drug within the United States, generally for a period of 20 years. There is a research exemption that protects generic drug companies from patent infringement lawsuits during the time in which the generic drug company is preparing its application for the FDA.[44] This allows generic drug companies time to learn how to manufacture the drug in a process that would otherwise run them afoul of federal patent law and subject them potentially to patent infringement litigation.

Drug Manufacture

The FDA ensures the quality of the United States' drug products by carefully monitoring drug manufacturer's compliance with its Current Good Manufacturer's Practice Regulations. (CGMP), which are the main regulatory standard for ensuring pharmaceutical quality for human pharmaceuticals.[45] The CGMP regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, packaging, and labeling pharmaceuticals. The regulations are found at 21 CFR Part 211 and specify the responsibilities of the quality control unit, personnel qualifications and responsibilities, the design and construction of facilities, the equipment requirements, production and process controls, packaging and labelling operation, including tamper-evident package requirements, and returned drug products.

Drug Distribution

The Drug Supply Chain Security Act[46] (DSCSA) establishes procedures to ensure the integrity of prescription drugs as they are distributed along the supply chain. Effective July 1, 2015, the DSCSA requires manufacturers, re-packagers, wholesale distributers, and dispensers to exchange product tracing information when transferring a product along the distribution chain. As noted earlier, this national product tracing process replaces Florida's previous pedigree paper system.

This product tracing information includes the following:

- Name of the drug.
- Strength and dosage form of the drug.
- National Drug Code number of the drug.
- Container size and number of containers.
- Lot number of the drug.
- Date of the transaction.
- Date of the shipment, if more than 24 hours after the date of transaction.
- Business name and address of the person from whom ownership is being transferred.

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[43] U.S. Food and Drug Administration, *The FDA's Drug Review Process: Ensuring Drugs are Safe an Effective, supra* note 39.
[44] U.S. Food and Drug Administration, *Frequently Asked Questions on Patents and Exclusivity*, https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079031.htm#howlongpatentterm (last visited March 21, 2019).
[45] U.S. Food and Drug Administration, *Questions and Answers on Current Good Manufacturing Practices (CGMPs),* https://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm124740.htm (last visited March 21, 2019).
[46] *See* Title II of DQSA, the Drug Supply Chain Security Act, Pub. Law 113-54 (2015).

- Business name and address of the person to whom ownership is being transferred.

These entities must maintain these records for 6 years and provide them to the FDA upon request.

Drug Supply Chain Security

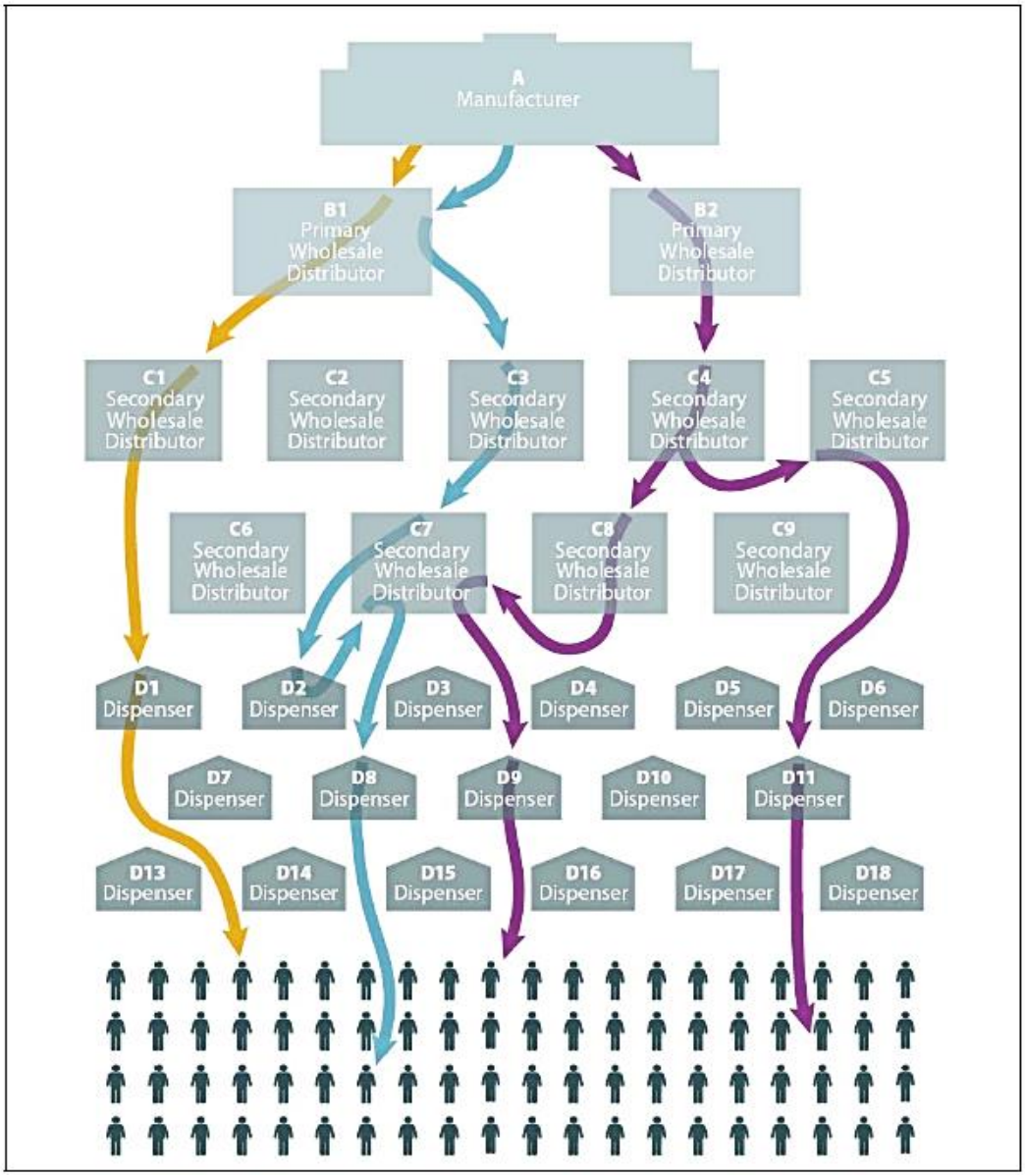
The path a drug takes from unfinished product to when it is handed to a patient, either at a hospital bedside or to a customer at a community pharmacy, is called the supply or distribution chain. Along that path, there are several opportunities in that chain for the product to become mishandled or adulterated, whether it is in the United States or abroad.

The first legislation that dealt with such issues was the 1906 Food and Drugs Act, which addressed the labeling of drugs; then the 1938 Food, Drug, and Cosmetics Act (FDCA), which introduced the concepts of adulteration, misbranding, registration, and inspection of manufacturing establishments, and the Prescription Drug Marketing Act (PDMA, P.L. 100-293), which required that wholesale distributors be licensed by the states and that a wholesale distributor, except in certain circumstances, must issue a pedigree, which has since been superseded by the tracing requirements in the DQSA in 2015.[47]

Supply security issues can include contamination of products, diversion, counterfeiting, and other adulteration, according to statements made by the Director of the Center for Drug Evaluation and Research (CDER) at the FDA, Dr. Janet Woodcock, in testimony to Congress in 2013.[48] In her testimony, she referenced cases involving counterfeit and fraudulent versions of Botox sold in the United States, Lipitor sold in the United Kingdom, and Avastin in the United States.[49] The chart below illustrates the downstream pharmaceutical supply chain and the different actors and components involved in the production and distribution process:

[47] Susan Thaul, Congressional Research Service, *Pharmaceutical Supply Chain Security* (October 31, 2013), Summary, http://www.ncsl.org/documents/statefed/health/CRS-PharmSupChSec2013.pdf (last visited March 22, 2019).
[48] Susan Thaul, Congressional Research Service, *supra* note 47, at 1.
[49] Susan Thaul, Congressional Research Service, *supra* note 47, at 2.

Downstream Pharmaceutical Supply Chain[50]



Interaction with the Foreign Market

As globalization has increased, the FDA has established foreign offices to work closely with foreign governments, industry, and other stakeholders to enable the FDA to more effectively protect American consumers, including inspections and investigations in those countries. The FDA indicates that about 35 percent of the medical devices used in the United States are imported.[51]

[50] Susan Thaul, Congressional Research Service, *supra* note 47, at 6.
[51] U.S. Food and Drug Administration, *FDA Globalization*, https://www.fda.gov/InternationalPrograms/FDABeyondOurBordersForeignOffices/default.htm (last visited March 22, 2019).

Foreign companies that manufacture, prepare, propagate, compound, or process drugs that are offered for import in the United States must register with the FDA.[52] Today, there are 136,400 foreign facilities in more than 150 countries that export FDA-regulated products to the United States.[53] The FDA estimates that 80 percent of the active pharmaceutical ingredients and 40 percent of the finished drugs in the U.S. market are actually manufactured in FDA-registered facilities in other countries, primarily India and China.[54]

The FDA does not regularly inspect every foreign facility and instead relies on a risk-based assessment to determine which facilities to inspect and how often.[55] In federal fiscal year 2017-18, the FDA conducted 94 on-site inspections of foreign drug manufacturing facilities, and 381 historically since 2014-15.[56] This means that less than 1 percent of foreign FDA-registered drug manufacturing facilities are inspected by the FDA each year.

Since the FDA does not have the resources to effectively enforce drug manufacturing regulations in every facility overseas, it must instead rely on cooperation with the governments of each country to ensure the safety of drugs or pharmaceutical products imported into the United States. The FDA may memorialize these partnerships in an international arrangement, which is a written understanding between two or more countries recognizing one another's conformity with certain processes or procedural standards and describes the willingness and good-faith intentions of the countries to engage in cooperative activities.[57] International arrangements can have a variety of titles, including "cooperation agreement," "memorandum of understanding," or "mutual recognition agreement." The FDA currently has at least 80 such international arrangements with foreign governments.[58]

In instances where the U.S. determines that another country adheres to current good manufacturing practices for pharmaceutical products, it may enter into an international arrangement and authorize the foreign government to conduct facility inspections on the FDA's behalf. The FDA has such international arrangements with Australia, Austria, Belgium, Canada, China, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Ireland,

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[52] Section 510 of the federal Food, Drug, and Cosmetic Act.
[53] U.S. Food and Drug Administration, *FDA Globalization, supra* note at 51.
[54] FDA Commissioner Margaret Hamburg, *The Safety of Prescription Drugs Made Outside the U.S.*, The Diane Rehm Show (February 20, 2014), *transcript available at* https://dianerehm.org/shows/2014-02-20/safety-prescription-drugs-made-outside-us (last visited March 22, 2019).
[55] Section 705 of the FDA Safety and Innovation Act, 2012. Factors considered include the establishment's compliance history or history and nature of recalls, the inherent risk of the drug being manufactured, whether the establishment has been inspected in the last 4 years, whether a foreign government has inspected the establishment, and anything else the FDA determines is important in determining where inspection resources should be spent.
[56] U.S. Food and Drug Administration, *Total Number of Inspections Completed in the Month*, https://www.accessdata.fda.gov/scripts/fdatrack/view/track.cfm?program=oip&id=OIP-Number-of-inspections-completed-in-country-by-commodity (last visited March 22, 2019).
[57] U.S. Food and Drug Administration, *International Agreements*, https://www.fda.gov/InternationalPrograms/Agreements/default.htm (last visited Mar. 8, 2019); *See also, FAQs: The Mutual Recognition Agreement*, https://www.fda.gov/downloads/InternationalPrograms/Agreements/UCM544394.pdf (last visited March 22, 2019)
[58] U.S. Food and Drug Administration, *Cooperative Arrangements* https://www.fda.gov/InternationalPrograms/Agreements/MemorandaofUnderstanding/ucm2016755.htm (last visited March 22, 2019).

Italy, Japan, Latvia, Lithuania, Malta, Romania, Poland, Portugal, Slovenia, Spain, Sweden, Switzerland, and the United Kingdom.

Drug Importation

The FDCA generally prohibits the importation of foreign drugs into the U.S. unless the drug was manufactured by a foreign facility registered with the FDA and the foreign drug is specifically FDA-approved, or the drug was manufactured in the U.S., is FDA-approved, and is being reintroduced into the U.S. by the original manufacturer.

FDA approval requires the manufacturer to submit documentation establishing the drug's safety and efficacy, which includes information as to the method, facilities, and manner of manufacture.[59] Without this FDA-approval, these drugs are considered misbranded and illegal for importation. The FDCA prohibits interstate shipment, including importation, of 'unapproved new drugs,'[60] which includes any drugs, including foreign-made versions of U.S.-approved drugs, which have not been manufactured in accordance with and pursuant to FDA approval (i.e. not in an FDA-registered facility or by an FDA-approved manufacturer).[61] The FDCA further prohibits importation of an FDA-approved drug by anyone other than the original manufacturer of the drug.[62]

Additionally, the DSCSA requires all health care entities that distribute, dispense, and administer prescription drugs to patients must purchase their prescription drug products only from authorized "trading partners" (wholesale distributors, manufacturers, re-packagers, and dispensers) that are licensed or registered with the state or federal government.[63]

Therefore, any importation, by any person or entity other than the original manufacturer, of drugs not FDA-approved in the manner described above, would be a violation of federal law.

However, federal law does authorize the Department of Health and Human Services to grant individual persons waivers to import drugs, exercise discretion in enforcing the law against individuals importing for personal use, and focus enforcement efforts on cases that pose a significant threat to public health.[64] The FDA has stated in guidance documents that enforcing such prohibitions against individual persons was not considered a priority.[65]

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[59] 21 U.S.C. s. 355(b)(1).
[60] 21 U.S.C. s. 355(a).
[61] Marvin Blumberg, *Information on Importation of Drugs Prepared by the Division of Import Operations and Policy, FDA*, U.S. Food & Drug Admin., (Sept. 25, 2015), https://www.fda.gov/ForIndustry/ImportProgram/ucm173751.htm (last visited March 21, 2019).
[62] 21 U.S.C. s. 381(d)(1). This prohibition also applies to wholesalers, 21 U.S.C. sec. 384(a)(5)(B). The FDA justifies this by saying that the safety and integrity of the drugs cannot be ensured by any other entity but the manufacturer, *Imported Drugs Raise Safety Concerns*, U.S. Food & Drug Admin. (May 4, 2016), https://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143561.htm (last visited March 22, 2019).
[63] Pub.L. 113–54
[64] 21 U.S.C. s. 384(j).
[65] U.S. Food and Drug Administration, *Importations of Drugs*, Information on the Importation of Drugs, https://www.fda.gov/ForIndustry/ImportProgram/ucm173751.htm (last visited March 22, 2019).

The Medicare Modernization Act of 2003 [66]

The federal Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) included a provision on the importation of pharmaceutical drugs. It authorizes a wholesaler or pharmacist to import prescription drugs from Canada under certain conditions with the approval of the Department of Health and Human Services (HHS). Specifically, after consulting with relevant federal agencies and determining that such importation would produce costs savings and would not pose an additional risk to public health and safety, HHS must adopt regulations to allow licensed pharmacists and wholesalers to import prescription drugs[67] from Canada into the U.S. These regulations must:

- Require compliance with safeguard requirements of 21 U.S. sections 355 (regarding new drugs) and 351 (regarding adulteration) and 352 (regarding misbranding);
- Require an importer of a prescription drug to comply with the documentation and sample-testing requirements of the MMA; and
- Contain any additional provisions the Secretary deems appropriate to safeguard public health or to facilitate the importation of prescription drugs.

This would allow licensed or permitted entities to import FDA-approved drugs from Canada, whereas currently only the original manufacturer may do so.

However, this section of the MMA provides that it becomes effective only if the HHS Secretary certifies to the Congress that the implementation will pose no additional risk to the public's health and safety and will result in a significant reduction in the cost of covered products to the American consumer. To date, no HHS Secretary has done so or has otherwise authorized an importation program under this provision.[68] Shortly after the MMA passed, states and local governments requested waivers from the FDA in an attempt to import prescription drugs within their jurisdictions, but states that sought prior approval have all been denied on the basis that they did not ensure the safety of drugs that would be imported.[69]

In 2004, Illinois announced a plan to allow residents to order medications through a pharmacy-benefits manager network based in Canada that would access pharmacies located in Canada, Ireland, or the United Kingdom.[70] Only prescriptions that were refills, did not require refrigeration, were not controlled substances, and were for chronic conditions, would be allowed under the program.[71] Pharmacies that participated would also have to agree to allow state

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[66] Pub. L. No. 108-173 s. 1121.
[67] Excluding controlled substances, biological products, infused drugs, IV-injected drugs, drugs inhaled during surgery, or a parenteral drug the HHS Secretary deems to pose a threat to public health.
[68] Additionally, in March 2017, the four most recent FDA commissioners sent a letter to Congress attesting that drug importation would "harm patients and consumers and compromise the carefully constructed system that guards the safety of our nation's medical products." *letter available at* http://www.safemedicines.org/wp-content/uploads/2017_03_16_commissioners_letter_final.pdf (last visited March 10, 2019).
[69] Peral, Eloy A. *FDA Regulation on the Importation of Prescription Drugs: Opportunities and Barriers to Legal Importation*. HEALTH LAW & POLICY Brief 3, no. 1 (2009), 48 - 55, *available at* https://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?referer=https://www.google.com/&httpsredir=1&article=1094&context=hlp (last visited March 10, 2019).
[70] Donna Young, *Illinois Initiates Importation Plan*, www.ashp.org, https://www.ashp.org/news/2004/08/17/illinois_initiates_importation_plan (last visited March 22, 2019).
[71] Donna Young, *supra* note at 70.

inspectors on-site.[72] News reports indicated that the program incurred $1 million in start-up costs and enrolled fewer than 4,000 before it was terminated at the end of 2008.[73]

Maine passed legislation in 2013 to facilitate personal importation of prescription drugs through the mail from Canada, the United Kingdom, Australia, and New Zealand via retail pharmacies shortly after the passage of the MMA.[74] The law was introduced after the City of Portland, Maine, was banned in August 2012 by the state's then-Attorney General from purchasing pharmaceuticals from Canada.[75] Before implementation could begin, a lawsuit was filed by the Maine Pharmacy Association, Maine Society of Health-System Pharmacists, and the Retail Association of Maine alleging that the federal FDCA preempted the new state importation law and the changes to the Maine Pharmacy Act; jeopardized the safety of the nation's prescription drug supply; and opened the door to counterfeit and tainted medications.[76] The Seventh District Court in Maine agreed, citing the basics of federalism in its opinion:

> *Federalism, central to the constitutional design, adopts the principal that both the National and State Government have elements of sovereignty the other is bound to respect. From the existence of two sovereigns follows the possibility that laws can be in conflict or at cross-purposes. The Supremacy Clause provides a clear rule that federal law shall be the supreme Law of the Land and the Judges in every State shall be bound thereby, any Thing in the Constitution or Law of any State to the contrary notwithstanding." U.S. Const. art. VI, cl. 2. Under this principle, Congress has the power to preempt state law.*

Arizona v. United States, 132 S. Ct. 2492, 2500 (2012) (citations omitted).

Since 2015, there has been renewed interest in drug importation. Over a dozen states each year have considered drug importation legislation in different formats, and in 2018, Vermont was the first state to pass wholesale prescription drug importation program legislation.[77] Vermont's program is not a waiver of existing law but is an importation program that seeks to satisfy both the safety and security assurances. Drugs may be imported only from Canada under this provision, 21 U.S.C. section 384, with the inclusion of the required laboratory testing. Controlled substances, biological products, infused drugs, intravenously injected drugs, and drugs inhaled during surgery are excluded.[78] The initial program design focused on providing savings to the

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[72] Donna Young, *supra* note at 70.
[73] Sally C. Pipes, *Blagojevich's failed drug importation plan a cautionary tale,* https://www.pacificresearch.org/blagojevichs-failed-drug-importation-plan-a-cautionary-tale/ (last visited March 22, 2019).
[74] 2013 Me. Laws 373. *See* http://legislature.maine.gov/ros/LawsOfMaine/breeze/Law/getDocById/?docId=20663 (last visited March 22, 2019).
[75] Thomas Hemphill, *Prescription Drug Imports: Maine Leads, the Nation Follows?* Americanactionforum.org, https://www.americanactionforum.org/insight/prescription-drug-imports-maine-leads-the-nation-follows/ (last visited March 22, 2019).
[76] *Ouellette et al v. Mills et al*, 13-347 - *Order on Parties Competing Motions on Facial Preemption (Docket No: 1:13-cv-00347-NT)(U.S. D.Ct. Maine)(February 23, 2015).*
[77] NATIONAL ACADEMY FOR STATE HEALTH POLICY, *State Legislative Action to Lower Pharmaceutical Costs* (updated March 1, 2019), https://nashp.org/rx-legislative-tracker-2019/ (last visited March 8, 2019).
[78] Vermont Agency of Human Services, *Wholesale Importation Program for Prescription Drugs Legislative Report* (December 31, 2018), https://nashp.org/wp-content/uploads/2019/01/Report-to-VT-Legislature-on-Rx-Wholesale-Importation-1_3_2019.pdf (last visited March 22, 2019).

Vermont Medicaid program; however, the benefit to the Medicaid was minimal because Vermont Medicaid was already yielding substantial savings through existing rebates, and implementation of the drug importation program for that population would not result in any net savings.[79]

Vermont found that a small number of drugs imported through Canada may be more cost-effective for a limited period of time; however, the state's stakeholders decided to see if greater savings could be found for the state's commercial health insurers.[80] Using conservative estimates, participating plans estimated savings in the range of $2.61- $2.82 per member per month, or $1-$5 million per year, without taking into account the state's operating costs.[81]

As part of the proposed regulatory process, Vermont plans to create two new licenses: Rx Drug Importer Wholesaler License and a Canadian Rx Drug Supplier License. Vermont will extend the DCSA requirements to the licensees and has also established other participation requirements for both licenses.[82] Licensure fees will be potential revenue sources for the program through application, registration, and audit fees.[83]

Vermont has not yet sent a plan to the federal government for approval. The state still has a list of tasks and options listed in its document that need to be worked through before a plan can be submitted.

The Trump Administration has also shown interest in lowering the costs of prescription drugs for American consumers, including the possibility of drug importation.

In May 2018, American Patients First, the Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs was released.[84] The Blueprint includes four challenges in the American drug market:

- High list prices for drugs.
- Seniors and government programs overpaying for drugs due to lack of the latest negotiation tools.
- High and rising out-of-pocket costs for consumers.
- Foreign governments taking advantage of American investments in innovation.

Some of the opportunities listed in the *Blueprint* for lower costs include restricting the use of rebates, calling for Medicaid demonstration projects to test coverage and financing reforms that build on private sector best practices with drug formularies, creating incentives to lower list prices, addressing transparency in pricing in Medicare and Medicaid, and seeking public comment on further ideas and opportunities.

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[79] Vermont Agency of Human Services, *supra* note 78, at 3.
[80] Vermont Agency of Human Services, *supra* note 78, at 3.
[81] Vermont Agency of Human Services, *supra* note 78, at 4.
[82] Vermont Agency of Human Services, *supra* note 78, at 5-6.
[83] Vermont Agency of Human Services, *supra* note 78, at 10.
[84] U.S. Department of Health and Human Services, *American Patients First,* https://www.hhs.gov/about/leadership/secretary/priorities/drug-prices/index.html (last visited March 22, 2019).

In July 2018, the HHS directed the FDA to establish a work group on drug importation.[85] The work group is examining the potential for importation to promote competition for drugs that are off-patent or off-exclusivity and produced by one manufacturer. The work group has not yet issued any recommendations or reports.

Personal Importation

The MMA also authorized the HHS to allow individuals to import drugs from Canadian-licensed pharmacies for personal use without penalty in certain circumstances, either on a case-by-case waiver basis or by regulation.[86] The HHS has not implemented this provision, either; however the FDA uses its enforcement discretion and does not generally enforce violations of drug importation for personal use.

The FDA generally does not object to a person importing a drug from any country so long as it is for personal use, even though such importation would violate the FDCA.[87] The FDA recognizes there are situations where foreign medications may be appropriate for a particular individual consumer and that the FDA's resources are better served enforcing regulations against commercial shipments of foreign medication into the United States.[88]

The FDA does not examine personal baggage or mail, leaving that to the U.S. Customs and Border Protection (CBP). The CBP is instructed to only notify the FDA when it appears that there is an FDA-regulated drug intended for commercial distribution, the FDA has specifically requested that drug be detained, or the drug appears to represent a health fraud or an unknown risk to health.[89]

This FDA policy is not intended to cover importation of foreign-made chemical versions of drugs available in the U.S. (i.e., cheaper, foreign versions of U.S. drugs). However, since there is a permissive attitude towards drugs for personal use shipped or brought into the U.S., it is likely that people are importing such drugs undetected. A 2016 poll showed that 8 percent of U.S. households have bought prescription drugs from Canada or other countries in order to pay a lower price.[90]

A limited exception applies to individuals with terminal illnesses, who can legally import non-FDA approved drugs.[91] They must have exhausted all other treatment options in the United States and be unable to participate in a clinical trial for an investigational drug. The particular drug imported must be actively pursuing FDA-approval and have completed the first phase of clinical trials.

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[85] U.S. Department of Health and Human Services, *Press Release* (July 19, 2018) https://www.hhs.gov/about/news/2018/07/19/hhs-secretary-azar-directs-fda-establish-working-group-drug-importation-address-price-spikes.html (last visited March 22, 2019).
[86] 21 U.S.C. s. 384(j).
[87] U.S. Food and Drug Administration, *Personal Importation*, https://www.fda.gov/ForIndustry/ImportProgram/ImportBasics/ucm432661.htm (last visited March 22, 2019).
[88] U.S. Food and Drug Administration, *Regulatory Procedures Manual, Chapter 9: Import Operations and Actions*, (December 2017) at 9-2, *available at* https://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074300.pdf (last visited March, 22, 2019).
[89] U.S. Food and Drug Admin., *supra* note 90.
[90] KAISER FAMILY FOUNDATION, *Kaiser Health Tracking Poll: November 2016*, http://files.kff.org/attachment/Kaiser-Health-Tracking-Poll-November-2016-Topline (last visited March 8, 2019).
[91] Right to Try Act of 2017, Pub. Law No 115-176.

State Regulation of Prescription Drugs

The Department of Business and Professional Regulation's (DBPR) Division of Drugs, Devices, and Cosmetics and the Department of Health's (DOH) Board of Pharmacy together regulate prescription drugs in the state from manufacture to distribution and dispensing. All entities engaged in any process along this continuum must be either licensed or permitted to engage in such activity, subject to relevant laws and rules and enforcement authority of DBPR or DOH, as applicable. Due to the overlap in these two industries, the law requires entities permitted or licensed under either DBPR or the Board to comply with the laws and rules of both.[92]

DBPR Division of Drugs Devices and Cosmetics

The DBPR's Division of Drugs, Devices, and Cosmetics protects the health, safety, and welfare of Floridians from adulterated, contaminated, and misbranded drugs, drug ingredients, and cosmetics by enforcing Part I of ch. 499, F.S., the Florida Drug and Cosmetic Act.[93] The Florida Drug and Cosmetic Act conforms to FDA drug laws and regulations and authorizes DBPR to issue permits to Florida drug manufacturers and wholesale distributors and register drugs manufactured, packaged, repackaged, labeled, or relabeled in Florida.[94]

Florida has 18 distinct permits based on the type of entity and intended activity and includes permits for entities within the state, out of state, or even outside of the United States.[95] The DBPR has broad authority to inspect and discipline permittees for violations of state or federal laws and regulations, which can include seizure and condemnation of adulterated or misbranded drugs or suspension or revocation of a permit.[96]

Prescription Drug Manufacturer Permit

Drug manufacturing includes the preparation, deriving, compounding, propagation, processing, producing, or fabrication of any drug.[97] A prescription drug manufacturer permit is required for any person that is a manufacturer of a prescription drug and that manufactures or distributes such prescription drugs in this state.[98] Such manufacturer must comply with all state and federal good manufacturing practices. A permitted prescription drug manufacturer may engage in distribution of its own manufactured drug without requiring a separate permit.[99] The distribution of drugs includes the selling, purchasing, trading, delivering, handling, storing, and receiving of drugs, but does not include the administration or dispensing of drugs.[100]

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[92] Sections 499.067 and 465.023, F.S.
[93] Florida Department of Business and Professional Regulation, *Division of Drugs, Devices, and Cosmetics*, http://www.myfloridalicense.com/DBPR/drugs-devices-and-cosmetics/ (last visited March 22, 2019).
[94] Section 499.01, F.S.
[95] A permit is required for a prescription drug manufacturer; a prescription drug repackager; a nonresident prescription drug manufacturer; a prescription drug wholesale distributor; an out-of-state prescription drug wholesale distributor; a retail pharmacy drug wholesale distributor; a restricted prescription drug distributor; a complimentary drug distributor; a freight forwarder; a veterinary prescription drug retail establishment; a veterinary prescription drug wholesale distributor; a limited prescription drug veterinary wholesale distributor; an over-the-counter drug manufacturer; a device manufacturer; a cosmetic manufacturer; a third party logistics provider; or a health care clinic establishment. Section 499.01(1), F.S.
[96] Section 499.051, 499.062, 499.065. 499.066, 499.0661, and 499.067, F.S.
[97] Section 499.003(28), F.S.
[98] Section 499.01(2), F.S.
[99] Section 499.01(2), F.S.
[100] Section 499.003(16), F.S.

Prescription Drug Wholesale Distributor Permit

Wholesale distribution is the distribution of a prescription drug to a person other than a consumer or patient, or the receipt of a prescription drug by a person other than the consumer or patient, with various exceptions for activities related to healthcare entities, governmentally-contracted public health services, and charitable organizations.[101] A prescription drug wholesale distributor permit is required for any person who is a wholesale distributor of prescription drugs and that wholesale distributes such prescription drugs in this state.[102]

Out-of-State Prescription Drug Wholesale Distributor Permit

An out-of-state prescription drug wholesale distributor permit is required for any person that is a wholesale distributor located outside this state, but within the United States or its territories, which engages in the wholesale distribution of prescription drugs into this state.[103] The out-of-state prescription drug wholesale distributor must maintain at all times a license or permit to engage in the wholesale distribution of prescription drugs in compliance with laws of the state in which it is a resident. If the state from which the wholesale distributor distributes prescription drugs does not require a license to engage in the wholesale distribution of prescription drugs, the distributor must be licensed as a wholesale distributor by the FDA.[104]

Board of Pharmacy

The Board of Pharmacy (Board) within the DOH regulates the practice of pharmacy by enforcing the Florida Pharmacy Act (Act), adopting rules that set the standards of practice in the state, and licensing and monitoring pharmacists and pharmacies to ensure safe practice.[105] To operate a pharmacy, an entity must first obtain a pharmacy permit with the Board.[106] Any person or entity licensed, permitted, or registered pursuant to ch. 465, F.S., must practice pharmacy in accordance with the provisions of the Act and the Board rules.

The practice of pharmacy is also subject to the requirements of ch. 499, F.S., the Florida Drug and Cosmetic Act, ch. 893, F.S., the Florida Comprehensive Drug Abuse Prevention and Control Act, the FDCA, and the Federal Comprehensive Drug Abuse Prevention and Control Act. The DOH has broad authority to inspect pharmacies for violations and the Board can discipline a person or entity's license, permit, or registration for violation of any of these provisions, including suspension or revocation of the ability to practice pharmacy in the state.[107]

III. Effect of Proposed Changes:

Section 1 creates the Canadian Prescription Drug Importation Program (Program) under newly created s. 381.02035, F.S. The Agency for Health Care Administration (AHCA) is directed to establish the Program for the safe and effective importation of prescription drugs from Canada which will have the highest potential cost savings to the state.

[101] Section 499.003(48), F.S.
[102] Section 499.01(2), F.S.
[103] Section 499.01(2), F.S.
[104] Section 499.01(2), F.S.
[105] Chapter 465, F.S.; Florida Board of Pharmacy, https://floridaspharmacy.gov/ (last visited March 22, 2019).
[106] Section 465.022, F.S
[107] Section 465.0465(1), F.S.

Definitions for the Program are specifically created:

- *Agency* means the Agency for Health Care Administration.
- *Canadian supplier* means a manufacturer, wholesale distributor, or pharmacy appropriately licensed or permitted under Canadian law to manufacture, distribute, or dispense prescription drugs.
- *Drug or Prescription drug* has the same meaning as "prescription drug" in s. 499.003, F.S.
- *Federal Act* means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. ss. 301 et seq.; Stat. 1040 et seq. as amended by the Drug Quality and Security Act, 21 U.S.C. 351 et seq.
- *Importer* means a wholesale distributer, pharmacy, or pharmacist importing prescription drugs into this state under this Program.
- *Pharmacist* means a person who holds an active and unencumbered license to practice pharmacy pursuant to chapter 465.
- *Program* means the Canadian Prescription Drug Importation Program.
- *Track and Trace* means the product-tracing process for the components of the pharmaceutical distribution supply chain as described in Title II of the Drug Quality and Security Act, Drug Supply Chain Security Act, 21 U.S.C. 351 et seq.
- *Vendor* means the entity contracted by the Agency to manage specified functions of the Program.

An importation process for the Program is established which includes the selection of a vendor by the Agency, the identification of importers and suppliers, and establishment of eligibility for these entities. Some of these steps in the implementation process are delegated to the vendor or other entities to perform and have designated deadlines which are reflected in the chart below.

Responsibilities of the Parties – Drug Importation Program		
Party	**Responsibility**	**Deadline/Timeframe**
Agency Responsibilities		
Contract	Contract with Vendor to provide services	No deadline, but the Agency must submit its plan to HHS by January 1, 2020.
Safety concerns: Immediate Suspension	The Agency is authorized to immediately suspend the importation of a specific drug or the importation of specific drugs by a specific importer if there are safety concerns or there is any activity in violation of Canadian, federal, or state law. The suspension may be revoked if, after conduction and investigation, the Agency determines that no threat to public safety exists from unsafe drugs.	No time constraints.
Vendor Responsibilities		

Responsibilities of the Parties – Drug Importation Program		
Party	**Responsibility**	**Deadline/Timeframe**
Drug List	Develop a list of prescription drugs every 3 months that have the highest potential for cost savings to the state. Vendor should consider which drugs have shortages, specialty prescriptions, and high volume prescription drugs. The Agency may direct the vendor to revise the list, as necessary.	Review list every 3 months and revise as necessary
Relationship with Suppliers	Identify Canadian suppliers that are in full compliance with Canadian federal and provincial laws and regulations and the Federal Act who have agreed to export drugs on the list. Such suppliers must have also agreed to meet all or exceed federal track and trace requirements and applicable federal and state laws and regulations. Verify that all Canadian suppliers on the list meet all of the requirements and will export drugs at prices that will provide the state with cost savings. Contract with or facilitate contracts between eligible Canadian suppliers and eligible importers to import drugs under the Program. Ensure compliance with Title II of the DQSA by all suppliers, importers, and other distributors and participants in the Program. Assist the Agency with the annual report and provide any requested information on a timely basis.	No deadline
	For an imported shipment, the vendor shall statistically sample and test for authenticity and degradation in a manner consistent with the Federal Act: - For the initial shipment: **Each batch** of the drug in the shipment. - For each subsequent shipment: A statistically valid sample of the **shipment**.	Each batch or each shipment has requirements, depending on whether it is an initial or subsequent shipment of the drug.
Drug Importation Safety *Lab Testing Requirements*	Maintains qualified laboratory records, including data derived from all tests necessary to ensure drug comply with these requirements. Maintains information and documentation which demonstrates required testing was done in compliance with the Federal Act and any required federal and state testing guidelines. All testing must be done in a qualified lab which meets federal standards under the	

Responsibilities of the Parties – Drug Importation Program		
Party	**Responsibility**	**Deadline/Timeframe**
	Federal Act, applicable federal laws and regulations, and state laws and regulations.	
Certification Requirements	The vendor must certify that any imported drug is approved for marketing in the U.S., is not adulterated or misbranded, and meets all of the required U.S. labeling standards.	Certification for every drug.
Drug Importation Safety Certification Requirements	Vendor must maintain records, information, and documentation under this section for at least seven years.	Seven-year requirement
Records Retention	Must maintain a list of all registered importers participating in the Program.	The vendor must maintain a current list of importers.
Importers and Eligible Drugs for Importation		
Eligibility	The following entities or persons may be eligible to import drugs from a Canadian supplier under the Program after registering with the vendor and being deemed in compliance with all other requirements: 1. A wholesale distributor. 2. A pharmacy. 3. A pharmacist.	
Eligible Drugs	Eligible importers may import a drug from an eligible Canadian supplier, if the importer: - Meets the FDA's standards relating to safety, effectiveness, misbranding, and adulteration. - Importation would not violate patent law. - Importation is expected to generate cost savings; and - The drug is not: *A controlled substance as defined in 21 U.S.C. section 802; *A biological product as defined in 42 U.S.C. section 262; *An infused drug; *An intravenously injected drug; *A drug that is inhaled during surgery; or *A drug that is a parenteral drug, a drug which is determined by the Secretary of Health and Human Services to pose a threat.	
Drug Eligibility – Information Requirements	Participating importers must provide the following information to the Vendor: 1. The name and quantity of the active ingredient of the drug. 2. A description of the dosage form of the drug. 3. The date on which the drug is received. 4. The quantity of the drug that is received.	

Responsibilities of the Parties – Drug Importation Program		
Party	**Responsibility**	**Deadline/Timeframe**
	5. The point of origin and destination of the drug. 6. The price paid by the importer of the drug.	
	An importer must submit all of the following to the vendor: 1. The name and quantity of the active ingredient of the drug. 2. A description of the dosage of the drug. 3. The date on which the drug is received. 4. The quantity of the drug that is received. 5. The point of origin and destination of the drug. The price paid by the importer for the drug.	
Suppliers		
Supplier Eligibility Requirements	A supplier may export prescription drugs into this state under the Program if the supplier is: *In full compliance with relevant Canadian federal and provincial laws and regulations; *Complies with track and trace at the package level. *Identified by the vendor as eligible to participate in the Program.	No deadline.
Information and Documentation requirements	A participating Canadian supplier must submit the following information and documentation specifying all of the following, in addition to any other information deemed necessary by the Agency to ensure the protection of the public health: 1. The original source of the drug, including: a. The name of the manufacturer of the drug. b. The date on which the drug was manufactured. c. The location (country, state/province, and city) where the drug was manufactured. 2. The date on which the drug was shipped. 3. The quantity of each lot of the drug originally received and from which source. 4. The quantity of each lot of the drug originally received and from which source. 5. The lot or control number and the batch number assigned to the drug by the manufacturer.	Information must be submitted for each drug imported.

Responsibilities of the Parties – Drug Importation Program		
Party	**Responsibility**	**Deadline/Timeframe**
	The Agency may require that the vendor collect any other information necessary to ensure the protection of the public health.	
Required information submission	Eligible Canadian suppliers and importers participating under the Program must: 1. Comply with the tracking and tracing requirements under federal law. 2. May not distribute, dispense, or sell prescription drugs under the Program outside of the state.	No deadline.
Responsibilities – Applicable to Multiple Parties		
Surety Bond – Administrative Penalties for non-performance *Vendor, Suppliers and Wholesalers*	Requires the vendor and all suppliers and wholesalers to secure a $1 million minimum surety bond or comparable security arrangement which escalates in value as volume escalates for contractual performance issues to ensure: 1. Payment of administrative penalties imposed by the AHCA or any other state agencies. 2. Performance of contractual and statutory obligations while acting on behalf of the AHCA, the state, or other state agencies. 3. Assessment of unpaid administrative which are unpaid 30 days after assessment. 4. Assessment of claims up to one year after the end of the contract, the vendor, supplier, or wholesaler's licensure is no longer valid, or the Program has ended, whichever occurs later.	Must secure surety bond or comparable arrangement at contract award and maintain throughout contract term.
Surety Bond Requirements for Claims related to civil and criminal litigation. *Vendor Suppliers Wholesalers*	Requires the vendor and all suppliers and wholesalers to secure a $1 million minimum surety bond or comparable security arrangement which escalates in value as volume escalates for negligence related claims issues and other torts, for example, to ensure: 1. Payment of legal claims awarded in a court of law; 2. Performance of contractual and statutory obligations while acting on behalf of the AHCA, the state, or other state agencies. 3. Assessment of judgements or claims which are unpaid 60 days after final judgement. 4. Assessment of claims up to one year after the end of the contract, the vendor, supplier, or wholesaler's licensure is no	Must secure surety bond or comparable arrangement at contract award and maintain throughout contract term.

Responsibilities of the Parties – Drug Importation Program		
Party	**Responsibility**	**Deadline/Timeframe**
	longer valid, or the Program has ended, whichever occurs later.	
Track and Trace Requirements *Suppliers and Importers*	Eligible Canadian suppliers and importers participating under the Program must comply with tracking and tracing requirements of 21 U.S.C. ss. 360eee et seq. Suppliers and importers may not distribute, dispense, or sell drugs imported under the Program outside of the Program or the state.	No deadline.
Federal Approval of Program	Once approved by the HHS, the Agency will notify the President of the Senate, the Speaker of the House of Representatives, and the relevant committees of the Senate and the House. The Program may not be implemented until reviewed and approved by the Legislature. The bill requires that the estimated cost savings to the state and whether proposed Program meets the safety standards must be considered as part of the final review process.	No deadline. The review process starts when notified by the Agency that the plan has been approved by HHS.
Annual Report	The Agency must submit an Annual Report to the Governor, the President of the Senate, and the Speaker of the House of Representatives on the operation of the Program during the previous fiscal year along with other components detailed below.	December 1 each year.

The plan that is submitted for federal approval by July 1, 2020, must include, at a minimum, the following elements:

- The AHCA's plan for operating the Program.
- A demonstration of how the prescription drugs will be imported into the state and meet the applicable federal and state standards for safety and cost effectiveness.
- A demonstration of how the drugs imported into the state under the Program will comply with federal tracing procedures.
- A list of prescription drugs that have the highest potential for cost savings to the state through importation at the time the request is submitted.
- Inclusion of an estimate of the total cost savings attributable to the Program.
- Inclusion of an estimate of the total costs of Program implementation to the state.
- Inclusion of a list of potential Canadian suppliers from which the state would import drugs and a demonstration that the suppliers are in full compliance with relevant Canadian federal and provincial laws and regulations.

The AHCA is also responsible for an Annual Report and its components which must include, at a minimum, each year:

- A list of prescription drugs that were imported under the Program.

- The number of participating entities.
- The number of prescriptions dispensed through the Program.
- The estimated cost savings during the previous fiscal year and to date.
- A description of the methodology used to determine which prescription drugs should be included on the Wholesale Prescription Drug Importation List.
- Documentation demonstration how the Program ensures how the Program ensures that:
  - Canadian suppliers participating in the Program are of high quality, of high performance, and in full compliance with relevant Canadian federal and provincial laws and regulations;
  - Prescription drugs imported under the Program are not shipped, sold, or dispensed outside of the state once in the possession of the importer;
  - Prescription drugs imported under the Program are pure, unadulterated, potent, and safe;
  - The Program does not put consumers at a higher health and safety risk than if the Program did not exist; and
  - The Program provides cost savings to the state on imported prescription drugs.

Rulemaking authority is granted to the AHCA to implement the Program.

Section 2 provides an effective date of July 1, 2019.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

Supremacy Clause

As noted earlier in the analysis, in Maine, several Maine pharmacy groups sued the state under a couple of theories, including the Supremacy Clause of the United States Constitution, Art. VI, cl. 2, arguing that federal law preempted state law and that federal law had, for now, created a "closed regulatory scheme which strictly limited the introduction of prescription drugs into interstate commerce. The plaintiffs also point out that Congress contemplated the potential importation of prescription drugs from Canada

in the MMA, but that this section had not taken effect because the HHS Secretary has not granted the necessary certification."[108]

The opinion further discusses those situations where state law can still rebut the presumption regarding preemption. The Court must begin with the "presumption that the state statute is valid,[109] particularly if the state law is a matter involving issues regulating public health.[110] There is also a presumption for the state if the area and subject matter is "in any field in which there is a history of state law regulation, even if there is also a history of federal law regulation."[111] Congress must clearly preempt state law if it is regulating in an area where the state traditionally regulates.[112] In the present case, *Ouellette,* the Plaintiffs' argument is that preemption should apply because the amendments passed by the state of Maine to allow for the drug importation program touch on foreign affairs and that subject matter is reserved traditionally for the federal government.[113]

The Court noted in *Ouellette* that Congress had legislated explicitly with respect to the importation of drugs from Canada and the MMA has provided a specific path to legally permissible importation.[114] The Eighth Circuit had also weighed in on this issue and the *Ouellette* court repeated those findings:

> That Congress created a special procedure for authorizing importation of prescription drugs from Canada supports our conclusion that the pre-existing system established by the FDCA does not permit such importation. While it is true that no federal statute by its express terms bans importation of prescription drugs from Canada, such an explicit country-by-country prohibition is unnecessary to accomplish the task. By creating the comprehensive regulatory system described above, Congress has effectively precluded importation of these drugs absent the sort of special authorization contemplated by 21 U.S.C. section 384.[115]

Foreign Dormant Commerce Clause

A state's drug importation program must also be carefully reviewed to ensure that it can meet the constitutionality tests of the foreign dormant commerce clause and does not place an undue burden on foreign commerce and the role that the federal government plays in the implementation of foreign policy. The possibility of potential conflicts, therefore are likely less here since there is a federal statute that sets

[108] *Ouellette et al v. Mills et al, supra* note 76, at 9.
[109] *Pharm. Research & Mfrs. of Am. v. Walsh,* 538 U.S. 644, 661 (2003); quoted in *Ouellette v. Mills, at 10.*
[110] *See Hillsborough Cnty., Fla. v. Automated Med. Lab., Inc.,* 471 U.S. 707, 718 (1985); quoted in *Ouellette et al v. Mills et al, at 10.*
[111] *In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d 156., 176 (1st Cir. 2009) (citing *Wyeth,* 555 U.S. at 565, n. 3).
[112] *Nat'l Foreign Trade Council v. Natsios,* 181 F.3d 38, 73 (1st Cir. 1999)(citing *Rice,* 331 U.S. at 230). The *Natsios* case dealt with a claim by Massachusetts' that its law restricting trade with Burma was an exercise of its procurement authority, a traditional area of state power.
[113] *Supra* note 76, at 11.
[114] *Ouellette v. Mills, supra* note 76, at 15.
[115] *In re Canadian Import Antitrust Litig.,* 470 F.3d 785, 790 (8th Cir. 2006). (cited in *Ouellette v. Mills*).

forward a path for federal approval of a program. Concerns of intersections with other pharmaceutical programs and arguments, such as those made below about multiple regulatory schemes, may be issues to be aware of, but they should not have an impact on international relations.[116]

Most recently in Maryland, the U.S. Supreme Court declined to review an appeal from the U.S. District Court of Appeals for the Fourth Circuit on a determination that Maryland's state-based price-gouging statute was a violation of the dormant commerce clause as it interfered with interstate commerce as it regulated transactions outside of the state.[117]"The principle against extraterritoriality as it relates to the dormant commerce clause is derived from the notion that 'a state may not regulate commerce occurring wholly outside of its borders."[118]

Maryland had sought an appeal at the U.S. Supreme Court of an unfavorable ruling in 2018 from the federal appeals court. That ruling had held that Maryland had illegally regulated wholesale pricing by drug companies through a provision it had enacted in 2017 which prohibited what the state termed as "unconscionable" price increases for essential drugs no longer covered by patents or generics that were sold in the state.[119] The conduct targeted by the law was the upstream pricing and sale of prescription drugs, all of which occurred outside of Maryland which as the court noted then requires the manufacturers and wholesalers to act in accordance with Maryland law outside of Maryland.[120]

From its "cases concerning extraterritorial effects of state economic regulation," the Supreme Court outlined the principle against extraterritoriality in a Connecticut case where residents were prohibited from crossing state lines to purchase cheaper beer:

1) A state statute may not regulate "commerce that takes place wholly outside of the State's borders, whether or not the comer has effects within the State.[121] Specifically, a state law may not have the practical effect of establishing a scale of prices for use in other states."[122]
2) A statute that directly controls commerce occurring wholly outside the {legislating state's} boundaries… is invalid regardless of whether the

[116] Anna Zaret and Darien Shanske, *The Dormant Commerce Clause: What Impact Does It Have on the Regulation of Pharmaceutical Costs?*(November 2017) National Academy for State Health Policy, https://nashp.org/wp-content/uploads/2017/11/DCC-White-Paper.pdf (last visited March 22, 2019).
[117] *Association for Accessible Medicines v. Frosh*, (887 F.3d 664. App 1a) (April 13, 2018).
[118] *Star Sci., Inc. v. Beales*, 278 F. 3d 339, 355 (4th Cir. 2002) (citing *Healy v. Beer Inst.*, 324, 335-36 (1989); *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 582-83 (1986); *Edgar v. MITE Corp.*, 456 U.S. 624, 642-43 (1082)(plurality opinion).
[119] Andrew Chung, *U.S. Top Court Rejects Maryland Bid to Revive Drug Price Gouging Law*, Reuters, https://www.reuters.com/article/us-usa-court-pharmaceuticals-idUSKCN1Q81T9 (last visited March 22, 2019).
[120] *Supra* note 117, at 14.
[121] *Healy* at 336.
[122] *Healy* (quoting *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 528 (1935).

statute's extraterritorial reach was intended by the legislature."[123] The statute's "practical effect" is the focus of the inquiry.[124]

3) In evaluating a statute's "practical effect," the Court considers "not only… the consequences of the statute itself, but also …how the challenged statute may interact with the legitimate regulatory regimes of other States and what effect would arise if…every {} State adopted similar legislation.[125] This is because "the Commerce Clause protects against inconsistent legislation arising from the projection of one state regulatory regime into the jurisdiction of another State."[126]

Because the Act targets wholesale rather than retail pricing, the court notes that it has the potential to subject the manufacturers to conflicting state requirements.[127]

"The manufacturer's compliance would require more than modification of their distribution systems; it would force them to enter into a separate transaction for each state in order to tailor their conduct so as not to violate any state's price restrictions…The potential for 'the kind of competing and interlocking local economic regulation that the Commerce Clause was meant to preclude'[128] is therefore both real and significant. We are thus pressed to invalidate the Act."[129]

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Wholesalers, pharmacies, and pharmacists who are licensed entities would potentially be eligible under the bill to participate as importers under the Program which they are not currently able to do. To the extent that such entities participate in the Program to import less expensive FDA-approved drugs, they may experience cost savings which may be passed along to entities that purchase those drugs in Florida.

C. Government Sector Impact:

The AHCA could need additional resources to implement the bill before any cost savings from the importation Program is implemented.[130]

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[123] *Id.*
[124] *Id.*
[125] *Healy* at 336.
[126] *Healy* at 336-37.
[127] *Supra* note 117, at 17.
[128] *Healy* at 337.
[129] *Supra* note 117, at 18.
[130] Agency for Health Care Administration, *House Bill 19 Analysis* (March 1, 2019) (on file with the Senate Committee on Health Policy).

The AHCA has identified the need for six additional personnel dedicated to the project who will be developing, procuring, and managing and conducting oversight and monitoring activities. The AHCA would begin recruitment activities immediately upon adoption of the bill as staff are needed to start Program design activities, development of the competitive solicitation, request for federal authority, etc.

The positions could include:

- One AHC Administrator – SES Supervisor position
- Five Government Analyst II positions
  - Identify Canadian suppliers that are in full compliance with federal and provincial laws.
  - Contract with eligible Canadian suppliers or facilitate contracts between eligible importers and Canadian suppliers as described in the bill.
  - Complete a comprehensive pharmacy cost analysis to demonstrate the cost savings achieved through the importation of specific drugs.

AHCA Fiscal Impact		
(Contingent Upon Federal Approval)	**First Year of Implementation**	**2nd Year and Beyond: Recurring Expenditures**
FTE:		
1.00 - AHCA Administrator - SES	$ 98,345	$ 98,345
5.00 - Government Analyst II	$ 409,770	$ 409,770
Operational Expenses:	$ 64,380	$ 37,722
Grand Total:	**$ 572,495**	**$ 545,837**

The underlying bill was expected to yield an indeterminate amount of savings in the Medicaid program, the Department of Corrections, and possibly other state programs, but the CS no longer targets those programs directly. The fiscal impact of the CS/SB 1528 on government expenditures is indeterminate.

The AHCA did not provide an estimate of the costs to contract with a third-party vendor to administer the Program.

The Board of Pharmacy, within the Department of Health, would be responsible for the licensing and permitting of business entities acting as importers, wholesalers, or suppliers.

VI. Technical Deficiencies:

The Department of Business and Professional Regulation indicates that the bill applies to "prescription drugs" which, pursuant to s. 499.003(40), F.S., applies not only to finished dosage forms, but also to active pharmaceutical ingredients (API) that are routinely imported for further manufacturing and/or distribution by Florida companies.[131]

[131] Dep't of Business and Professional Regulation, *Senate Bill 1528 Analysis*, at 11 (March 5, 2019) (on file with the Senate Committee on Health Policy).

VII. Related Issues:

Canadian Drug Supply

Canada's population is one-ninth the population of the United States, 35 million, compared to 318 million in 2015.[132] The number of prescriptions dispensed in the United States was almost seven times larger than in Canada and, taking into account the number of individuals and the number of prescriptions, one researcher in 2010, and again in 2015, calculated how long Canada's drug supply would last if 20 percent of Americans sought to have their prescriptions filled in Canada. In 2015, the number of days' supply without any additional manufacturing or imports is 150.83 days.[133] In 2010, the days' supply was 201 days before the Canadian drug supply was depleted.[134]

The researcher does point out that Canada has options to meet a growing demand, such as increasing its drug manufacturing output, increasing pharmaceutical imports, continuing the practice of allowing internet pharmacies to fill medications from foreign sources while looking the other way from a regulatory standpoint, or calling a halt to foreign sales of prescriptions.[135] The researcher also noted that Canada imported $13.180 billion in pharmaceuticals from the United States in 2015 and the United States was Canada's largest supplier of pharmaceuticals at 33.1 percent.[136]

Another concern is that Canada has been experiencing its own access to drug issues and rising drug prices. Health Canada, Canada's national health ministry, recently released its own *Interim Report of the Advisory Council on the Implementation of National Pharmacare* on how to implement a national drug care program.[137] How Canada moves forward with this plan may impact how pharmacies and vendors in Canada operate in the future.

Canadian Law Provisions

The import and export of health products in Canada is regulated under Canada's *Food and Drugs Act* and its associated regulations. No drugs may be sold that are mislabeled, or adulterated.[138] Depending on how a product is labeled as it leaves Canada, for the Canadian market or the U.S. market, it may be considered "mislabeled" under one of the markets.

Additionally, under Canadian Federal Regulation A.01.045, all exports of food and drugs from Canada must have a certificate attached which is signed by the exporter attesting to the legality of the items and that the items being shipped are done so accordance with the laws of its

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[132] Marv Shephard, *U.S. Drug Importation: Impact on Canada's Prescription Drug Supply,* Health Economics & Outcome Research: Open Access, Vol. 4, Iss.1 (February 5, 2018) http://www.safemedicines.org/wp-content/uploads/2017/08/us-drug-importation-impact-on-canadas-prescription-drug-supply-2471-268X-1000146.pdf (last visited March 22, 2019).
[133] Marv Shephard, *supra* note 132, at 3.
[134] Marv Shephard, *supra* note 132, at 3.
[135] Marv Shephard, *supra* note 132, at 4.
[136] Marv Shephard, *supra* note 132, at 4.
[137] Health Canada, *Advisory Council on the Implementation of National Pharmacare, https://www.canada.ca/en/health-canada/corporate/about-health-canada/public-engagement/external-advisory-bodies/implementation-national-pharmacare.html#a1* (last visited March 22, 2019).
[138] R.S., c. F-27, s. 8. (Can.)

destination.[139] An inspector is also authorized by law to take samples of an article at any reasonable time if the inspector believes that a package contains an item which is covered by the *Food and Drugs Act* and those items may also be subject to seizure.[140]

Federal Approval

The CS directs the AHCA to, by July 1, 2020, submit a request to the federal HHS Secretary for approval of the Florida Program under 21 USC s. 384(l). That subsection of federal law provides that the federal drug importation program under 21 USC s. 384 becomes effective only if the Secretary certifies to Congress that the implementation of the federal program will pose no additional risk to the public's health and safety and result in a significant reduction in the cost of covered products to the American consumer. No HHS Secretary has yet sent such a certification to Congress. The cited subsection also provides for termination of the federal program. However, the subsection contains no authority for the Secretary to approve any state-based drug importation program under any circumstances, nor to waive any aspects of the federal program regarding public health and safety or cost reduction, which other states have requested through the FDA for their own state-based program proposals.

VIII. Statutes Affected:

This bill creates section 381.02035 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Policy on March 25, 2019:
The CS removes several provisions from the underlying bill, adds several safety and transparency components, clarifies existing components, and aligns the Program with updated tracing procedures under federal law. The CS:

- Removes from the underlying bill the provision that pharmacists or wholesalers may import Canadian prescription drugs under the Program only if they are employed by or under contract with:
  - The Department of Health's central pharmacy, for distribution to a county health department or free clinic for clients served in those settings;
  - A Medicaid pharmacy, for dispensing to the pharmacy's Medicaid recipients;
  - The Department of Corrections (DOC), for dispensing to inmates in DOC custody;
  - A developmental disabilities center, for dispensing to clients treated in those settings; or
  - A state-owned, state-operated, or state-supported treatment facility for persons with mental illness, or a private facility designated by the Department of Children and Families for that purpose, for dispensing to persons treated in those settings.

[139] C.R.C., SOR/80-318, s-1(Can.)
[140] R.S.C., 1985, C. F-27, Part II(23)

- Removes from the underlying bill the requirement for the AHCA to begin operating the Program within 6 months of receiving federal approval.
- Requires that any Canadian supplier must comply fully with U.S. law and any other federal and state laws and regulation relating to track and trace procedures. The definitions were updated to define what is meant by track and trace procedures.
- Requires the vendor, suppliers, and importers under the Program to post two surety bonds of at least $1 million each at the time of contract execution to ensure contractual performance and non-payment of any administrative penalties over the contract term and to ensure participation in any civil or criminal litigation and payment of any claims or judgment that may arise from those actions. For suppliers and importers, the minimum amount of the bonds may escalate over time depending on Program volume.
- Requires the vendor under contract with the AHCA to maintain a list of all registered importers participating in the Program.
- Requires the vendor to ensure that all suppliers, importers, distributers, and other Program participants remain in compliance with all laws and regulations, U.S. and Canadian.
- Requires that a maximum administrative fee and profit margin amount or rate will be set by the state in the General Appropriations Act for any participating wholesaler, pharmacy, or pharmacist in the Program.
- Adds a limitation for participating suppliers and importers that drugs imported under this Program may not be sold outside of the Program.
- Sets a record retention requirement for laboratory testing records of seven years.
- Adds components to what should be included in the state's plan submission to HHS to include information about the state's track and trace procedures, the state's estimated costs to implement the Program, and a list of Canadian suppliers willing to do business in Florida.
- Requires that the Program approved at the federal level must receive final approval from the Legislature before being implemented. Additional information about safety and cost effectiveness of the plan must accompany the approval request to the Legislature.
- Requires that the AHCA must describe how it has complied with federal track and trace requirements in its Annual Report.

B. Amendments:

None.

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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/25/2019	.	
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The Committee on Health Policy (Bean) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Section 381.02035, Florida Statutes, is created to read:

381.02035 Canadian Prescription Drug Importation Program.—

(1) PROGRAM ESTABLISHED.—The Agency for Health Care Administration shall establish a program for the importation of safe and effective prescription drugs from Canada which have the highest potential for cost savings to the state.

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

(a) "Agency" means the Agency for Health Care Administration.

(b) "Canadian supplier" means a manufacturer, wholesale distributor, or pharmacy appropriately licensed or permitted under Canadian law to manufacture, distribute, or dispense prescription drugs.

(c) "Drug" or "prescription drug" has the same meaning as "prescription drug" in s. 499.003.

(d) "Federal Act" means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq. as amended by the Drug Quality and Security Act, 21 U.S.C. 351 et seq.

(e) "Importer" means a wholesale distributor, pharmacy, or pharmacist importing prescription drugs into this state under the program.

(f) "Pharmacist" means a person who holds an active and unencumbered license to practice pharmacy pursuant to chapter 465.

(g) "Program" means the Canadian Prescription Drug Importation Program.

(h) "Track-and-trace" means the product-tracing process for the components of the pharmaceutical distribution supply chain as described in Title II of the Drug Quality and Security Act, Drug Supply Chain Security Act, 21 U.S.C. 351 et seq.

(i) "Vendor" means the entity contracted by the agency to manage specified functions of the program.

(3) ELIGIBLE CANADIAN SUPPLIERS.—A Canadian supplier may export drugs into this state under the program if the supplier

meets all of the following requirements:

(a) Complies fully with relevant Canadian federal and provincial laws and regulations.

(b) Complies fully with the Federal Act, including all other state and federal law and regulations relating to the track-and-trace requirements at the package level.

(c) Submits evidence at time of contract award and throughout the contract term of a surety bond or comparable security arrangement from this state or any other state in the United States in the minimum amount of $1 million. The agency shall reevaluate and adjust the amount of the bond annually, based on program volume. The surety bond or comparable security arrangement must include the State of Florida as a beneficiary. In lieu of the surety bond, the supplier may provide a comparable security arrangement such as an irrevocable letter of credit or a deposit into a trust account or financial institution which includes the State of Florida as a beneficiary. The purposes of the bond or other security arrangements for the program are to:

1. Ensure payment of any administrative penalties imposed by the agency or any other state agency under the contract when the supplier fails to pay within 30 days after assessment;

2. Ensure performance of contractual and statutory obligations by the supplier through use of a bond or other comparable security arrangements to receive payment of any other costs or fees incurred by the agency, the state, or other entities acting on behalf of the state if the supplier is non-compliant with its contractual and statutory obligations. If the supplier is assessed a penalty under the program and fails to

pay within 30 days after that assessment, the agency, the state, or an entity acting on behalf of the state may file a claim for reimbursement against the bond or other comparable security arrangement; and

3. Allow for claims to be made against the bond or other comparable security arrangements for up to 1 year after the supplier's contract under the program has ended with the agency or the state, the supplier's license is no longer valid, or the program has ended, whichever occurs last.

A surety bond or other comparable security arrangement is required regardless of the time of bid or negotiation process used by the agency or the type of final contract or agreement executed for services.

(d) Is identified by the vendor as eligible to participate in the program.

(e) Submits evidence at the time of contract award and throughout the contract term of a surety bond or comparable security arrangement from this state or any other state in the United States in the minimum amount of $1 million. The agency shall reevaluate and adjust the amount of the bond annually, based on program volume. The surety bond or comparable security arrangement must include the State of Florida as a beneficiary. In lieu of the surety bond, the supplier may provide a comparable security arrangement such as an irrevocable letter of credit or a deposit into a trust account or financial institution which includes the State of Florida as a beneficiary. The purposes of the bond or other security arrangements for the program are to:

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1. Indemnify the supplier in the event that any civil or criminal legal action is brought by the state, the agency, any other state agency, or private individuals or entities against the supplier because of the supplier's failure to perform under the contract, including, but not limited to, causes of actions for personal injury, negligence, and wrongful death;

2. Ensure payment by the supplier of legal judgements and claims that have been awarded to the state, the agency, other entities acting on behalf of the state, individuals, or organizations if the supplier is assessed a final judgement or other monetary penalty in a court of law for a civil or criminal action related to participation in the program. The bond or comparable security arrangement may be accessed if the supplier fails to pay any judgement or claim within 60 days after final judgement; and

3. Allow for civil and criminal litigation claims to be made against the bond or other comparable security arrangements for up to 1 year after the supplier's contract under the program has ended with the agency or the state, the supplier's license is no longer valid, or the program has ended, whichever occurs last.

(4) ELIGIBLE IMPORTERS.—

(a) The following entities or persons may import prescription drugs from a Canadian supplier under the program:

1. A wholesale distributor.

2. A pharmacy.

3. A pharmacist.

(b) An eligible importer must meet all of the following requirements at time of contract award and throughout the

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contract term:

1. Register with the vendor before importing drugs into the state under the program and be deemed in compliance with all requirements, including any relevant provisions of the Federal Act.

2. Submit evidence at time of contract award and throughout the contract term of a surety bond or other comparable security arrangement from this state or any other state in the United States in the amount of $1 million. The surety bond or comparable security arrangement must include the State of Florida as a beneficiary. In lieu of the surety bond, the supplier may provide a comparable security agreement such as an irrevocable letter of credit or a deposit into a trust account or financial institution which includes the State of Florida as a beneficiary, payable to the State of Florida. The purposes of the bond or other security arrangements for the program are to:

a. Ensure payment of any administrative penalties imposed by the agency or any other state agency under the contract when the importer fails to pay within 30 days after assessment;

b. Ensure performance of contractual and statutory obligations by the importer through use of a bond or other comparable security arrangements to receive payment of any other costs or fees incurred by the agency, the state, or other entities acting on behalf of the state if the importer is non-compliant with its contractual and statutory obligations. If the importer is assessed a penalty under the program and fails to pay within 30 days after that assessment, the agency, the state, or an entity acting on behalf of the state may file a claim for reimbursement against the bond or other comparable security

arrangement; and

c. Allow for claims to be made against the bond or other comparable security arrangements for up to 1 year after the importer's contract under the program has ended with the agency or the state, the importer's license is no longer valid, or the program has ended, whichever occurs last.

A surety bond or comparable document is required regardless of the time of bid or negotiation process used by the agency or the type of final contract or agreement executed for services.

(c) Submits evidence at the time of contract award and throughout the contract term of a surety bond or comparable security arrangement from this state or any other state in the United States in the minimum amount of $1 million. The agency shall reevaluate and adjust the amount of the bond annually, based on program volume. The surety bond or comparable security arrangement must include the State of Florida as a beneficiary. In lieu of the surety bond, the supplier may provide a comparable security agreement such as an irrevocable letter of credit or a deposit into a trust account or financial institution which includes the State of Florida as a beneficiary, payable to the State of Florida. The purposes of the bond or other security arrangements for the program are to:

1. Ensure participation of the supplier in any civil or criminal legal action by the state, the agency, any other state agency, or private individuals or entities against the supplier because of the supplier's failure to perform under the contract, including, but not limited to causes of actions for personal injury, negligence, and wrongful death;

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2. Ensure payment by the supplier through the use of a bond or other comparable security arrangements of legal judgements and claims that have been awarded to the agency, the state, other entities acting on behalf of the state, individuals, or organizations if the supplier is assessed a final judgement or other monetary penalty in a court of law for a civil or criminal action under the program. The bond or comparable security arrangement will be accessed if the supplier fails to pay any judgement or claim within 60 days after final judgement; and

3. Allow for civil and criminal litigation claims to be made against the bond or other comparable security arrangements for up to 1 year after the supplier's contract under the program has ended with the agency or the state, the supplier's license is no longer valid, or the program has ended, whichever occurs last.

(5) IMPORTATION PROCESS.—

(a) The agency shall contract with a vendor to provide services under the program. The vendor must submit evidence of a surety bond with any bid or initial contract negotiation documents and maintain documentation of evidence of such a bond with the agency throughout the throughout the contract term of a surety bond from this state or any other state in the United States in the same amount of $1 million. The surety bond or comparable security arrangement must include the State of Florida as a beneficiary. In lieu of the surety bond, the supplier may provide a comparable security agreement such as an irrevocable letter of credit or a deposit into a trust account or financial institution which includes the State of Florida as a beneficiary, payable to the State of Florida. The purposes of


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the bond or other security arrangements for the program are to:

1. Ensure payment of any administrative penalties imposed by the agency or any other state agency under the contract when the vendor fails to pay within 30 days after assessment;

2. Ensure performance of contractual and statutory obligations by the vendor through use of a surety bond or other comparable security arrangements to receive payment of any other costs or fees incurred by the agency, the state, or other entities acting on behalf of the state if the vendor is non-compliant with its contractual and statutory obligations. If the vendor is assessed a penalty under the program and fails to pay within 30 days after that assessment, the agency, the state, or an entity acting on behalf of the state may file a claim for reimbursement against the bond or other comparable security arrangement; and

3. Allow for claims to be made against the bond or other comparable security arrangements for up to 1 year after the vendor's contract under the program has ended with the agency or the state, the importer's license is no longer valid, or the program has ended, whichever occurs last.

A surety bond or comparable document is required regardless of the time of bid or negotiation process used by the agency or the type of final contract or agreement executed for services.

(b) Submits evidence at the time of contract award and throughout the contract term of a surety bond or comparable security arrangement from this state or any other state in the United States in the minimum amount of $1 million. The agency shall reevaluate and adjust the amount of the bond annually,

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based on program volume. The surety bond or comparable security arrangement must include the State of Florida as a beneficiary. In lieu of the surety bond, the supplier may provide a comparable security arrangement such as an irrevocable letter of credit or a deposit into a trust account or financial institution which names the State of Florida as a beneficiary. The purposes of the bond or other security arrangements for the program are to:

1. Ensure participation of the vendor in any civil or criminal legal action by the state, the agency, any other state agency, or private individuals or entities against the vendor because of the vendor's failure to perform under the contract, including, but not limited to causes of actions for personal injury, negligence, and wrongful death;

2. Ensure payment by the vendor through the use of a bond or other comparable security arrangements of legal judgements and claims that have been awarded to the agency, the state, other entities acting on behalf of the state, individuals, or organizations if the vendor is assessed a final judgement or other monetary penalty in a court of law for a civil or criminal action under the program. The bond or comparable security arrangement will be accessed if the vendor fails to pay any judgement or claim within 60 days after final judgement; and

3. Allow for civil and criminal litigation claims to be made against the bond or other comparable security arrangements for up to 1 year after the vendor's contract under the program has ended with the agency or the state, the vendor's license is no longer valid, or the program has ended, whichever occurs last.

(c) The vendor shall provide all of the following services at a minimum:

1. Develop a list every 3 month of drugs that have the highest potential for cost savings to the state if imported from Canada. In developing the list, the vendor shall consider, at a minimum, which drugs will provide the greatest cost savings to the state, including drugs for which there are shortages, specialty drugs, and high-volume drugs. The agency may direct the vendor to revise the list, as necessary.

2. Identify Canadian suppliers that are in full compliance with relevant Canadian federal and provincial laws and regulations and the Federal Act and who have agreed to export drugs identified on the list. The vendor must verify that such Canadian suppliers meet all of the requirements of the program and will export drugs at prices that will provide cost savings to the state while meeting or exceeding the track-and-trace federal and state laws and regulations.

3. Contract with such eligible Canadian suppliers, or facilitate contracts between eligible importers and Canadian suppliers, to import drugs under the program.

4. Maintain a listing of all registered importers that participate in the program.

5. Ensure compliance with Title II of the federal Drug Quality and Security Act P.L. 113-54 by all suppliers, importers and other distributors and participants in the program.

6. Assist the agency with the annual report as required in subsection (12) and provide any information requested by the agency for such report on a timely basis.

(d) The profit margin and administrative fees of any

participating wholesaler, pharmacy, or pharmacist on imported drug products is limited to a maximum amount as specified annually in the General Appropriations Act.

(6) ELIGIBLE PRESCRIPTION DRUGS.—Eligible importers may import a drug from an eligible Canadian supplier if:

(a) The drug meets the United States Food and Drug Administration's standards related to safety, effectiveness, misbranding, and adulteration;

(b) Importing the drug would not violate the patent laws of the United States;

(c) Importing the drug is expected to generate cost savings; and

(d) The drug is not:

1. A controlled substance as defined in 21 U.S.C. s. 802;

2. A biological product as defined in 42 U.S.C. s. 262;

3. An infused drug;

4. An intravenously injected drug;

5. A drug that is inhaled during surgery; or

6. A drug that is a parenteral drug, the importation of which is determined by the United States Secretary of Health and Human Services to pose a threat to the public health.

(7) DISTRIBUTION REQUIREMENTS.—Eligible Canadian suppliers and importers participating under the program:

(a) Must comply with the tracking and tracing requirements of 21 U.S.C. ss. 360eee et seq.

(b) May not distribute, dispense, or sell drugs imported under the program outside of the program or outside of this state.

(8) PRESCRIPTION DRUG SUPPLY CHAIN DOCUMENTATION.—


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(a) The vendor shall ensure the safety and quality of drugs imported under the program. The vendor shall:

1. For an initial imported shipment, ensure that each batch of the drug in the shipment is statistically sampled and tested for authenticity and degradation in a manner consistent with the Federal Act.

2. For any subsequent imported shipment, ensure that a statistically valid sample of the shipment was tested for authenticity and degradation in a manner consistent with the Federal Act.

3. Certify that the drug:

a. Is approved for marketing in the United States and is not adulterated or misbranded; and

b. Meets all of the labeling requirements under 21 U.S.C. s. 352.

4. Maintain qualified laboratory records, including complete data derived from all tests necessary to ensure that the drug is in compliance with the requirements of this section.

5. Maintain documentation demonstrating that the testing required by this section was conducted at a qualified laboratory in accordance with the Federal Act and any other applicable federal and state laws and regulations governing laboratory qualifications.

(b) All testing required by this section must be conducted in a qualified laboratory that meets the standards under the Federal Act and any other applicable federal and state laws and regulations governing laboratory qualifications for drug testing.

(c) The vendor shall maintain information and documentation

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submitted under this section for a period of at least 7 years.

(d) A participating importer must submit the all of following information to the vendor:

1. The name and quantity of the active ingredient of the drug.

2. A description of the dosage form of the drug.

3. The date on which the drug is received.

4. The quantity of the drug that is received.

5. The point of origin and destination of the drug.

6. The price paid by the importer for the drug.

(e) A participating Canadian supplier must submit the following information and documentation to the vendor specifying all of the following:

1. The original source of the drug, including:

a. The name of the manufacturer of the drug.

b. The date on which the drug was manufactured.

c. The location (country, state or province, and city) where the drug was manufactured.

2. The date on which the drug is shipped.

3. The quantity of the drug which is shipped.

4. The quantity of each lot of the drug originally received and from which source.

5. The lot or control number and the batch number assigned to the drug by the manufacturer.

(f) The agency may require that the vendor collect any other information necessary to ensure the protection of the public health.

(9) IMMEDIATE SUSPENSION.—The agency shall immediately suspend the importation of a specific drug or the importation of

drugs by a specific importer if it discovers that any drug or activity is in violation of this section or any federal or state law or regulation. The agency may revoke the suspension if, after conducting an investigation, it determines that the public is adequately protected from counterfeit or unsafe drugs being imported into the state.

(10) FEDERAL APPROVAL.—By July 1, 2020, the agency shall submit a request to the United States Secretary of Health and Human Services for approval of the program under 21 U.S.C. s. 384(1). At a minimum, the request must do all of the following:

(a) Describe the agency's plan for operating the program.

(b) Demonstrate how the drugs imported into the state under the program will meet the applicable federal and state standards for safety and effectiveness.

(c) Demonstrate how the drugs imported into the state under the program will comply with federal tracing procedures.

(d) Include a list of proposed drugs that have the highest potential for cost savings to the state through importation at the time that the request is submitted.

(e) Estimate the total cost savings attributable to the program.

(f) Provide the costs of program implementation to the state.

(g) Include a list of potential Canadian suppliers from which the state would import drugs and demonstrate that the suppliers are in full compliance with relevant Canadian federal and provincial laws and regulations as well as all applicable federal and state laws and regulations.

(11) NOTIFICATION OF FEDERAL APPROVAL.—Upon receipt of

federal approval of the program, the agency shall notify the President of the Senate, the Speaker of the House of Representatives, and the relevant committees of the Senate and the House of Representatives. The program may not be implemented until the Legislature approves the program as authorized by the federal government. As part of its review process for implementation approval, the Legislature shall consider the estimated cost savings to the state and whether the program has met the required safety standards.

(12) ANNUAL REPORT.—By December 1 of each year, the agency shall submit a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives on the operation of the program during the previous fiscal year. The report must include, at a minimum:

(a) A list of the drugs that were imported under the program;

(b) The number of participating entities;

(c) The number of prescriptions dispensed through the program;

(d) The estimated cost savings during the previous fiscal year and to date in the program;

(e) A description of the methodology used to determine which drugs should be included; and

(f) Documentation of how the program ensures the following criteria:

1. Canadian suppliers participating in the program are of high quality, high performance, and in full compliance with relevant Canadian federal and provincial laws and regulations as well as all United States and Florida laws and regulations;

2. Drugs imported under the program are not shipped, sold, or dispensed outside of the state or the program once in the possession of the importer;

3. Drugs imported under the program are unadulterated, potent, and safe;

4. The program does not put consumers at a higher health and safety risk than if the consumer did not participate; and

5. The program provides cost savings to the state.

(13) RULEMAKING.—The agency may adopt rules necessary to implement this section.

Section 2. This act shall take effect July 1, 2019.

================ T I T L E A M E N D M E N T ================

And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled

An act relating to the Canadian Prescription Drug Importation Program; creating s. 381.02035, F.S.; requiring the Agency for Health Care Administration to establish the Canadian Prescription Drug Importation Program; defining terms; authorizing a Canadian supplier to export drugs into this state under the program under certain circumstances; providing eligibility criteria and requirements for drug importers; requiring the agency to contract with a vendor to facilitate wholesale prescription drug importation under the program; providing responsibilities for the vendor; providing eligibility

criteria for prescription drugs, Canadian suppliers, and importers under the program; requiring participating Canadian suppliers and importers to comply with specified federal requirements for distributing prescription drugs imported under the program; prohibiting Canadian suppliers and importers from distributing, dispensing, or selling prescription drugs imported under the program outside the state; providing certain documentation requirements; requiring the agency to suspend the importation of drugs in violation of this section or any federal or state law or regulation; authorizing the agency to revoke the suspension under certain circumstances; requiring the agency to request federal approval of the program; requiring the request to include certain information; requiring the agency to begin operating the program within a specified timeframe after receiving federal approval; requiring the agency, in consultation with the vendor, to submit an annual report to the Governor and the Legislature by a specified date; providing requirements for such report; authorizing the agency to adopt rules; providing an effective date.

209730

LEGISLATIVE ACTION

Senate	.	House
Comm: WD	.	
03/25/2019	.	
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	.	

The Committee on Health Policy (Rouson) recommended the following:

Senate Amendment to Amendment (958184) (with title amendment)

Between lines 456 and 457
insert:

(14) REPEAL.—This section shall be repealed July 1, 2024, unless reviewed and saved from repeal through reenactment by the Legislature.

========== T I T L E A M E N D M E N T ==========

209730

And the title is amended as follows:

Between lines 497 and 498

insert:

providing for future legislative review and repeal of the program;

By Senator Bean

4-02077-19 20191528__

A bill to be entitled

An act relating to prescription drug importation programs for public programs; creating s. 381.02035, F.S.; establishing the Canadian Prescription Drug Importation Program within the Agency for Health Care Administration for a specified purpose; providing definitions; requiring the agency to contract with a vendor to facilitate wholesale prescription drug importation under the program; providing responsibilities for the vendor; providing eligibility criteria for prescription drugs, Canadian suppliers, and importers under the program; requiring participating Canadian suppliers and importers to comply with specified federal requirements for distributing prescription drugs imported under the program; prohibiting Canadian suppliers and importers from distributing, dispensing, or selling prescription drugs imported under the program outside of the state; requiring the agency to request federal approval of the program; providing requirements for such request; requiring the agency to begin operating the program within a specified timeframe after receiving federal approval; requiring the agency, in consultation with the vendor, to submit an annual report to the Governor and Legislature by a specified date; providing requirements for such report; authorizing the agency to adopt rules; providing an effective date.

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

Section 1. Section 381.02035, Florida Statutes, is created to read:

381.02035 Canadian Prescription Drug Importation Program.—

(1) PROGRAM ESTABLISHED.—The agency shall establish a program for the importation of safe and effective prescription drugs from Canada which have the highest potential for cost savings to the state.

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

(a) "Agency" means the Agency for Health Care Administration.

(b) "Canadian supplier" means a manufacturer, wholesale distributor, or pharmacy appropriately licensed or permitted under Canadian law to manufacture, distribute, or dispense prescription drugs.

(c) "County health department" means a health care facility established under part I of chapter 154.

(d) "Department" means the Department of Health.

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

(f) "Medicaid pharmacy" means a pharmacy licensed under chapter 465 which has a Medicaid provider agreement in effect with the agency and is in good standing with the agency.

(g) "Pharmacist" means a person who holds an active and unencumbered license to practice pharmacy pursuant to chapter 465.

(h) "Prescription drug" has the same meaning as in s. 499.003.

(i) "Program" means the Canadian Prescription Drug Importation Program.

(3) IMPORTATION PROCESS.—

(a) The agency shall contract with a vendor to provide services under the program.

(b) By December 1, 2019, the vendor shall develop, and each year thereafter shall revise, a Wholesale Prescription Drug Importation List that identifies the prescription drugs that have the highest potential for cost savings to the state. In developing the list, the vendor shall consider, at a minimum, which prescription drugs will provide the greatest cost savings to state programs, including prescription drugs for which there are shortages, specialty prescription drugs, and high-volume prescription drugs. The agency, in consultation with the department, shall review the Wholesale Prescription Drug Importation List every 3 months to ensure that it continues to meet the requirements of the program and may direct the vendor to revise the list, as necessary.

(c) The vendor shall identify Canadian suppliers who are in full compliance with relevant Canadian federal and provincial laws and regulations and who have agreed to export prescription drugs identified on the list. The vendor must verify that such Canadian suppliers meet all of the requirements of the program and will export prescription drugs at prices that will provide cost savings to the state. The vendor shall contract with such eligible Canadian suppliers, or facilitate contracts between eligible importers and eligible Canadian suppliers, to import prescription drugs under the program.

(d) The vendor must assist the agency with the annual

report required in subsection (9) and provide any information requested by the agency for such report.

(4) ELIGIBLE PRESCRIPTION DRUGS.—Eligible importers may import a prescription drug from an eligible Canadian supplier if:

(a) The drug meets the United States Food and Drug Administration's standards related to safety, effectiveness, misbranding, and adulteration;

(b) Importing the drug would not violate the patent laws of the United States;

(c) Importing the drug is expected to generate cost savings; and

(d) The drug is not:

1. A controlled substance as defined in 21 U.S.C. s. 802;

2. A biological product as defined in 42 U.S.C. s. 262;

3. An infused drug;

4. An intravenously injected drug;

5. A drug that is inhaled during surgery; or

6. A drug that is a parenteral drug, the importation of which is determined by the United States Secretary of Health and Human Services to pose a threat to the public health.

(5) ELIGIBLE CANADIAN SUPPLIERS.—A Canadian supplier may export prescription drugs into this state under the program if the supplier is:

(a) In full compliance with relevant Canadian federal and provincial laws and regulations; and

(b) Identified by the vendor as eligible to participate in the program.

(6) ELIGIBLE IMPORTERS.—The following entities may import

prescription drugs from a Canadian supplier under the program:

(a) A pharmacist or wholesaler employed by or under contract with the department's central pharmacy, for distribution to a county health department or free clinic for dispensing to clients treated in such department or clinic.

(b) A pharmacist or wholesaler employed by or under contract with a Medicaid pharmacy, for dispensing to the pharmacy's Medicaid recipients.

(c) A pharmacist or wholesaler employed by or under contract with the Department of Corrections, for dispensing to inmates in the custody of the Department of Corrections.

(d) A pharmacist or wholesaler employed by or under contract with a developmental disabilities center, as defined in s. 393.063, for dispensing to clients treated in such center.

(e) A pharmacist or wholesaler employed by or under contract with a treatment facility, as defined in s. 394.455, for dispensing to patients treated in such facility.

(7) DISTRIBUTION REQUIREMENTS.—Eligible Canadian suppliers and importers participating under the program:

(a) Shall comply with the tracking and tracing requirements of 21 U.S.C. ss. 360eee et seq.; and

(b) May not distribute, dispense, or sell prescription drugs imported under the program outside of the state.

(8) FEDERAL APPROVAL.—By July 1, 2020, the agency shall submit a request to the United States Secretary of Health and Human Services for approval of the program under 21 U.S.C. s. 384(l). The agency shall begin operating the program within 6 months after receiving such approval. The request must, at a minimum:

(a) Describe the agency's plan for operating the program;

(b) Demonstrate how the prescription drugs imported into the state under the program will meet the applicable federal and state standards for safety and effectiveness;

(c) Include a list of prescription drugs that have the highest potential for cost savings to the state through importation at the time that the request is submitted;

(d) Estimate the total cost savings attributable to the program; and

(e) Include a list of potential Canadian suppliers from which the state would import prescription drugs and demonstrate that the suppliers are in full compliance with relevant Canadian federal and provincial laws and regulations.

(9) ANNUAL REPORTING.—By December 1 of each year, the agency shall submit a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives on the operation of the program during the previous fiscal year. The report must include, at a minimum:

(a) A list of the prescription drugs that were imported under the program;

(b) The number of participating entities;

(c) The number of prescriptions dispensed through the program;

(d) The estimated cost savings during the previous fiscal year and to date;

(e) A description of the methodology used to determine which prescription drugs should be included on the Wholesale Prescription Drug Importation List; and

(f) Documentation demonstrating how the program ensures

that:

1. Canadian suppliers participating in the program are of high quality, of high performance, and in full compliance with relevant Canadian federal and provincial laws and regulations;

2. Prescription drugs imported under the program are not shipped, sold, or dispensed outside of the state once in the possession of the importer;

3. Prescription drugs imported under the program are pure, unadulterated, potent, and safe;

4. The program does not put consumers at a higher health and safety risk than if the program did not exist; and

5. The program provides cost savings to the state on imported prescription drugs.

(10) RULEMAKING AUTHORITY.—The agency may adopt rules to implement this section.

Section 2. This act shall take effect July 1, 2019.

The Florida Senate

Committee Agenda Request

To: Senator Gayle Harrell, Chair
Committee on Health Policy

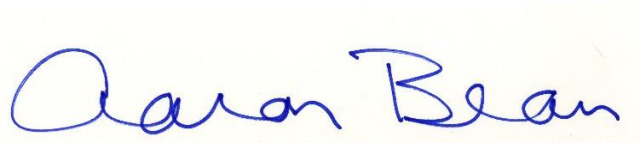
Subject: Committee Agenda Request

Date: March 19, 2019

I respectfully request that **Senate Bill # 1528**, relating to Prescription Drug Importation Programs for Public Programs, be placed on the:

☐ committee agenda at your earliest possible convenience.

☒ next committee agenda.



Senator Aaron Bean
Florida Senate, District 4

File signed original with committee office

THE FLORIDA SENATE

APPEARANCE RECORD

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

3/25/19
Meeting Date

1528
Bill Number (if applicable)

958184
Amendment Barcode (if applicable)

Topic Importation

Name Don Bell

Job Title Consultant

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Phone 705.330.2240

Orillia Ont. Canada L3V 2H3
City *State* *Zip*

Email dwbell.hockeye@gmail.com

Speaking: ☐ For ☒ Against ☐ Information

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

Representing PSM

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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3/25/19
Meeting Date

1528
Bill Number (if applicable)

958184
Amendment Barcode (if applicable)

Topic Importation

Name Peter Pitts

Job Title President, Center for Medicine in the Public Interest

Address 54 Riverside Drive
Street

New York NY 10024
City *State* *Zip*

Phone 212-729-3618

Email ppitts@cmpi.org

Speaking: ☐ For ☒ Against ☐ Information

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

Representing Center for Medicine in the Public Interest

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☑ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

3/25/19
Meeting Date

1528
Bill Number (if applicable)

Topic Importation

Amendment Barcode (if applicable)

Name George Karavestas

Job Title

Address 5580 SW 84th Terrace
Street
Miami FL 33143
City *State* *Zip*

Phone 305 608 1554

Email

Speaking: ☐ For ☒ Against ☐ Information

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

Representing Partnership For Safe Medicines

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☐ No

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

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

S-001 (10/14/14)

Duplicate

THE FLORIDA SENATE

APPEARANCE RECORD

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

3/25/2019
Meeting Date

SB 1528
Bill Number (if applicable)

Topic Prescription Drug Importation Programs for Public Programs

Amendment Barcode (if applicable)

Name Zayne Smith

Job Title Associate State Director

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Phone 850-228-4243

Tallahassee FL 32301
City *State* *Zip*

Email zsmith@aarp.org

Speaking: ☐ For ☐ Against ☐ Information

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

Representing AARP Florida

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

3/25/19
Meeting Date

1528
Bill Number (if applicable)

Topic Importation

Amendment Barcode (if applicable)

Name Shabbir Safdar

Job Title Executive Director

Address 315 Montgomery St. #[redacted]9004
Street

Phone 703-679-7233

San Francisco CA 94106
City *State* *Zip*

Email shabbir@safemedicines.or

Speaking: ☐ For ☒ Against ☐ Information

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

Representing Partnership for Safe Medicines

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

3/25/19
Meeting Date

1528
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic Importation

Name Sven Bergmann

Job Title Senior Advisor Anti Illicit Strategies

Address 315 Montgomery St., Suite 900
Street

Phone 9175706993

San Francisco CA 94104
City *State* *Zip*

Email SBergmann@venture-global.com

Speaking: ☐ For ☒ Against ☐ Information

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

Representing Partnership for Safe Medicines

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

March 25, 2019
Meeting Date

SB1528
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic Prescription Drug Importation

Name Michael Jackson

Job Title Executive Vice President and CEO

Address 610 North Adams Street
Street

Phone (850) 222-2400

Tallahassee — Florida — 32301
City — *State* — *Zip*

Email mjackson@pharmivew.com

Speaking: ☐ For ☐ Against ☒ Information

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

Representing Florida Pharmacy Association

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

3/25/19
Meeting Date

SB 1528
Bill Number (if applicable)

Topic Prescription Drug Importation Programs

Amendment Barcode (if applicable)

Name Bill Mincy

Job Title Govt Affairs VP, PPSC

Address 3375-I Capital Circle NE
Street

Phone 850-322-7740

Tallahassee FL 32308
City *State* *Zip*

Email bill.mincy@ppsconline.com

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Independent Pharmacy Owners

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☐ Yes ☑ No

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

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

SB 1528

Meeting Date | *Bill Number (if applicable)*

Topic Drug Importation

Amendment Barcode (if applicable)

Name Bill Hepscher

Job Title ~~Death~~ Founder The Canadian Medstore

Address 10708 Cory Lake Drive (*Street*) Phone

Tampa (*City*) FL (*State*) 33647 (*Zip*) Email

Speaking: ☐ For ☐ Against ☐ Information

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

Representing

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☐ No

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S-001 (10/14/14)

2019 AGENCY LEGISLATIVE BILL ANALYSIS

AGENCY: Department of Business & Professional Regulation

BILL INFORMATION	
BILL NUMBER:	HB 19
BILL TITLE:	Prescription Drug Importation Programs
BILL SPONSOR:	Rep. Leek
EFFECTIVE DATE:	7/1/19

COMMITTEES OF REFERENCE
1) Health Quality Subcommittee
2) Appropriations Committee
3) Health & Human Services Committee
4) Click or tap here to enter text.
5) Click or tap here to enter text.

CURRENT COMMITTEE
Health Quality Subcommittee

SIMILAR BILLS	
BILL NUMBER:	SB 1452
SPONSOR:	Sen. Gruters

PREVIOUS LEGISLATION	
BILL NUMBER:	N/A
SPONSOR:	N/A
YEAR:	N/A
LAST ACTION:	N/A

IDENTICAL BILLS	
BILL NUMBER:	N/A
SPONSOR:	N/A

Is this bill part of an agency package?
No

BILL ANALYSIS INFORMATION	
DATE OF ANALYSIS:	March 5, 2019
LEAD AGENCY ANALYST:	Drew F. Winters, Director; Div. of Drugs, Devices and Cosmetics
ADDITIONAL ANALYST(S):	Tom Coker, Technology Tracy Dixon, Service Operations Nick DuVal, OGC Rules Andy Janecek, Chief of Education and Testing, Division of Professions Kathryn E. Price, OGC DDC

	Andrew Butler, OGC DDC
LEGAL ANALYST:	Robin E. Smith, Deputy General Counsel
FISCAL ANALYST:	Raleigh Close, AFM

POLICY ANALYSIS

1. EXECUTIVE SUMMARY

The proposed bill creates two new programs for the importation of prescription drugs into the state of Florida: the Canadian Prescription Drug Importation Program under the Agency for Health Care Administration (AHCA) and the International Prescription Drug Importation Program under the Department of Business and Professional Regulation (Department). Both programs establish eligibility criteria and reporting requirements for importers and exporters of prescription drugs and require the assigned agency to coordinate with the federal government to receive federal approval prior to operating the programs. The International Prescription Drug Importation Program creates additional permit types and registration requirements under the Division of Drugs, Devices and Cosmetics (DDC) and the Florida Board of Pharmacy (FBOP). The bill provides for an effective date of July 1, 2019.

2. SUBSTANTIVE BILL ANALYSIS

1. PRESENT SITUATION:

The Florida Agency for Health Care Administration (AHCA) and the Florida Department of Health (DOH) are impacted by the provisions of the proposed bill. This analysis addresses those items and impacts that are applicable to the Department of Business and Professional Regulation (Department) and defers to AHCA and DOH representative to provide additional analyses regarding the impacts of the proposed legislation to their respective agencies.

The Department of Business and Professional Regulation, Division of Drugs, Devices and Cosmetics (DDC) safeguards the health, safety, and welfare of the citizens of the state of Florida from injury due to the use of adulterated, contaminated, misbranded drugs and drug ingredients by administering the provisions of the Florida Drug and Cosmetic Act created under ch. 499, F.S., and the Federal Food, Drug, and Cosmetic Act under 21 United States Code Chapter 9. DDC implements these requirements through the permitting, inspection and regulation of individuals and businesses that engage in the distribution of prescription drugs in and/or into the state of Florida, including the permitting of manufacturers and wholesale distributors of prescription drugs.

Pursuant to s. 499.01(2)(c), F.S., a Nonresident Prescription Drug Manufacturer permit is required for any person that is a manufacturer of prescription drugs located outside of this state or outside the United States that distributes such prescription drugs into Florida. Each such manufacturer must be permitted by the Department and comply with all of the provisions required of a prescription drug manufacturer under this part. Such person must comply with the licensing or permitting requirements of the jurisdiction in which the establishment is located and the federal act. A Nonresident Prescription Drug Manufacturer located outside the United States who intends to import prescription drugs from a foreign country may only import prescription drugs that are approved by the United States Food and Drug Administration (FDA) for importation and marketing in the U.S. Such facility must have a current FDA establishment registration and adhere to FDA approval standards prior to receiving a Florida Nonresident Prescription Drug Manufacturer permit. Currently, DDC has 126 permitted Nonresident Prescription Drug Manufacturers located in foreign countries. A Nonresident Prescription Drug Manufacturer who imports drugs must meet all documentation and record keeping requirements established under ch. 499, F.S., the rules promulgated thereunder, and the federal act for manufacturing and distribution of prescription drugs. Those records must be maintained by the permitted entity and retained at their facility for inspection upon request of the Department. Drugs received from a Florida Nonresident Prescription Drug Manufacturer may be marketed and sold to authorized recipients in Florida and outside of Florida. Nonresident prescription drug manufacturers must pay a biennial fee of $1,000.00 for issuance and/or renewal of their permit.

Pursuant to s. 499.01(2)(f), F.S., an Out-of-State Prescription Drug Wholesale Distributor permit is required for any person that is a wholesale distributor located outside this state, but within the United States or its territories, which engages in the wholesale distribution of prescription drugs into this state. The Out-of-State Prescription Drug Wholesale Distributor permit holder must maintain at all times a license or permit to engage in the wholesale

distribution of prescription drugs in compliance with the laws of the state in which it is a resident. If the state from which the wholesale distributor distributes prescription drugs does not require a license to engage in the wholesale distribution of prescription drugs, the distributor must be licensed as a wholesale distributor as required by the federal act. All prescription drugs offered for wholesale distribution must meet FDA requirements for marketing in interstate commerce. An Out-of-State Prescription Drug Wholesale Distributor permit holder must pay a biennial fee of $1,600.00 for issuance and/or renewal of their permit and must employ a licensed Certified Designated Representative to supervise the operations of the facility.

Currently, a Florida Out-of-State Wholesale Distributor permit cannot be issued to an establishment located in a foreign country and a foreign located facility would not be allowed to import prescription drugs into the state of Florida, unless it met the requirements for a Nonresident Prescription Drug Manufacturer permit set forth above. Additionally, the FDA does not currently permit the importation of prescription drugs by drug wholesalers under the Federal Food, Drug and Cosmetic Act.

Pursuant to s. 499.015, F.S., prescription drug and over-the-counter drug products manufactured, packaged or repackaged within the state of Florida must register their products with the Department prior to that product being sold. The Department may not register products that are not in compliance with the Federal Food, Drug and Cosmetic Act or Title 21 C.F.R.

2. EFFECT OF THE BILL:

Section 1:

Creates the Canadian Prescription Drug Importation Program with the Agency for Health Care Administration. The Department defers to AHCA to provide analysis and comment regarding this section.

Section 2:

Amends ch. 499, F.S., to create s. 499.0285, F.S., establishing the “International Prescription Drug Importation Program” within the Division of Drugs, Devices and Cosmetics (DDC) under the Department of Business and Professional Regulation (Department), for the importation of safe and effective prescription drugs. The program as established would permit eligible importers located in the state of Florida to import eligible prescription drugs from exporters located in foreign countries under the following conditions:

Exporters: An entity must be registered with the Department as an exporter and be licensed as: an International Prescription Drug Wholesale Distributor, a Nonresident Prescription Drug Manufacturer or an International Export Pharmacy, to export prescription drugs into Florida. A prescription drugs exported under the program must be exported to a properly registered and permitted importer and may not be distributed, sold or dispensed by the exporter to anyone residing outside of Florida.

Importers: An entity must be registered with the Department as an importer and be licensed as a wholesale distributor, a pharmacy, or pharmacist to import prescription drugs into Florida. An importer may not distribute, sell, or dispense prescription drugs imported under the program to anyone outside of Florida.

Laboratories: Registered importers and/or exporters of prescription drugs would be required to have a “qualified laboratory” conduct laboratory testing on each batch or shipment of prescription drugs, as required by proposed s. 499.0285(6), F.S. Qualified laboratories must be approved by the Department.

Eligible Prescription Drugs: The prescription drug imported pursuant to the program would need to meet United States Food and Drug Administration’s (FDA) standards related to safety, effectiveness, misbranding and adulteration. These standards are set forth under 21 U.S.C. ss. 351, 352, and 355. Importation of the specific prescription drug must not violate US patent laws and the drug may not be one of the following categories of prescription drug:

1.) a controlled substance under federal law;
2.) a biological product under federal law;
3.) an infused drug, intravenous drug;
4.) inhaled during surgery; or
5.) a parenteral drug determined to be unsafe by the US Secretary of Health and Human Services.

Prescription Drug Supply Chain Documentation: A participating importer registered under the program would be required to submit the following information and documentation to the Department regarding each prescription drug imported from a foreign country into Florida under the program:

1. The name and quantity of the active ingredient of the prescription drug.

2. A description of the dosage form of the prescription drug.

3. The date on which the prescription drug is shipped.

4. The quantity of the prescription drug that is shipped.

5. The point of origin and destination of the prescription drug.

6. The price paid by the importer for the prescription drug.

7. Documentation from the exporter specifying: a) the original source of the prescription drug; and b) the quantity of each lot of the prescription drug originally received by the seller from that source.

8. The lot or control number assigned to the prescription drug by the manufacturer.

9. The name, address, telephone number and professional license or permit number of the importer.

10. In the case of a prescription drug that is shipped directly by the first foreign recipient from the manufacturer:

a. Documentation demonstrating that the prescription drug was received by the recipient from the manufacturer and subsequently shipped by the first foreign recipient to the importer.

b. Documentation of the quantity of each lot of the prescription drug received by the first foreign recipient demonstrating that the quantity being imported into the state is not more than the quantity that was received by the first foreign recipient.

c. For an initial imported shipment, documentation demonstrating that each batch of the prescription drug in the shipment was statistically sampled and tested for authenticity and degradation.

d. For any subsequent imported shipment, documentation demonstrating that a statistically valid sample of the shipment was tested for authenticity and degradation.

11. In the case of a prescription drug that is not shipped directly from the first foreign recipient, documentation demonstrating that each batch in each shipment offered for importation into the state was statistically sampled and tested for authenticity and degradation.

12. Certification from the importer or manufacturer that the prescription drug: a) is approved for marketing in the United States and is not adulterated or misbranded; and b) meets all of the labeling requirements under 21 U.S.C. s. 352.

13. Qualified laboratory records, including complete data derived from all tests necessary to ensure that the prescription drug is in compliance with the requirements of this section.

14. Documentation demonstrating that the testing required by this section was conducted at a qualified laboratory.

15. Any other information the Department determines is necessary to ensure the protection of the public health.

The Department would be required to establish a reporting system for the above information and maintain the information and documentation submitted for a period of 4 years. The Department would be authorized to suspend the importation of a specific prescription drug or an importer's ability to import prescription drugs if it was determined that any prescription drug or activity by an importer or exporter is in violation of the Prescription Drug Importation Program. The Department would be required to reinstate importation of the drug or the exporter/importers authority if after investigation it was determined that the public health was adequately protected.

The Department is granted rulemaking authority to implement the provision of the program.

Sections 3 and 4:

Amends ss. 465.0157 and 465.017, F.S., to establish the permit and criteria for issuance of the "International Export Pharmacy" permit under the Florida Board of Pharmacy within the Department of Health (DOH), and amends DOH's inspection authority to include specific authorization for its agents and employees to inspect permitted International Export Pharmacies.

Section 5:

Amends s. 499.01, F.S., to create subsections (1)(s) and (2)(s) providing for the issuance, scope of work and licensure criteria for the "International Prescription Drug Wholesale Distributor" permit. The International Prescription Drug Wholesale Distributor would be required to have a resident prescription drug wholesale distributor permit from a foreign jurisdiction with which the United States has a current mutual recognition agreement, cooperation agreement, memorandum of understanding, or other federal mechanism recognizing the country's adherence to current good manufacturing practices for pharmaceutical products.

The bill further amends the definition of the Nonresident Prescription Drug Manufacturer permit under s. 499.01(2)(c), F.S., to establish registration requirements for such permit holders to participate in the International Prescription Drug Importation Program and to exempt such registrants from submitting prescription drugs importation lists currently required under s. 499.01(2)(c)2., F.S.

Section 6:

Amends permit application requirements under s. 499.012, F.S., to update cross references to include the International Prescription Drug Wholesale Distributor permit type within the subsections applicable to other Florida wholesale distributor permits, including the requirements for International Prescription Drug Wholesale Distributors to employ a Certified Designated Representative. Section 6 of the bill also requires International Prescription Drug Wholesale Distributor participating in the International Prescription Drug Importation Program to provide documentation demonstrating that proper agreements with the United States recognizing the foreign jurisdiction's adherence to current good manufacturing practices (cGMP).

Section 7:

Amends s. 499.005(20), F.S., to remove prescription drugs imported under the International Prescription Drug Importation Program from the list of prohibited acts.

Section 8:

Amends s. 499.0051, F.S., to remove importation of prescription drugs under the International Prescription Drug Importation Program from the list of criminal acts.

Section 9:

Amends s. 499.015, F.S., to clarify that prescription drugs imported under the International Prescription Drug Importation Program are not required to complete product registration.

Section 10:

Amends s. 499.065, F.S., amending cross references to include the International Prescription Drug Wholesale Distributor with other wholesale distributor permit types that must be inspected as often as necessary to ensure compliance and allowing immediate closure of the facility if it is determined that the facility is an imminent danger to the public health.

Section 11:

Requires the Department to negotiate with the federal government for authorization to operate a pilot program for importation of prescription drugs into Florida and provide a proposal that demonstrates the program's safety standards are consistent with the current federal requirements, limits importation of prescription drugs to entities permitted or licensed by Florida, and provides inspection and enforcement authority. Implementation of the International Prescription Drug Importation Program is contingent upon receiving arrangements or guidance from the federal government allowing operation of the program.

Section 12:

Provides an effective date of July 1, 2019.

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

If yes, explain:	Yes, the DDC would need to develop rules for the permitting of International Prescription Drug Wholesale Distributor permits and registration of importers and exporters, including application adoption and licensure requirements, under s. 499.0285, F.S.

	DDC would need to adopt rules for the review and approval of qualified laboratories, including applications and approval criteria. DDC would need to amend rules regarding: general definitions; inspections; wholesale distribution of prescription drugs; inspections; product tracking and tracing; and records of drugs, devices and cosmetics to conform references for the new permit and program. Amend Rule 61N-2.011, F.A.C., to adopt application updates for Nonresident Prescription Drug Manufacturer requirements specific to the International Prescription Drug Importation Program.
Is the change consistent with the agency's core mission?	Y☒ N☐
Rule(s) impacted (provide references to F.A.C., etc.):	Rule 61N-1.001, F.A.C. Rule 61N-1.011, F.A.C. Rule 61N-1.012, F.A.C. Rule 61N-1.018, F.A.C. Rule 61N-1.019, F.A.C. Rule 61N-1.028, F.A.C. Rule 61N-1.029, F.A.C. Rule 61N-1.031, F.A.C. Rule 61N-2.011, F.A.C.

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

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

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

If yes, provide a description:	The Agency for Health Care Administration must submit a report to the Governor, Senate President, and Speaker of the House on Operation of the Canadian Prescription Drug Importation Program. This analysis defers to AHCA to provide further information regarding the annual reporting requirements and its impacts.
Date Due:	Annually by December 1.
Bill Section Number(s):	Section 1

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

Board:	N/A
Board Purpose:	N/A

Who Appoints:	N/A
Changes:	N/A
Bill Section Number(s):	N/A

FISCAL ANALYSIS

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

Revenues:	No anticipated impact.
Expenditures:	No anticipated impact.
Does the legislation increase local taxes or fees? If yes, explain.	No
If yes, does the legislation provide for a local referendum or local governing body public vote prior to implementation of the tax or fee increase?	No

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

Revenues:	No impact on state revenues is expected based on current bill language.
Expenditures:	The Department will see additional expenditures to implement, process, and issue the International Prescription Drug Wholesale Distributor permit, importer registration, exporter registration, and qualified laboratory approval. The extent of these additional expenditures is indeterminate at this time and will depend on the number and type of permits, registrations or approvals requested and need for additional processing and inspection personnel. Any additional expenditures would require general revenue funding be approved by the legislature. The Department anticipates that it will need at least one additional application staff position (Regulatory Specialist II) and one Senior Pharmacist to review application documentation for compliance with federal standards. The Department will see additional expenditures associated with the development, implementation and administration of the Prescription Drug Supply Chain Documentation requirements of s. 499.0285(6), F.S., proposed in the bill. The Department anticipates that it would need 1 additional Senior Pharmacist drug inspector and funding for a consultant for qualified laboratory approvals.
Does the legislation contain a State Government appropriation?	No
If yes, was this appropriated last year?	N/A

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

Revenues:	The bill would result in International Prescription Drug Wholesale Distributor permit holders being able to sell and distribute prescription drugs into Florida, increasing their available market and potential sales. The total impact is indeterminate and would be dependent on the amount of sales realized by the newly permitted establishments.
Expenditures:	Florida citizens could see a reduction in costs associated with prescription drug purchases due to increased competition and greater availability of prescription drug supplies in Florida. The extent of this impact is indeterminate.
Other:	N/A

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

If yes, explain impact.	N/A
Bill Section Number:	N/A

TECHNOLOGY IMPACT

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

If yes, describe the anticipated impact to the agency including any fiscal impact.	This bill will require modification of Versa: Regulation, Versa: Online, OnBase document management system, reporting and the Interactive Voice Response (IVR) System to accommodate new license categories for permitting and registration (see Additional Comments below). Changes to Versa: Regulation – 120 hours Changes to Versa: Online – 120 hours Changes to OnBase – 48 hours Changes to reports – 12 hours Changes to IVR – 12 hours These modifications can be made using existing resources. In addition, modifications to the Controlled Substance Reporting (CSR) system will be needed for the new data and document submission requirements. It is estimated that these modifications could require up to 900 work hours to complete. Due to the large work effort and limited dedicated resources for this system, it would be extremely challenging to complete these modifications by the effective date of the bill. Staff augmentation would require $67,500 (at $75 per hour), and would still likely require additional time for completion.

FEDERAL IMPACT

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

If yes, describe the anticipated impact including any fiscal impact.	The Department of Business and Professional Regulation, in collaboration with Department of Health, will be required to negotiate with the federal government to obtain approval of arrangements and guidance for operation of the Department's International Prescription Drug Importation Program.

ADDITIONAL COMMENTS

Division of Drugs, Devices and Cosmetics: The bill as drafted appears to have been intended to provide an alternative methodology for the importation of prescription drugs when a Nonresident Prescription Drug Manufacturer, International Export Pharmacy or International Prescription Drug Wholesale Distributor's country of residence has been recognized by the United State as adhering to current good manufacturing practices for pharmaceuticals. However, the language under the proposed bill appears to require all entities exporting or importing prescription drugs into Florida to comply with the requirements of the program unless re-importing a previously exported prescription drug or importing a prescription for export, pursuant to 21 U.S.C § 381(d). Currently, a Florida Nonresident Prescription Drug Manufacturer permit holder located in a foreign country may import prescription drugs into Florida that they manufactured at their foreign facility if: their facility is an FDA inspected and approved establishment, holds a current FDA establishment registration, the prescription drug product being imported is FDA approved for importation and marketing in the United States, and the permit holder complies with all other requirements of ch. 499, F.S. The drug products received from the Nonresident Prescription Drug Manufacturer can be marketed by the authorized recipient for sale and distribution to both in state and out of state buyers. If the bill is interpreted to apply to all exports to and importation into Florida, any authorized recipient of those drugs would now be required to be permitted as a wholesale distributor, a pharmacy or be a licensed pharmacist and obtain an additional registration as an importer. The bill would further limit the sale and/or distribution of prescription drugs exported under the Florida Nonresident Prescription Drug Manufacturer to only recipients in Florida. Additional

language may be needed to clarify that the requirements of the International Prescription Drug Importation Program do not apply to drugs lawfully imported into Florida under 21 U.S.C. § 381.

The definition of "importer" under the bill is limited to: wholesale distributors, pharmacists and pharmacies. This definition specifically excludes prescription drug manufacturers. Many prescription drug manufacturers located in the State of Florida purchase prescription active pharmaceutical ingredients from Nonresident Prescription Drug Manufacturers located in foreign countries. Such a prohibition from importing prescription drug active pharmaceutical ingredients could have the unintended consequence of preventing them from receiving prescription active pharmaceutical ingredients under the program.

The Department will be required to implement and administer the permitting and registration of International Prescription Drug Wholesale Distributor, Importer Registration, and Exporter Registration. No fee authority is established in the proposed bill for these new licensure requirements to offset any expenses associated therewith.

The proposed bill requires the Department to approve qualified testing laboratories. There are currently no specific criteria for approval of qualified laboratories available to the Department.

The Prescription Drug Supply Chain Documentation requirements set forth under s. 499.0285(6), F.S., of the proposed bill creates a new reporting requirement on Nonresident Prescription Drug Manufacturers that was previously not required for them to import prescription drugs into Florida. This requirement will likely result in additional expenditures by permit holders associated with document and information submission. Additionally, many documents submitted pursuant to the Prescription Drug Supply Chain Documentation requirements will be written in foreign languages. The Department would need to have specific statutory authority to require these documents be submitted either in English or to require an English language translation of any documents be submitted along with required foreign language document.

Currently, the Department can rely upon the FDA establishment inspection process to determine compliance for facilities located in other countries due to FDA's limitation of importation from FDA inspected establishments. However, if direct inspection by Department staff is required, the current $3,000.00 annual limitation on costs that may be assessed to a permit applicant under s. 499.041(8), F.S., may be insufficient to cover the actual costs associated with on-site inspection, including travel, lodging, per diem, and any other necessary costs.

Division of Service Operations: No impact.

Bureau of Education and Testing: The Bureau is responsible for ensuring the availability of licensure examinations for Certified Designated Representatives employed by Out-of-State and International Prescription Drug Wholesale Distributors. This will likely require an increase in the number of international testing locations to ensure candidate access to examinations, resulting in changes to the current contract agreement with the Department's computer-based testing vendor.

Fiscal Comment:

Any additional expenditures will require General Revenue funding.

The Department will have indeterminate expenditures due to implementing the requirements of the bill. DDC will be required to process and issue the International Prescription Drug Wholesale Distributor permit, implement importer and exporter registrations, and determine qualified laboratory approval. The extent of these indeterminate additional expenditures will depend on the number and type of permits, registrations or approvals requested, and need for additional processing and inspection personnel.

The Department anticipates that it will need at least one additional application staff position (Regulatory Specialist II) and one Senior Pharmacist to review application documentation for compliance with federal standards. The Department will have additional expenditures associated with the development, implementation, and administration of the Prescription Drug Supply Chain Documentation requirements of s. 499.0285(6), F.S., proposed in the bill. The Department anticipates that it would need one additional Senior Pharmacist drug inspector and funding for a consultant for qualified laboratory approvals. Anticipated initial funding requirements for three FTEs: $520,191 ($305,679 recurring) General Revenue.

Additional resources may be necessary after the full scope of complying with the requirements of the bill are determined.

OGC Rules: No additional comments.

LEGAL - GENERAL COUNSEL'S OFFICE REVIEW

Issues/concerns/comments:	The proposed bill applies to "prescription drugs," which, pursuant to s. 499.003(40), F.S., applies not only to finished dosage forms, but also to active pharmaceutical ingredients ("API") that are routinely imported for further manufacturing and/or distribution by Florida companies. The proposed bill prevents importers and exporters from distributing, selling, or dispensing prescription drugs imported under the program to any person residing outside of the state of Florida, which may cause unintended consequences in some circumstances (for example, imported API or nonresident prescription drug manufacturers exporting prescription drugs to their in-state affiliates for further distribution). The proposed bill also appears to not prevent circumvention of this provision by first distributing a prescription drug to an affiliated company that does not fit the definition of importer or exporter, and then having that company distribute the prescription drug out of the State of Florida. The proposed bill would require the Department to determine whether importation of a particular drug would violate the patent laws of the United States in order to determine whether a drug is eligible for import under the program. That determination may raise questions of jurisdiction and possibly place the Department in civil litigation between private parties. See Section 2 at line 289, specifically s. 499.0285(3)(b), F.S., of the proposed bill. The proposed bill requires importers to submit information and documentation described as "drug supply chain documentation," which may be preempted by 21 U.S.C. § 360eee-4. See Section 2 at line 325, specifically s. 499.0285(6), F.S., of the proposed bill. As amended by the proposed bill, s. 499.01(2)(c)2., F.S., appears to imply that nonresident prescription drug manufacturer participation in the International Prescription Drug Importation Program is optional by stating one set of requirements for nonresident prescription drug manufacturers importing drugs who are not participating in the program and another set of requirements for nonresident prescription drug manufacturers importing drugs under the program. However, Section 2 (lines 554-563) and Section 7 (lines 894-896) of the proposed bill do not appear to make participation in the program optional for nonresident prescription drug manufacturers who intend to import prescription drugs.

	The proposed bill allows importation of prescription drugs under three circumstances: re-importation of prescription drugs by the manufacturer of the prescription drugs after they have been exported from the United States of America; importing prescription drugs for export; and importation pursuant to the International Prescription Drug Importation Program. To the extent that this is more stringent than federal law regarding importation of prescription drugs, it may raise issue under the Dormant Commerce Clause of the United States Constitution.

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	SB 1526
INTRODUCER:	Senator Harrell
SUBJECT:	Telehealth
DATE:	March 22, 2019
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Lloyd	Brown	HP	**Favorable**
2.			AHS	
3.			AP	

I. Summary:

SB 1526 establishes a statutory basis and definition for telehealth.

The bill creates s. 456.4501, F.S., as Florida's telehealth statute. Telehealth is defined as the practice of a Florida-licensed provider in which patient care, treatment, or services are provided through the use of medical information exchanged between one physical location and another through electronic communications. A telehealth provider is limited to a Florida provider licensed under either ch. 458 or ch. 459, F.S., including those providers who become licensed through the Interstate Medical Licensure Compact.

A telehealth standard of practice is established as the same standard applied to in-person care under current law. Controlled substances may not be prescribed via telehealth except in limited circumstances as provided in the bill. Physicians are responsible for the quality and safety of the equipment that is used for telehealth.

A telehealth provider must document a telehealth encounter in the patient's medical records according to the same standards used for in-person services, and such information must be kept confidential. These provisions do not prohibit telehealth providers from holding consultations between practitioners if acting within the scope of their practice.

An exemption is provided for emergency medical services provided by emergency physicians, emergency medical technicians, paramedics, or emergency dispatchers. The exemption also applies to a health care provider caring for a patient in consultation with another provider or in an on-call or cross coverage situation where the provider has access to the patient's medical records.

The Department of Health (DOH) or the applicable boards are authorized to adopt any necessary rules.

The bill prohibits individual, group, blanket, franchise health insurance and health maintenance organization (HMO) policies from denying coverage for telehealth services on any insurance policy delivered, renewed, or issued, to any insured person in this state on or after January 1, 2020 on the basis of the service being provided through telehealth if the same service would be covered if provided through an in-person encounter.

For HMO contracts under s. 641.31, F.S., the bill also adds a provision prohibiting the HMO from requiring the subscriber to seek any type of referral or prior approval from telehealth provider.

The bill prohibits Medicaid Managed Medical Assistance (MMA) health plans from using providers who exclusively provide services through telehealth to meet Medicaid provider network adequacy requirements under the Medicaid managed care plan accountability standards.

The fiscal impact of the bill is indeterminate.

The effective date is July 1, 2019.

II. Present Situation:

Telehealth and Telemedicine

The term, "telehealth," is sometimes used interchangeably with "telemedicine." Telehealth; however, generally refers to a wider range of health care services that may or may not include clinical services. The American Telemedicine Association refers to telemedicine as the use of medical information exchanged from one site to another via electronic communications to improve a patient's clinical health status.[1]

Telehealth often collectively defines the telecommunications equipment and technology that are used to collect and transmit the data for a telemedicine consultation or evaluation. Telemedicine is not a separate medical specialty and does not change what constitutes proper medical treatment and services.

The federal Health Resource Services Administration (HRSA) defines telehealth as the use of electronic information and telecommunications technologies to support and promote long-distance clinical-health care, patient, and professional health-related education, public health and health administration. Technologies include videoconferencing, the Internet, store-and-forward imaging, streaming media, and terrestrial and wireless communications.[2]

For another definition, the Medicare and Medicaid regulatory agency, the federal Centers for Medicare & Medicaid Services (CMS) defines telehealth as:

[1] Ron Hedges, *Telemedicine, Information Governance and Litigation: The Chicken and the Egg, IGIQ: A Journal of AHMIA Blog,* (Feb. 15, 2018) https://journal.ahima.org/2018/02/15/telemedicine-information-governance-and-litigation-the-chicken-and-the-egg/ (last visited Mar. 11, 2019).
[2] *Id.*

> The use of telecommunications and information technology to provide access to health assessment, diagnosis, intervention, consultation, supervision and information across distance. Telehealth includes technologies such as telephones, facsimile machines, electronic mail systems, and remote patient monitoring devises, which are used to collect and transmit data for monitoring and interpretation.[3]

Federal Medicaid law does not recognize telemedicine as a distinct service but as an alternative method for the delivery of services. Medicaid defines telemedicine and telehealth separately, using telemedicine to define the interactive communication between the provider and patient and telehealth to describe the technologies, such as telephones and information systems.[4]

The Florida Medicaid Managed Medical Assistance (MMA) contract defines telemedicine as the practice of health care delivery by a practitioner who is located at a site other than the site where the patient is located for the purposes of evaluation, diagnosis, or recommendation of treatment.[5]

Payment Parity Laws

Parity in telehealth can mean two things: service levels or payment amount. At the service level, if a service is available in-person, then an attempt is made to match that same service or benefit coverage through telehealth. In this way, for individuals who are unable to travel or leave their homes, or live in areas where there may be a lack of providers or lack of a certain kind of providers, telehealth becomes a viable option for those patients.

Under payment parity, if a provider is paid for a service that is provided in-person and that service is also available via telehealth, then the payment level for the actual services should not be impacted by the mode of the delivery of the actual service if it is the exact same service as an in-person encounter.

Telehealth coverage laws also often include language to prohibit different co-payments, deductibles, or benefit caps for services that are provided via telehealth to avoid cost shifting by insurers.[6]

However, a study by the Millbank Memorial Fund in 2016 found that while at least 31 states may have passed laws that broadly require coverage or payment for telehealth services, most of these laws had additional provisions limiting the application of that mandate to different terms and conditions of a policyholder's or payer's policy or contract, the modality of the delivery of the service, the types of providers that may deliver the services, or the location the service can be

[3] Department of Health and Human Services, Centers for Medicare and Medicaid Services *Telemedicine*, available at https://www.medicaid.gov/medicaid/benefits/telemed/index.html (last viewed March 14, 2019).
[4] *Id.*
[5] Agency for Health Care Administration, Core Contract Provisions (Effective 02/01/2018), Attachment II, p. 30, http://ahca.myflorida.com/medicaid/statewide_mc/pdf/Contracts/2018-02-01/Attachment_II_Core_Contract_Provisions_Feb_1_2018.pdf (last visited March 18, 2019).
[6] Northeast Telehealth Resource Center, *Examining parity in telehealth laws, mHealth News* (August 10, 2015), http://netrc.org/news/examining-payment-parity-in-telehealth-laws/ (last viewed March 14, 2019).

delivered.[7] The study identifies only three states with an explicit mandate for unconditional payment parity: Delaware, Hawaii, Michigan.[8,9]

Electronic Consultations

Most states with statutes or regulations dealing with telehealth or telemedicine specifically exclude consultations or communications via email or similar communication from the definitions of telehealth and telemedicine.

More than one-third of patients are referred to a specialist each year in the non-elderly population, and specialist visits account for more than half of all outpatient visits.[10] For a referral to be successful, however, there must be a provider available for the patient. Access to specialists may be inadequate because of lack of specialists in the community or lack of specialists who take a particular patient's insurance, which can also be true for primary care services.[11]

A suggested strategy to improve the integration of primary care referrals to specialists is the utilization of virtual consultations through video conferencing.[12] Primary care physician (PCP) satisfaction with electronic consults (e-consults)[13] is high at 70 - 95 percent;[14] however, satisfaction by specialists was not so high, ranging from 93 percent at the Veterans Administration (VA) to 53 percent at other facilities and 26 percent dissatisfied.[15] Patients reported very high levels of satisfaction.[16]

Other positive impacts felt by systems that have implemented e-consults have been decreases in wait times for specialty appointments.[17] At one large facility, a clinician reviewer screened each specialty referral request. If the request was unclear, the request was redirected. All other requests were sorted into four categories: those that could be managed by the referring clinical with specialist guidance without being seen; those needing additional diagnostic work before an appointment could be made; routine appointments that could wait for the next available appointment; and urgent cases that required an expedited appointment.[18] For some specialties, like rheumatology, the wait times decreased from 126 days to 29 days.[19] Among participating

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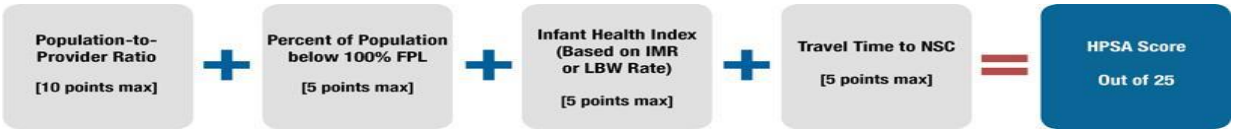
[7] The Center for Connected Health Policy, *Telehealth Private Payer Laws: Impact and Issues* (August 2017), p. 6, The Millbank Memorial Fund, https://www.milbank.org/wp-content/uploads/2017/08/MMF-Telehealth-Report-FINAL.pdf, https://www.milbank.org/wp-content/uploads/2017/08/MMF-Telehealth-Report-FINAL.pdf (last viewed March 14, 2019).
[8] Northeast Telehealth Resource Center, *supra note 6, at 9.*
[9] *Id at 28; Appendix B, Table 1.*
[10] Ateev Mehrotra, Christopher B. Forest, et al, *Dropping the Baton: Specialty Referrals in the United States,* MILBANK QUARTERLY, 2011 March, v. 89(1), p. 40. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3160594/ (last visited March 18, 2019).
[11] *Id* at *52.*
[12] Mehrotra, et al, *supra* note 9, at *56.*
[13] An asynchronous consultative communication between providers occurring within a shared electronic health record or secure web-based platform. E-consults are interactions that occur between providers and is most frequently used between primary care providers and specialty care providers to receive feedback that can be achieved through chart reviews and diagnostic tests. *See:* Varsha G. Vimalananda, Gouri Gupte, *Electronic consultations (e-consults) to improve access to specialty care: A systematic review and narrative synthesis, J Telemed Telecare,* 2015 Sept 21(6) 323-33, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4561452/ (last visited March 18, 2019).
[14] Vimalananda, V., *supra* note 9, at 327.
[15] *Id.*
[16] *Id.*
[17] Alice Hm Chen, et al, *A Safety-Net System Gains Efficiencies Through 'e-Referrals to Specialists,* HEALTH AFFAIRS, (May 2010) https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2010.0027 (last visited March 18, 2019).
[18] *Id.*
[19] *Id.*

providers, 72 percent said e-Referrals improved care and 89 percent said it made tracking referrals easier; however, 42 percent said it was a more burdensome system administratively.[20]

Florida Physician Shortages

Health Professional Shortage Areas (HPSAs) are designated by the federal Health Resources and Services Administration (HRSA) according to criteria developed in accordance with Section 332 of the Public Health Services Act (PHSA). HPSA designations are used to identify areas and groups within the United States that are experiencing a shortage of health professionals. A HPSA can be a geographic area, a population group, or a health care facility. These areas have a shortage of health care professional or have population groups who face specific barriers to health care. There are three categories for a HPSA designation: primary medical care; dental care; and mental health.

The primary factor used to determine a HPSA designation is the number of health care professionals relative to the population with consideration of areas with high need. State Primary Care Offices, usually located within a state's main health agency, apply to HRSA for most designation of HPSAs. HRSA will review provider level data, whether providers are actively engaged in clinical practice, if a provider has any additional practice locations, the number of hours served at each location, the populations served, and the amount of time that a provider spends with specific populations.[21] Primary care and mental health HPSAs can score between 0-25 and the scoring criteria is shown below:[22]



As of December 31, 2018, Florida had 275 primary care HPSA designations which met 22.09 percent of the need. It was estimated that 1,658 practitioners were needed to remove the HPSA designation for primary care.[23] For mental health, Florida had 182 HPSA designations which met 16.13 percent of the need. To remove the HPSA designation for mental health, Florida would need 409 additional mental health practitioners.[24]

Florida Telehealth and Telemedicine Issues

Florida Board of Medicine and Telemedicine

The Florida Board of Medicine (board) regulates the practice of physicians licensed under ch. 458, F.S. In 2013, the board convened a Telemedicine Workgroup to review its rules on

[20] *Id.*
[21] U.S. Department of Health and Human Services, HRSA Health Workforce, *Health Professional Shortage Area (HPSA), Shortage Application and Scoring Process*, Shortage Designation Management System, https://bhw.hrsa.gov/shortage-designation/application-scoring-process (last visited March 18, 2019).
[22] U.S. Department of Health and Human Services, HRSA Health Workforce, *HPSA Application and Scoring Process*, https://bhw.hrsa.gov/shortage-designation/hpsa-process (last visited March 18, 2019).
[23] HRSA Data Warehouse, *Designated Health Professional Shortage Area Statistics – Tab 3:Primary Care* (as of December 31, 2018), https://ersrs.hrsa.gov/ReportServer?/HGDW_Reports/BCD_HPSA/BCD_HPSA_SCR50_Qtr_Smry_HTML&rc:Toolbar=false (last visited March 18, 2019).
[24] HRSA Data Warehouse, *Designated Health Professional Shortage Area Statistics – Tab 5: Mental Health Care Health Professional Shortage Areas, by States*, (as of December 31, 2018) https://ersrs.hrsa.gov/ReportServer?/HGDW_Reports/BCD_HPSA/BCD_HPSA_SCR50_Qtr_Smry_HTML&rc:Toolbar=false (last visited March 18, 2019).

telemedicine, which had not been amended since 2003. The 2003 rules focused on standards for the prescribing of medicine via the Internet.

On March 12, 2014, the board's new Telemedicine Rule, 64B8-9.0141 of the Florida Administrative Code, became effective. The rule defined telemedicine,[25] established standards of care, prohibited the prescription of controlled substances, permitted the establishment of a doctor-patient relationship via telemedicine, and exempted emergency medical services.[26]

Two months after the initial rule's implementation, the board proposed an amendment to address concerns that the rule prohibited a physician from ordering controlled substances via telemedicine for hospitalized patients. The board indicated such a prohibition was not intended.[27] Additional changes followed to clarify medical record requirements and the relationship between consulting or cross-coverage physicians.

On December 18, 2015, the board published another proposed rule change to allow controlled substances to be prescribed through telemedicine for the limited treatment of psychiatric disorders.[28] The change relating to psychiatric disorders under Rule 64B8-9.0141-Standards for Telemedicine Practice, of the Florida Administrative Code, became effective March 7, 2016.[29]

On February 3, 2017, the Board of Medicine held a public hearing on a proposed amendment to Rule 64B8-9.0141 of the Florida Administrative Code, to prohibit the ordering of low-THC cannabis or medical cannabis through telemedicine. Additional public hearings were noticed for April and August of that year on the amended rule; however, the rule was eventually withdrawn in August 2017 without being amended.

On March 7, 2019, a variance request was filed with the board seeking a waiver to the provision which prohibits a physician or physician assistant from providing treatment or treatment recommendations and issuing a prescription based solely on responses to an electronic medical questionnaire. The petitioners argue that the medical questionnaire is used only for low acuity conditions and a physician reviews the patient's responses which includes the patient's demographics, current medication list and allergies, and when necessary the patient's medical record where the provider has access to it, and the patient is provided a response to his or her request within an hour if the request is made within the hours of 8 a.m. to 7 p.m. Central Time.[30] The petition lists 14 medical conditions that would be included in the service for patients age 18

[25] The term, "telemedicine," is defined to mean the practice of medicine by a licensed Florida physician or physician assistant where patient care, treatment, or services are provided through the use of medical information exchanged from one site to another via electronic communications. Telemedicine shall not include the provision of health care services only through an audio only telephone, email messages, text messages, facsimile transmission, U.S. Mail or other parcel service, or any combination thereof.
[26] Telemedicine, Rule 64B15-14.0081, Florida Administrative Code, also went into effect March 12, 2014, for osteopathic physicians.
[27] Florida Board of Medicine, *Latest News - Emergency Rule Related to Telemedicine,* http://flboardofmedicine.gov/latest-news/emergency-rule-related-to-telemedicine/ (last visited March 15, 2019).
[28] Vol. 41/244, Fla. Admin. Weekly, Dec. 18, 2015, available at https://www.flrules.org/BigDoc/View_Section.asp?Issue=2011&Section=1 (last visited March 15, 2019).
[29] Florida Board of Medicine, Latest News, Feb. 23, 2016, available at http://flboardofmedicine.gov/latest-news/board-revises-floridas-telemedicine-practice-rule/ (last visited March 15, 2019).
[30] State of Florida, Department of Health, Board of Medicine, Petition for Waiver or Variance, Floyd B. Willis, M.D., et al, Mayo Clinic; Rule No. 64B8-9.0141, F.A.C. (March 8, 2019, Florida Admin. Register, Vol. 45, No. 47 p. 954)

months through age 75.[31] The clinics are currently offered by the Mayo Clinic in Minnesota, Iowa, and Wisconsin. The conditions currently covered are:

- Allergies
- Cold (upper respiratory infections)
- Cold sores
- Conjunctivitis (pink eye)
- Influenza
- Lice
- Oral contraceptives (females age 18-34)
- Sinusitis
- Smoking cessation (age 18 plus)
- Sore throat
- Sunburn
- Tick exposure
- Urinary tract infections (females age 12-75)
- Vaginal yeast infections.[32]

In June 2019, the program, will add six new conditions:

- Acne
- Athlete's foot
- Impetigo
- Poison ivy
- Shingles
- Pertussis exposure without cough.

After a health care professional, a physician assistant, or nurse practitioner has reviewed the responses, the patient may be contacted if there are discrepancies between the form and an existing medical record with Mayo Health, discrepancies between the responses, or to clarify any information that was submitted electronically. Some patients may be prescribed a legend drugs, other patients may be advised that an in-person visit is more appropriate.[33] The patient receives an email message letting them know that a clinical note is in his or her patient portal, and if a drug has been prescribed, prescriptions are transmitted electronically to the patient's designated pharmacy via SureScripts service. No controlled substances are prescribed.[34]

Florida Medicaid Program's Use of Telehealth[35]

Medicaid managed care plans may elect to use telemedicine for any service as long as the managed care plan includes fraud and abuse procedure to detect potential or suspected fraud or abuse in the use of telemedicine services.[36] The Agency for Health Care Administration's (AHCA) Medicaid managed care contracts for the Managed Medical Assistance (MMA)

[31] State of Florida, Department of Health, Board of Medicine, Petition for Waiver or Variance, *Id* at 10.
[32] *Id.*
[33] *Id at 12.*
[34] *Id.*
[35] *See* Agency for Health Care Administration, *Analysis of SB 280* (Oct. 9, 2017) (on file with the Senate Banking and Insurance Committee).
[36] *Id* at 172.

component of Statewide Medicaid Managed Care, include specific contractual provisions for managed care plans that elect to use telehealth to deliver services, including, but not limited to:

- Must be licensed practitioners acting within the scope of their licensure.
- Telephone conversations, chart review, electronic mail message, or facsimile transmission are not considered telemedicine.
- Equipment and operations must meet technical safeguards required by 45 CFR 164.312.
- Providers must meet federal and state laws pertaining to patient privacy.
- Patient's record must be documented when telemedicine services are used.
- No reimbursement for equipment costs to provide telemedicine services.
- Must ensure the patient has a choice whether to access services through telemedicine or a face to face encounter.[37]

The MMA contracts also allow an MMA plan to assure access to specialists by providing telemedicine consultations with specialists not listed in the MMA plan's network at a location or via the patient's PCP office within 60 minutes travel time or 45 miles from the patient's zip code.[38] MMA plans must also have policies and procedures specific to telemedicine, if they elect to provide services through this delivery system, relating to fraud and abuse, record-keeping, consent for services, and privacy.

Florida Medicaid statutes and the federal Medicaid statutes and regulations consider telemedicine to be a delivery system rather than a distinct service; as such, Florida Medicaid does not have reimbursement rates specific to the telemedicine mode of service. In the fee-for-service system, Florida Medicaid reimburses services delivered via telemedicine at the same rate and in the same manner as if the service were delivered face-to-face.

Medicaid health plans can negotiate rates with providers, so they have the flexibility to pay different rates for services delivered via telemedicine. The managed care plans are required to submit their telemedicine policies and procedures to the AHCA for approval, but are not required to do so prior to use.[39]

Other Statutory References to Telehealth or Telemedicine

Sprinkled through the Florida Statutes are numerous other references to the use of telehealth, telemedicine, or teleconference services to deliver health care services, including the following references:

- Department of Management Services, to facilitate the development of applications, programs, and services, including, but not limited to telework and telemedicine.[40]
- Legislative intent for the Department of Children and Families (DCF) to use telemedicine for the delivery of health care services to children and adults with mental health and substance

[37] Agency for Health Care Administration, MMA Contract, Attachment II, Exhibit II-A (Effective 02/01/2018), p. 37, *available at* http://ahca.myflorida.com/medicaid/statewide_mc/pdf/Contracts/2018-02-01/EXHIBIT_II-A_MMA_Managed_Medical_Assistance_(MMA)_Program_Feb_1_2018.pdf (last visited March 18, 2019).
[38] *Id* at 57.
[39] Agency for Health Care Administration, *Statewide Medicaid Managed Care (SMMC) Policy Transmittal* (March 11, 2016), http://ahca.myflorida.com/medicaid/statewide_mc/pdf/plan_comm/PT_16-06_Telemedicine_03-11-2016.pdf (last visited March 18, 2019).
[40] Section 365.0135(2)(d)4, F.S.

abuse disorders diagnoses for patient evaluation, case management, and ongoing patient care.[41]

- Recommendations by DCF for voluntary and involuntary outpatient and inpatient services under ch. 394, F.S., with authorizations or second opinions provided by a physician assistant, a psychiatrist, a clinical social worker, or a psychiatric nurse.[42]
- Opinions provided under s. 394.467, F.S., relating to admission to a treatment facility to be provided through face-to-face examination, in person, or by electronic means.[43]

Florida Telehealth Advisory Council

In 2016, legislation[44] was enacted that required the AHCA, with assistance from the DOH and the Office of Insurance Regulation (OIR), to survey health care practitioners, facilities, and insurers on telehealth utilization and coverage, and submit a report on the survey findings to the Governor, President of the Senate, and Speaker of the House of Representatives by December 31, 2016. The law also created a 15-member Telehealth Advisory Council and tasked the Council with developing recommendations and submitting a report on the survey findings to the Governor, President of the Senate, and Speaker of the House of Representatives by October 31, 2017.

Federal Telemedicine Provisions

Federal laws and regulations address telemedicine from several perspectives, including prescriptions for controlled substances, Medicare reimbursement requirements and privacy and security standards.

Special Registration Process – Drug Enforcement Agency

In Section 3232 of the federal Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) Act signed by President Trump on October 24, 2018,[45] Section 311(h)(2) requires the federal Attorney General, not later than one year after enactment, in consultation with the Department of Health and Human Services Secretary, to promulgate regulations specifying the limited circumstances under which a special registration for telemedicine may be issued and the procedure for obtaining the registration. Previously, the federal Controlled Substances Act (CSA) contained language directing the Attorney General to promulgate rules for a special registration process for telemedicine; however, to date, no rule has been issued from the Department of Justice or the Drug Enforcement Agency (DEA). The Fall 2018 Unified Agenda of Office of Management and Budget had indicated that the DEA planned

[41] Section 394.453(3), F.S. The provision states, in part: The Legislature further finds the need for additional psychiatrists to be of critical state concern and recommends the establishment of an additional psychiatry program to be offered by one of Florida's schools of medicine currently not offering psychiatry. The program shall seek to integrate primary care and psychiatry and other evolving models of care for persons with mental health and substance use disorders. Additionally, the Legislature finds that the use of telemedicine for patient evaluation, case management, and ongoing care will improve management of patient care and reduce costs of transportation.

[42] Sections 394.4655(3)(a)1, and 349.4655(3)(b), F.S.

[43] Section 394.467(2), F.S. The examination under this section may be performed by a psychiatrist, a clinical psychologist, or if neither one of those is available, the second opinion may be provided by a physician who has the postgraduate training and experience in diagnosis and treatment of mental illness or by a psychiatric nurse.

[44] Chapter 2016-240, Laws of Fla. The law designated the Secretary of the Agency for Health Care Administration (AHCA) as the council Chair, and designated the State Surgeon General and Secretary of the Department of Health as a member. The AHCA's Secretary and the State Surgeon General appointed 13 council members representing specific stakeholder groups.

[45] Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act, Pub. Law 115-271, 56-57 (2019).

to publish a proposed rule in the *Federal Register*.[46] A registration process would allow a practitioner[47] to deliver, distribute, dispense, or prescribe via telemedicine a controlled substance to a patient that has not been medically examined in-person by a prescribing practitioner.[48]

Federal law further requires that practitioners meet three general requirements for the special registration:

- Must demonstrate a legitimate need for the special registration.
- Must be registered to deliver, distribute, dispense, or prescribe controlled substances in the state where the patient is located.
- Must maintain compliance with federal and state laws when delivering, distributing, dispensing, and prescribing a controlled substance, unless the prescriber is:
- Exempted from such registration in all states,[49] or
- Is an employee or a contractor of the federal Department of Veterans Affairs (VA) who is acting within the scope of his or her contract or is utilizing the registration of a hospital or clinic operated by the VA as permitted under these regulations.[50]

Protection of Personal Health Information

The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) protects personal health information (PHI). Initial privacy rules were issued in 2000 by the federal Department of Health and Human Services and later modified in 2002. These rules address the use and disclosure of an individual's health information and create standards for privacy rights. Additional privacy and security measures were adopted in 2009 with the Health Information Technology for Economic Clinical Health (HITECH) Act as part of the American Recovery and Reinvestment Act (ARRA).[51] The Office of the National Coordinator (ONC) under the HITECH Act was given the responsibility of implementing provisions relating to interoperability, accessibility, privacy, and security of health information technology.[52]

Only certain entities are subject to HIPAA's provisions. These "covered entities" include:

- Health plans;
- Health care providers;
- Health care clearinghouses; and
- Business associates of the entities listed above.

While not a covered entity as an individual, the patient still maintains his or her privacy and confidentiality rights regardless of the method in which a medical service is delivered. The HITECH Act specifically identified telemedicine as an area for review and consideration, and funding was provided to, in part, strengthen infrastructure and tools to promote telemedicine.[53]

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[46] Victoria Elliot, Congressional Research Service, *The Special Registration for Telemedicine: In Brief* (December 7, 2018), p. 1, *available at* https://fas.org/sgp/crs/misc/R45240.pdf (last visited March 18, 2019).

[47] A practitioner is defined under Section 802(21) of Title 21, U.S.C., as a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

[48] *Supra* note 57, at 2.

[49] The Act exempts certain manufacturers, distributers, and dispensers of controlled substances.

[50] *Supra* note 56, and 21 U.S.C. ss. 823 and 831(h)(1) (January 2019).

[51] American Recovery and Reinvestment Act (ARRA); Public Law 111-5 (2009).

[52] Office of the National Coordinator for Health Information Technology, HealthIT.gov, *Health IT Legislation* (February 10, 2019), *available at* https://www.healthit.gov/topic/laws-regulation-and-policy/health-it-legislation (last visited March 18, 2019).

[53] American Recovery and Reinvestment Act (ARRA); Public Law 111-5 (2009), s. 3002(b)(2)(C) and s. 3011.

Under the provisions of HIPAA and the HITECH Act, a health care provider or other covered entity participating in telemedicine is required to meet the same technical and physical HIPAA and HITECH requirements as would be required for a physical office visit. These requirements include ensuring that the equipment and technology are HIPAA compliant, reduce travel requirements for patients in remote areas, and facilitate home health care and remote patient monitoring.[54]

The HITECH and ARRA legislation also expanded who was considered a "business associate" under the updated security and privacy rules. The final rule in January 2013 modified the definition to include patient safety organizations, health information organization, E-prescribing gateways, and other persons that facilitate data transmissions and vendors of personal health records to one or more persons. These organizations and businesses would be required to enter into business associate agreements under the revised definition.[55]

The final rule also includes two new e-prescribing measures relating to opioids (Schedule II controlled substances) in the performance based scoring methodology for the Medicare's EHR Incentive Program. Beginning in CY 2019, a query of a state's prescription drug monitoring program (PDMP) is optional; however, this query becomes required in CY 2020.[56]The second measure added is verification of an Opioid Treatment Agreement.[57] As with the PDMP query, the verification of the agreement is also optional for CY 2019 and mandatory in CY 2020.

Prescribing Via the Internet

Federal law has specifically prohibited the prescribing of controlled substances via the Internet without an in-person evaluation. A valid prescription is one that is issued for a legitimate medical purpose in the usual course of professional practice by a practitioner who has conducted at least one in-person medical evaluation of the patient or a covering practitioner.[58] The in-person evaluation requires that the patient be in the physical presence of the provider without regard to the presence or conduct of other professionals.[59]

Federal law at 21 U.S.C. s. 829 provides:

> No controlled substance that is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act may be delivered, distributed or dispensed by means of the Internet without a valid prescription.

Telemedicine Exception

The federal Drug Enforcement Agency and the federal Department of Justice issued their own definition of telemedicine in April 2009, as required under the Haight Act.[60] The federal

[54] ARRA, *supra* note 68, at 236.
[55] 78 Fed. Reg. 5687, (Jan. 25, 2013) (to be codified at 45 CFR 160.103, Definition of Business associate).
[56] Centers for Medicare and Medicaid Services, *Fiscal Year (FY) 2019 Medicare Hospital Inpatient Prospect Payment System (IPPS) and Long Term Acute Care Hospital (LTCH) Prospective Payment System Final Rule Fact Sheet)* (August 2, 2018), *available at* https://www.cms.gov/newsroom/fact-sheets/fiscal-year-fy-2019-medicare-hospital-inpatient-prospective-payment-system-ipps-and-long-term-acute-0 (last visited Mar. 19, 2019).
[57] *Id.*
[58] Ryan Haight Online Pharmacy Consumer Protection Act of 2008; Public Law 110-425 (H.R. 6353); 21 U.S.C. sec. 829(e)(2)(A)(2006 Ed., Supplement 4).
[59] Ryan Haight, 21 U.S.C. sec. 829(e)(2)(B)(i)(2006 Ed., Supplement 4).
[60] *Id.*, at sec. 3(j).

regulatory definition of telemedicine under the DEA includes, but is not limited to, the following elements:

- The patient and practitioner are located in separate locations;
- Patient and practitioner communicate via a telecommunications system;
- The practitioner must meet other registration requirements for the dispensing of controlled substances via the Internet; and
- Certain practitioners (Department of Veterans Affairs' employees, for example) or practitioners in certain situations (public health emergencies) may be exempted from registration requirements.[61]

However, the Ryan Haight Online Pharmacy Consumer Protection Act[62] created an exception for the delivery, distribution, or dispensing of a controlled substance by a practitioner engaged in the practice of telemedicine or for a covering practitioner where the practitioner has conducted the required one, in-person medical evaluation through the practice of telemedicine within the previous 24 months.[63] The practitioner is still subject to the requirement that all controlled substances be issued for a legitimate purpose by a practitioner acting in the usual course of professional practice. The definition of the "practice of telemedicine" includes seven distinct categories or exceptions. Those seven distinct categories require the practice of telemedicine be delivered or conducted:

- To a patient that is located in a hospital or a clinic.
- During an in-person examination with another practitioner.
- Through the Indian Health Service.
- During a public health emergency.
- By a practitioner that has obtained a special registration for telemedicine.
- During a medical emergency situation.
- At the discretion of the DEA.[64]

The DEA regulations require practitioners to meet certain requirements before issuing prescriptions for controlled substances electronically. All controlled substance prescriptions must be issued through an application that can meet standards which include but is not limited to user controls and locks, prescriber signature verification, final prescription review and approval by the prescriber, two factor authentication, and record archival and audit functionality.[65]

Medicare Provisions

In a proposed rule issued on November 30, 2018, prescription drug plan sponsors and Medicare Advantage organizations will be required to establish electronic prescription drug programs that comply with e-prescribing standards under the Medicare Prescription Drug, Improvement, and Modernization Act.[66] The law and regulation does not require that prescribers or dispensers comply with the requirement; however, any prescribers and dispensers who electronically

[61] Drug Abuse and Prevention, Definitions, 21 U.S.C. s. 802 (54).
[62] Ryan Haight, 21 U.S.C. sec. 829(e)(3)(A).(2006 Ed., Supplement 4).
[63] Ryan Haight, 21 U.S.C. sec. 829(e)(2)(C)(i) and (3)(2006 Ed., Supplement 4)
[64] Information from the Congressional Research Service, *The Special Registration for Telemedicine: In Brief* (December 7, 2018), *available at* https://www.everycrsreport.com/files/20181207_R45240_d2f8e1a6693c4181f2c46db32a29f0595dfb5d03.pdf. (last visited March 19, 2019). Based on 21 U.S.C. s. 802(54) and s. 831(h).
[65] Requirements for Electronic Orders and Prescriptions, 21 C.F.R., pt. 1311, sub. C.
[66] Fed. Reg. Vol. 83, No. 231 (Nov. 30, 2018), p. 62164, 423.160.

transmit and receive prescriptions and certain other pieces of information for covered drugs on behalf of Medicare Part D eligible beneficiaries, directly or through an intermediary, are required to comply with any standards.[67]

U.S. Department of Veterans Affairs (VA) Telehealth

The United States Department of Veterans Affairs (VA) has been using telehealth to increase access to health care for veterans through a variety of programs including real-time telehealth, the Polytrauma Rehabilitation Network, TeleMental Health, TeleRehabilitation, and Telesurgery. The VA's telehealth services use real-time technologies to provide health care access through Clinical Video Telehealth (CVT). Examples of services that might be provided include access to a specialty care physician with the patient located at a local clinic closest to the veteran's home and a specialty physician who may not be available at the clinic closest to the veteran's home. Not all of the clinics have the specialty care available and it may be difficult for some of the veterans to travel distances to receive care, so CVT is used to make diagnoses, manage care, perform check-ups, and actually provide care for these veterans.[68]

A 2013 VA telehealth report on home health services showed that home telehealth services had reduced bed days care 59 percent and hospital admissions by 35 percent, while clinical video telehealth services reduced bed days of care for mental health patients by 38 percent.[69] Clinical video telehealth saved approximately $34.45 per consult and store-and-forward telehealth saved approximately $38.81 per consult in travel costs for the patient.[70]

For the VA, a health care provider who is licensed to practice a health care specialty listed and qualified under 38 U.S.C. 7402(b),[71] is appointed to an occupation within the Veterans Health Administration that is listed as authorized, maintains his or her health credentials as required, and is not a contractor for the VA, the health care provider is authorized to provide telehealth services within the scope of their practice and in accordance with the privileges granted by the VA, irrespective of the state or location within the state where the health care provider or the beneficiary is located.[72] The health care provider must practice within the limitations imposed by the Controlled Substances Act, 21 U.S.C. 801, et seq, as well as any other provisions set forth by the VA. This federal regulation preempts state law to achieve an important federal interest to care for veterans.[73]

Federal Trade Commission

In recent years the Federal Trade Commission (FTC) has sent comments or intervened in state and federal actions relating to telehealth and telemedicine rulemaking and litigation and how it relates to competition. In one of its more recent letters on the topic, to the VA, the FTC commented on a proposed telemedicine rule allowing VA telehealth providers to provide

[67] *Id.*
[68] U.S. Department of Veterans Affairs, *VA Telehealth Services: Real-Time Clinic Based Video Telehealth, https://www.telehealth.va.gov/real-time/index.asp* (last visited March 11, 2019).
[69] Center for Connected Health Policy, *Telehealth Private Payer Laws: Impact and Issues,* Millbank Memorial Fund (August 2017), p. 4, https://www.milbank.org/wp-content/uploads/2017/08/MMF-Telehealth-Report-FINAL.pdf (last viewed March 14, 2019).
[70] *Id.*
[71] To be eligible for appointment in the Administration, a health care provider must meet the federal qualifications as listed in this statute for a physician, dentist, nurse, director of hospital, domiciliary, center, or outpatient clinic, podiatrist, optometrist, pharmacist, psychologist, social worker, marriage and family therapist, licensed professional mental health counselor, chiropractor, peer specialist, or other health care position as designated by the Secretary.
[72] 38 CFR section 17.417, Health care providers practicing via telehealth.
[73] 38 CFR section 17.417(c), Health care providers practicing via telehealth.

services to or from non-federal sites, regardless of whether the provider was licensed in the state where the provider was located.[74] The FTC writes in support of the proposed rules with the following:

> Our findings reinforce the view that the Proposed Rule would enable the use of telehealth to reach underserved areas and VA beneficiaries who are unable to travel, improving the ability of the VA to utilize its health care resources. Accordingly, we believe that the Proposed Rule would like increase access to telehealth services, increase the supply of telehealth providers, increase the range of choices available to patients, improve health care outcomes, and reduce the VA's health care costs, thereby benefitting veterans.
>
> …
>
> The VA's Proposed Rule involves the intersection of two important and current FTC advocacy areas that directly affect many consumers: occupational licensing and telehealth. Since the late 1970s, the Commission and its staff have conducted economic and policy studies relating to licensing requirements for various occupations and professions[75], and submitted numerous advocacy comments to state and self-regulatory entities on competition policy and anti-trust law issues relating to occupational regulation, including the regulation of health professions.[76]

The FTC also commented on telemedicine legislation in Alaska, occupational board rules in Delaware, investigated the Texas Board of Medicine and filed a joint brief with the DOJ over restrictions relating to dentistry in Texas.[77, 78, 79]

Interstate Medical Licensure Compact

The Interstate Medical Licensure Compact (IMLC) provides an expedited pathway for medical and osteopathic physicians to qualify to practice medicine across state lines within a Licensure Compact. Currently, 24 states and one territory which cover 31 medical and osteopathic boards

[74] U.S. Federal Trade Commission, Letter to Director of Regulation Policy and Management (November 1, 2017), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-department-veterans-affairs-regarding-its-proposed-telehealth-rule/v180001vatelehealth.pdf (last visited March 18, 2019).
[75] *See* Carolyn Cox & Susan Foster, BUREAU OF ECON., FED. TRADE COMM'N, The Costs and Benefits of Occupational Regulation (1990), http://www.ramblemuse.com/articles/cox_foster.pdf (last visited March 18, 2019).
[76] Center for Connected Health Policy, *supra* note 97, at 3.
[77] The Alaskan legislation would allow licensed Alaskan physicians located out of state to provide telehealth services in the same manner as in-state providers. *See* https://www.ftc.gov/news-events/press-releases/2016/03/ftc-staff-comment-alaska-legislature-should-consider-potential (last visited March 18, 2019).
[78] In Delaware, there were three situations, one involving whether telepractice was appropriate for Speech/Language Pathologists, another for the occupational board which regulates occupational therapists, and a third for the board which regulates the dietitians and nutritionists. https://www.ftc.gov/policy/advocacy/advocacy-filings/2016/08/ftc-staff-comment-delaware-board-occupational-therapy, https://www.ftc.gov/policy/advocacy/advocacy-filings/2016/11/ftc-staff-comment-delaware-board-speechlanguage , and https://www.ftc.gov/news-events/press-releases/2016/08/ftc-staff-comment-delaware-dieteticsnutrition-board-proposal (last visited March 18, 2019).
[79] In Texas, the FTC began an investigation of whether the Texas Medical Board violated federal antitrust law by adopting rules restricting the practice of telemedicine. *See* https://www.ftc.gov/news-events/press-releases/2017/06/federal-trade-commission-closes-investigation-texas-medical-board (last visited March 18, 2019).

participate in the IMLC and as of February 2019, six other states have active legislative to join the IMLC.[80, 81]

Approximately 80 percent of physicians meet the eligibility guidelines for licensure through the Compact.[82] The providers' applications are expedited by using the information previously submitted in their State of Principal Licensure (SPL). Once the SPL has been established and a Letter of Qualification has been awarded, the physician can select which states to practice in under his or her compact license. However, to qualify for consideration for that compact license, the physician must hold a full, unrestricted medical license from a compact member state and meet one of the following additional qualifications:

- The physician's primary residency is the State of Principal licensure (SPL).
- The physician's practice of medicine occurs in the SPL for at least 25 percent of the time.
- The physician's employer is located in the SPL.
- The physician uses the SPL as his or her state of residence for U.S. federal income tax purposes.

Additionally, the physician must maintain his or her licensure from the SPL at all times. The SPL may be changed after the original qualification. The application cost is $700 plus the cost of the license for the state in which the applicant wishes to practice. The individual state fees vary from a low of $75 in Alabama to a high of $700 in Maine.[83]

A current Senate bill (SB 7078) would enter Florida into the IMLC on July 1, 2019, if enacted into Florida law.

III. Effect of Proposed Changes:

Section 1 amends s. 409.967, F.S., to prohibit Medicaid managed care plans from using providers who exclusively provide services through telehealth, as defined in the bill, to meet the current-law network adequacy standards for Medicaid managed care.

The bill also deletes obsolete language from s. 409.967, F.S.

Section 2 creates s. 456.4501, F.S., and establishes statutory provisions for telehealth. The bill:

- Provides definitions for:
  - Telehealth: the practice of a Florida-licensed telehealth provider's profession in which patient care, treatment, or services are provided through the use of medical information exchanged between one physical location and another through electronic communications. The term excludes audio-only telephone calls, email messages, text messages, U.S. mail or other parcel services, facsimile transmissions, or any combination thereof.
  - Telehealth provider: an individual who provides health care and related services using telehealth and who holds a Florida license under chs. 458 (medical) or 459 (osteopathic),

[80] Interstate Medical Licensure Compact, *The IMLC*, https://imlcc.org/ (last visited Mar. 8, 2019).
[81] Interstate Medical Licensure Compact, Draft Executive Committee Meeting Minutes (February 5, 2019), https://imlcc.org/wp-content/uploads/2019/02/2019-IMLC-Executive-Committee-Minutes-February-5-2019-DRAFT.pdf (last visited Mar. 8, 2019).
[82] Interstate Medical Licensure Compact, *The IMLC*, https://imlcc.org/ (last visited Mar. 7, 2019).
[83] Interstate Medical Licensure Compact, *What Does It Cost?* https://imlcc.org/what-does-it-cost/ (last visited Mar. 8, 2019).

including providers who become Florida-licensed by way of the Interstate Medical Licensure Compact.[84]

- Establishes the practice standard for telehealth as the same standard for providers who provide in-person health care services.
- Provides that no controlled substances may be prescribed by a telehealth provider, except:
  - For the treatment of a psychiatric disorder;
  - For inpatient treatment at a hospital licensed under ch. 395, F.S.;
  - For the treatment of a patient receiving hospice services as defined in s. 400.601, F.S.;[85] and,
  - The treatment of a patient in a nursing home facility as defined in s. 400.021, F.S.
- Prohibits the use of electronic medical questionnaire solely to prescribe medications.
- Places responsibility for quality and safety of equipment on telehealth providers.
- Requires telehealth providers to document in the patient's medical record any health care services rendered using telehealth.
- Provides that any medical records generated as a result of a telehealth visit are confidential.[86]
- Clarifies that providers may continue to consult to the extent that such practitioners are acting within the scope of their practice.
- Provides that emergency medical services provided by paramedics or emergency dispatchers are excluded from the bill's provisions for telehealth and provides a definition of emergency services.
- Provides that health care providers who are providing immediate medical care to a patient with an emergency medical condition are excluded from the bill's provisions for telehealth.
- Provides that, to the extent that a health care provider is acting within his or her scope of practice, the bill does not prohibit:
  - A practitioner caring for a patient in consultation with another practitioner where the practitioner has an ongoing relationship and has agreed to supervise treatment, including prescribed medications; or
  - The health care provider from caring for a patient in on-call or cross-call situations in which another practitioner has access to patient records.
- Provides the Department of Health and the applicable boards with rulemaking authority.

Sections 3, 4, and 5, require insurers and health maintenance organizations (HMOs), including the plans that participate in the Medicaid MMA program, to reimburse healthcare providers the same amount for a billed service regardless of the modality of its delivery. The change would affect all policies renewed or contracted for as new contracts as of January 1, 2020. Insurers and HMOs would also be prohibited from:

- Denying coverage for a covered service on the basis of the service being provided through telehealth if the same service would have been covered through an in-person encounter.
- Excluding an otherwise covered service solely because the service is being providing through telehealth rather than through an in-person encounter.

[84] The Interstate Medical Licensure compact is one component of SPB 7028 (2019).
[85] Under s. 400.601(6), F.S., hospice services means "items and services furnished to a patient and family by a hospice or by others under arrangements with such a program, in a place of temporary or permanent residence used as the patient's home for the purpose of maintaining the patient at home; or, if the patient needs short-term institutionalization, the services shall be furnished in cooperation with those contracted institutions or in the hospice inpatient facility."
[86] Patient medical records are confidential under s. 395.3025, F.S., and any Florida licensed facility has a duty to maintain that confidentiality in accordance with the statute. Patient records held by health care providers are confidential under s. 456.056, F.S.

- Charging a greater deductible, copayment, coinsurance amount than would apply if the same service were provided through an in-person encounter.
- Imposing any deductible, copayment, coinsurance amount or other durational benefit limitation or maximum for benefits or services provided via telehealth that is not imposed equally upon all terms and services covered under the policy.

Insurers and HMOs may conduct utilization reviews for appropriateness of service delivery in comparison to in-person encounters and insurers may also elect to limit the covered services offered to enrollees.

Section 6 provides an effective date of July 1, 2019.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Providing a statutory definition for telehealth will add clarity to an area that has lacked a standard in state law. According to many users within the state, including respondents to the Telehealth Survey and the findings within the Telehealth Advisory Council Report mentioned previously, health practitioners indicated a need for a definition of the term, "telehealth." A definition would clarify the use of technological modalities as an acceptable way to treat patients within their scope of practice. Further, health plans noted

the need for clarity in the allowable modes for telehealth for coverage and reimbursement purposes.

These changes may encourage the use of telehealth options, which may result in reduced health care costs; increased patient access to providers, especially in medically underserved areas; improved quality and continuity of care; and faster and more convenient treatment resulting in reduction of lost work time and travel costs for patients. Preventing the unnecessary use of intensive services, such as emergency department visits, can reduce overall health care costs and improve health outcomes.

SB 1526 restricts the use of telehealth to only those licensed under ch. 458 (medical) and ch. 459 (osteopathic), F.S., with some limited exceptions for emergency medical care, hospice, and nursing homes. With committee testimony from previous years of telehealth bills, provisions in other state statutes, and current practices ongoing in the community, other non-physician health care professionals are currently providing telehealth services. It is unclear what would happen to their ability to continue to practice under this modality should this bill pass in its current form.

C. Government Sector Impact:

Similar to the private sector impact, these changes may encourage the expanded use of telehealth options by government entities and employers, which may result in reduced health care costs; increased patient access to providers, especially in medically underserved areas; improved quality and continuity of care; and faster and more convenient treatment resulting in reduction of lost work time and travel costs for patients.

The bill restricts the use of telehealth to only those licensed under ch. 458 (medical) and ch. 459 (osteopathic) in Florida with some limited exceptions for emergency medical care, hospice, and nursing homes. With committee testimony from previous years of telehealth bills, provisions in other state statutes, and current practices ongoing in the community, other non-physician health care professionals are already providing telehealth services. It is unclear what would happen to their ability to continue to practice this modality should this bill pass, especially in the Medicaid program which allows its Medicaid managed care plans to use telehealth beyond permitted in this bill. Medicaid also authorizes the use of telehealth services in its fee for service component. The definition restriction may especially impact access to mental health and substance abuse disorder practitioners where the statutes currently specifically allow for non-physician health care professionals to participate through telehealth options.[87]

The direct fiscal impact to the state and local entities should be minimal to address any rulemaking issues and potential changes in health care utilization.

[87] *See* ss. 394.453(3), 394.4655(3)(a)1., 394.4655(3)(b), 394.467.(2), F.S. *See also* Child protection teams made up of multidisciplinary members in each of the seven circuits of the Department of Children and Families under s. 39.303, F.S. The members are appropriate representatives from the school district and appropriate health, mental health, social service, legal service, and law enforcement agencies that have oversight for the operations of the child protection teams and sexual abuse treatment programs. Members include a director who must be a physician licensed under chs. 458 or 459, F.S., psychologists, attorneys, representatives from the community based care agency, Florida Sherriff's Association, Children's Medical Services, Children's Advocacy Center, and child protective service team members. The teams may meet or conduct evaluations or consultations by telephone.

VI. Technical Deficiencies:

None.

VII. Related Issues:

As noted in Section V., the definition of telehealth as proposed in the bill limits the practice of telehealth to only those physicians licensed under chs. 458 and 459, F.S. It is unclear what this adoption of this definition may mean for non-physician health care professionals that are currently using telehealth, either in whole or in part, in their practices.

Additionally, in other states where restrictions on who or which type of professions can participate in telehealth were proposed by the state or its regulatory boards, the FTC submitted comments with concerns that such restrictions were a possible restraint on trade and raised antitrust issues in some cases. In its report, *Options to Enhance Occupational License Portability,* in September 2018, the FTC noted that 30 percent of Americans require an occupational license today up from less than 5 percent in the 1950s.[88] The report suggested mechanisms in which states could reduce those barriers such as interstate compacts, model laws, mutual recognition, and license portability for cross-state practice.[89]

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 409.967 and 641.31.

This bill creates the following sections of the Florida Statutes: 456.4501, 627.42393, and 641.31093.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.

[88] Bilal Sayyed, et al, *Policy Perspectives: Options to Enhance Occupational License Portability* (September 2018), p. iv, https://www.ftc.gov/system/files/documents/reports/options-enhance-occupational-license-portability/license_portability_policy_paper.pdf (last visited Mar. 19, 2019).
[89] *Id* at 26.

By Senator Harrell

25-01317B-19 20191526__

A bill to be entitled

An act relating to telehealth; amending s. 409.967, F.S.; prohibiting Medicaid managed care plans from using providers who exclusively provide services through telehealth to achieve network adequacy; deleting obsolete language; creating s. 456.4501, F.S.; defining the terms "telehealth" and "telehealth provider"; establishing certain practice standards for telehealth providers; prohibiting a telehealth provider from using telehealth to prescribe a controlled substance; providing exceptions; clarifying that prescribing medications based solely on answers to an electronic medical questionnaire constitutes a certain failure to practice medicine; specifying equipment and technology requirements for telehealth providers; providing recordkeeping requirements; providing applicability; defining the terms "emergency medical services" and "emergency medical condition"; authorizing the applicable board or the Department of Health to adopt rules; creating s. 627.42393, F.S.; providing reimbursement requirements for health insurers relating to telehealth services; amending s. 641.31, F.S.; prohibiting a health maintenance organization from requiring a subscriber to receive services via telehealth; creating s. 641.31093, F.S.; providing reimbursement requirements for health maintenance organizations relating to telehealth services; providing an effective date.

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

Section 1. Paragraph (c) of subsection (2) of section 409.967, Florida Statutes, is amended to read:

409.967 Managed care plan accountability.—

(2) The agency shall establish such contract requirements as are necessary for the operation of the statewide managed care program. In addition to any other provisions the agency may deem necessary, the contract must require:

(c) *Access.*—

1. The agency shall establish specific standards for the number, type, and regional distribution of providers in managed care plan networks to ensure access to care for both adults and children. Each plan must maintain a regionwide network of providers in sufficient numbers to meet the access standards for specific medical services for all recipients enrolled in the plan. A plan may not use providers who exclusively provide services through telehealth, as defined in s. 456.4501, to meet this requirement. The exclusive use of mail-order pharmacies may not be sufficient to meet network access standards. Consistent with the standards established by the agency, provider networks may include providers located outside the region. ~~A plan may contract with a new hospital facility before the date the hospital becomes operational if the hospital has commenced construction, will be licensed and operational by January 1, 2013, and a final order has issued in any civil or administrative challenge.~~ Each plan shall establish and maintain an accurate and complete electronic database of contracted providers, including information about licensure or

registration, locations and hours of operation, specialty credentials and other certifications, specific performance indicators, and such other information as the agency deems necessary. The database must be available online to both the agency and the public and have the capability to compare the availability of providers to network adequacy standards and to accept and display feedback from each provider's patients. Each plan shall submit quarterly reports to the agency identifying the number of enrollees assigned to each primary care provider.

2. Each managed care plan must publish any prescribed drug formulary or preferred drug list on the plan's website in a manner that is accessible to and searchable by enrollees and providers. The plan must update the list within 24 hours after making a change. Each plan must ensure that the prior authorization process for prescribed drugs is readily accessible to health care providers, including posting appropriate contact information on its website and providing timely responses to providers. For Medicaid recipients diagnosed with hemophilia who have been prescribed anti-hemophilic-factor replacement products, the agency shall provide for those products and hemophilia overlay services through the agency's hemophilia disease management program.

3. Managed care plans, and their fiscal agents or intermediaries, must accept prior authorization requests for any service electronically.

4. Managed care plans serving children in the care and custody of the Department of Children and Families must maintain complete medical, dental, and behavioral health encounter information and participate in making such information available

to the department or the applicable contracted community-based care lead agency for use in providing comprehensive and coordinated case management. The agency and the department shall establish an interagency agreement to provide guidance for the format, confidentiality, recipient, scope, and method of information to be made available and the deadlines for submission of the data. The scope of information available to the department shall be the data that managed care plans are required to submit to the agency. The agency shall determine the plan's compliance with standards for access to medical, dental, and behavioral health services; the use of medications; and followup on all medically necessary services recommended as a result of early and periodic screening, diagnosis, and treatment.

Section 2. Section 456.4501, Florida Statutes, is created to read:

456.4501 Use of telehealth to provide services.—

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

(a) "Telehealth" means the practice of a Florida-licensed telehealth provider's profession in which patient care, treatment, or services are provided through the use of medical information exchanged between one physical location and another through electronic communications. The term does not include audio-only telephone calls, e-mail messages, text messages, U.S. mail or other parcel service, facsimile transmissions, or any combination thereof.

(b) "Telehealth provider" means an individual who provides health care and related services using telehealth and who holds a Florida license under chapter 458 or chapter 459, including

providers who become Florida-licensed by way of the Interstate Medical Licensure Compact.

(2) PRACTICE STANDARD.—

(a) The standard of practice for telehealth providers who provide health care services is the same as the standard of practice for health care professionals who provide in-person health care services to patients in this state. If the standard of practice does not require an in-person physical examination, a telehealth provider may use telehealth to perform a patient evaluation and to provide services to the patient within the provider's scope of practice.

(b) A telehealth provider may not use telehealth to prescribe a controlled substance unless the controlled substance is prescribed for the following:

1. The treatment of a psychiatric disorder;

2. Inpatient treatment at a hospital licensed under chapter 395;

3. The treatment of a patient receiving hospice services as defined in s. 400.601; or

4. The treatment of a resident of a nursing home facility as defined in s. 400.021.

(c) A telehealth provider and a patient may be in separate locations when telehealth is used to provide health care services to a patient.

(d) Prescribing medications solely based on answers to an electronic medical questionnaire constitutes a failure to practice medicine with the level of care, skill, and treatment that a reasonably prudent physician recognizes as being acceptable under similar conditions and circumstances.

(e) Telehealth providers are responsible for the quality of the equipment and technology employed and for the safe use of such equipment and technology. Telehealth equipment and technology must be able to provide, at a minimum, the same information to the physician or physician assistant which will enable them to meet or exceed the standard of practice for the telehealth provider's profession.

(3) RECORDS.—A telehealth provider shall document in the patient's medical record the health care services rendered using telehealth according to the same standards used for in-person services. Medical records, including video, audio, electronic, or other records generated as a result of providing telehealth services, are confidential under ss. 395.3025(4) and 456.057. Patient access to personal health information created by telehealth services is granted under ss. 395.3025 and 456.057.

(4) APPLICABILITY.—

(a) This section does not prohibit consultations between practitioners, to the extent that the practitioners are acting within their scope of practice, or the transmission and review of digital images, pathology specimens, test results, or other medical data related to the care of patients in this state.

(b) This section does not apply to emergency medical services provided by emergency physicians, emergency medical technicians, paramedics, or emergency dispatchers. For the purposes of this section, the term "emergency medical services" includes those activities or services designed to prevent or treat a sudden critical illness or injury and to provide emergency medical care and pre-hospital emergency medical transportation to sick, injured, or otherwise incapacitated

persons in this state.

(c) This section does not apply to a health care provider who is treating a patient with an emergency medical condition that requires immediate medical care. For the purposes of this section, the term "emergency medical condition" means a medical condition characterized by acute symptoms of sufficient severity that the absence of immediate medical attention will result in serious jeopardy to patient health, serious impairment to bodily functions, or serious dysfunction of a body organ or part.

(d) To the extent that a health care provider is acting within his or her scope of practice, this section does not prohibit:

1. A practitioner caring for a patient in consultation with another practitioner who has an ongoing relationship with the patient and who has agreed to supervise the patient's treatment, including the use of any prescribed medications; or

2. The health care provider from caring for a patient in on-call or cross-coverage situations in which another practitioner has access to patient records.

(5) RULEMAKING.—The applicable board, or the department if there is no board, may adopt rules to administer this section.

Section 3. Section 627.42393, Florida Statutes, is created to read:

627.42393 Requirements for insurer reimbursement of telehealth services.—

(1) An individual, group, blanket, or franchise health insurance policy delivered or issued for delivery to any insured person in this state on or after January 1, 2020, may not deny coverage for a covered service on the basis of the service being

provided through telehealth if the same service would be covered if provided through an in-person encounter.

(2) A health insurer may not exclude an otherwise covered service from coverage solely because the service is provided through telehealth rather than through an in-person encounter between a health care provider and a patient.

(3) A health insurer is not required to reimburse a telehealth provider for originating site fees or costs for the provision of telehealth services. However, a health insurer shall reimburse a telehealth provider for the diagnosis, consultation, or treatment of any insured individual provided through telehealth on the same basis that the health insurer would reimburse the provider if the covered service were delivered through an in-person encounter.

(4) A covered service provided through telehealth may not be subject to a greater deductible, copayment, or coinsurance amount than would apply if the same service were provided through an in-person encounter.

(5) A health insurer may not impose upon any insured receiving benefits under this section any copayment, coinsurance, or deductible amount or any policy-year, calendar-year, lifetime, or other durational benefit limitation or maximum for benefits or services provided via telehealth which is not equally imposed upon all terms and services covered under the policy.

(6) This section does not preclude a health insurer from conducting a utilization review to determine the appropriateness of telehealth as a means of delivering a covered service if such determination is made in the same manner as would be made for

the same service provided through an in-person encounter.

(7) A health insurer may limit the covered services that are provided via telehealth to providers who are in a network approved by the insurer.

Section 4. Subsection (45) is added to section 641.31, Florida Statutes, to read:

641.31 Health maintenance contracts.—

(45) A health maintenance organization may not require a subscriber to consult with, seek approval from, or obtain any type of referral or authorization by way of telehealth from a telehealth provider, as defined in s. 456.4501.

Section 5. Section 641.31093, Florida Statutes, is created to read:

641.31093 Requirements for reimbursement by health maintenance organization for telehealth services.—

(1) Each health maintenance organization that offers, issues, or renews a major medical or similar comprehensive contract in this state on or after January 1, 2020, may not deny coverage for a covered service on the basis of the covered service being provided through telehealth if the same covered service would be covered if provided through an in-person encounter.

(2) A health maintenance organization may not exclude an otherwise covered service from coverage solely because the service is provided through telehealth rather than through an in-person encounter between a health care provider and a subscriber.

(3) A health maintenance organization is not required to reimburse a telehealth provider for originating site fees or

costs for the provision of telehealth services. However, a health maintenance organization shall reimburse a telehealth provider for the diagnosis, consultation, or treatment of any subscriber provided through telehealth on the same basis that the health maintenance organization would reimburse the provider if the service were provided through an in-person encounter.

(4) A covered service provided through telehealth may not be subject to a greater deductible, copayment, or coinsurance amount than would apply if the same service were provided through an in-person encounter.

(5) A health maintenance organization may not impose upon any subscriber receiving benefits under this section any copayment, coinsurance, or deductible amount or any contract-year, calendar-year, lifetime, or other durational benefit limitation or maximum for benefits or services provided via telehealth which is not equally imposed upon all services covered under the contract.

(6) This section does not preclude a health maintenance organization from conducting a utilization review to determine the appropriateness of telehealth as a means of delivering a covered service if such determination is made in the same manner as would be made for the same service provided through an in-person encounter.

(7) A health maintenance organization may limit covered services that are provided via telehealth to providers who are in a network approved by the health maintenance organization.

Section 6. This act shall take effect July 1, 2019.

2018 AGENCY LEGISLATIVE BILL ANALYSIS

AGENCY: Agency for Health Care Administration

BILL INFORMATION	
BILL NUMBER:	SB 280
BILL TITLE:	Telehealth
BILL SPONSOR:	Sen. Bean
EFFECTIVE DATE:	July 1, 2018

COMMITTEES OF REFERENCE
1) Banking and Insurance
2) Health Policy
3) Appropriations Subcommittee on Health and Human Services
4) Appropriations
5)

CURRENT COMMITTEE
Banking and Insurance

SIMILAR BILLS	
BILL NUMBER:	
SPONSOR:	

PREVIOUS LEGISLATION	
BILL NUMBER:	
SPONSOR:	
YEAR:	
LAST ACTION:	

IDENTICAL BILLS	
BILL NUMBER:	
SPONSOR:	

Is this bill part of an agency package?
Y ___ N _X__

BILL ANALYSIS INFORMATION	
DATE OF ANALYSIS:	October 9, 2017
LEAD AGENCY ANALYST:	Matt Brackett and Christina Vracar, Division of Medicaid
ADDITIONAL ANALYST(S):	Nikole Helvey, Florida Center for Health Information and Transparency
LEGAL ANALYST:	Amy Miles, Office of the General Counsel
FISCAL ANALYST:	La-Shonna Austin

POLICY ANALYSIS

1. EXECUTIVE SUMMARY

Telehealth technology is being utilized to provide health care services nationally and in Florida. Telehealth can enable real-time (synchronous) communication between patients and healthcare practitioners (or practitioner to practitioner) through live video conferencing; facilitate the (asynchronous) storage and forwarding of clinical data to offsite locations for evaluation by specialist teams; and support remote monitoring of patients' chronic conditions via sensors and monitoring equipment. The United States Department of Health and Human Services notes that telehealth is not a type of healthcare service, but is rather a means or method used to deliver health care services. There are multiple established definitions of telemedicine and telehealth, varying by government agency, state, and use case.

Florida Medicaid currently covers real-time and store and forward telemedicine services in both the managed care and fee-for-service delivery systems. Coverage is defined in a Florida Administrative Code telemedicine rule and in the Statewide Medicaid Managed Care health plan contracts. Medicaid does not cover remote patient monitoring.

Senate Bill (SB) 280, relating to telehealth, amends Florida Statutes (F.S.) to promote use and provide standards for telehealth. The proposed bill provides technical definitions along with broadly applicable standards of practice for telehealth in Florida. The bill includes a definition of telehealth that includes synchronous-real time and asynchronous-store and forward. The bill creates language that encourages the state health insurance plan and workers' compensation plans to provide coverage for telehealth services, codifies telehealth as a Medicaid optional service, and details definitions and practice standards. If enacted, the standards set by this bill may result in increased patient access to preventive care and decrease preventable emergency department and hospital use, improving patient health outcomes and reducing costs. The bill authorizes the Agency to expand Medicaid's existing coverage of telemedicine to include remote patient monitoring and text messaging. The bill provides Florida Medicaid the authority to update federal authorities and make rules, systems, and managed care plan contract updates. There is no anticipated fiscal impact.

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

The Agency for Health Care Administration (Agency) is the single state agency responsible for the administration of the Florida Medicaid program, authorized under Title XIX of the Social Security Act. This authority includes establishing and maintaining a Medicaid state plan, approved by the federal Centers for Medicare and Medicaid Services. A Medicaid state plan is an agreement between a state and the federal government describing how that state administers its Medicaid programs; it establishes groups of individuals covered under the Medicaid program, services that are provided, payment methodologies, and other administrative and organizational requirements. In order to participate in Medicaid, federal law requires states to cover certain population groups (mandatory eligibility groups) and gives them the flexibility to cover other population groups (optional eligibility groups). States set individual eligibility and service coverage criteria within federal minimum standards.

The Statewide Medicaid Managed Care program was authorized in 2011 by the Florida Legislature via the creation of Part IV, Chapter 409, F.S. and was implemented in 2013 and 2014. The Agency contracts with Medicaid health plans on a regional basis to provide services to most Medicaid recipients.

The Florida Medicaid defines telemedicine as the practice of health care delivery by a practitioner who is located at a site other than the site where a recipient is located for the purposes of evaluation, diagnosis, or treatment. Florida Medicaid has allowed services to be delivered via telemedicine for a number of years and has promulgated a rule on telemedicine in Medicaid. Telemedicine services in Florida Medicaid must be provided by licensed practitioners operating within their scope of practice and involve the use of interactive telecommunications equipment which includes, at a minimum, audio and video equipment permitting two-

way, real time, communication between the enrollee and the practitioner. While not considered telemedicine, Florida Medicaid reimburses for laboratory tests, diagnostic tests, and x-rays independent of and in addition to the practitioner's reading, consultation, or diagnosis based upon these items. Additionally, Florida Medicaid reimburses for medically needed consultations for a recipient, independent of telemedicine. For the administration of telemedicine, the Agency has given the broadest and most flexible provisions to the Medicaid health plans. As such, Medicaid health plans have implemented text messaging initiatives and other telehealth pilot projects centered on behavioral health.

Florida Medicaid and the federal Medicaid statute consider telemedicine to be a delivery system rather than a distinct service; as such, Florida Medicaid does not have reimbursement rates specific to the telemedicine mode of service. In the fee-for-service system, Florida Medicaid reimburses services delivered via telemedicine at the same rate and in the same manner as if the service were delivered face-to-face. Medicaid health plans can negotiate rates with providers, so they have the flexibility to pay different rates for services delivered via telemedicine.

In 2016, the Florida Legislature passed House Bill 7087 (Chapter 2016-240, Laws of Florida), requiring a study of telehealth utilization and coverage in the state and establishing a Florida Telehealth Advisory Council (Council). The Agency Secretary was designated as the Chair of the Council and the state's Surgeon General and Secretary of Health was designated as a member. The Agency Secretary and the Surgeon General jointly appointed 11 additional members from specific stakeholder groups as outlined in the law. The law directed the Agency, the Department of Health (DOH), and Office of Insurance Regulation (OIR) to survey licensed health care facilities, practitioners, health insurers, and Health Maintenance Organizations (HMOs) and to submit a report of survey and research findings to the Governor, the President of the Senate, and the Speaker of the House of Representatives by December 31, 2016. The Council was charged with reviewing research and survey findings and developing a report of recommendations to support expansion or increased access to health services provided through telehealth in the state, to be submitted to the Governor and the legislature no later than October 31, 2017.

The Council first convened in October of 2016 and, as of September 30, 2017, has hosted eleven public meetings in multiple regions around the state. At least 30 providers, stakeholders, and national experts have provided formal presentations and testimony to the Council, and numerous stakeholders have provided additional public comments. The Council's final report of recommendations is near completion and scheduled to be submitted by October 31, 2017.

3. EFFECT OF THE BILL:

Senate Bill 280 creates subsection (28) to s. 409.906, F.S. Section 409.906, F.S. outlines optional services that are eligible for reimbursement by Florida Medicaid. These include services such as adult dental, birth center, case management, and optometric. The bill adds multiple telehealth services in the Medicaid optional services statute. These include: live video conferencing, store and forward, and remote patient monitoring of a covered service. The following points detail the authority the bill provides for each telehealth service to be provided by Medicaid:

- Live Video Conferencing: Florida Medicaid currently reimburses practitioners functioning within their scope of practice for live video conferencing through the existing telemedicine rule (Rule 59G-1.057, Florida Administrative Code). There is no operational or fiscal impact to the Florida Medicaid program, as this service modality is currently reimbursable.

- Store and Forward: Florida Medicaid offers store and forward as a covered benefit, however, it is not included in the Medicaid telemedicine rule, but rather is included in other coverage policies and fee schedules. For example, Florida Medicaid reimburses for laboratory tests, diagnostic tests, and x-rays independent of and in addition to the practitioner's reading, consultation, or diagnosis based upon these items. Additionally, Florida Medicaid reimburses for medically needed consultations for a recipient, independent of telemedicine. The proposed bill's store and forward definition will require minor operational changes and does not pose a significant impact to Florida Medicaid.

- Remote Patient Monitoring: Florida Medicaid does not currently have the authority to reimburse for remote patient monitoring of a covered service. Remote patient monitoring can include the reporting of vital signs, weight, blood pressure, oxygen levels, heart rate, and blood sugar. Florida Medicaid reimburses for devices such as pulse oximeters and continuous glucose monitors, and SB 280 provides authority for the Agency to also reimburse for the remote monitoring service. Remote monitoring has the potential to increase patients' engagement in maintaining their own health, provider communication, and patient compliance with recommended treatment, all of which could reduce preventable emergency department visits and hospitalizations. Preventing the unnecessary use of intensive services such as emergency department visits improves health outcomes and can reduce overall health care costs.

Senate Bill 280 creates s. 456.4501, F.S. (use of telehealth to provide services) which provides definitions and practice standards for practitioners. The section of the bill defines the following terms: information and telecommunication technologies, store and forward, synchronous, telecommunication systems, telehealth, and telehealth provider. The bill describes the types of allowable telecommunication technologies, including the use of text messaging. Florida Medicaid health plans currently provide text messaging services as a tool to interact with recipients. The Agency has the flexibility to leverage existing Medicaid health plans and fee-for-service vendors to increase patient communication and treatment compliance through text messaging capabilities.

Currently, Florida Medicaid refers to telehealth as "telemedicine" in its policies. Florida Medicaid and the Centers for Medicare and Medicaid Services define telemedicine as a modality that uses two-way, real-time interactive communication between the patient and the practitioner. To differentiate between telemedicine and telehealth and prevent confusion between the two terms' definitions and their interchangeable use, the Agency may need to amend its policies.

The bill identifies all provider types eligible to provide telehealth services. This provides the Agency the authority to implement routine changes to ensure reimbursement for eligible providers.

Senate Bill 280 amends multiple sections of the Florida Statutes related to the scope of practice and makes other technical modifications. These changes have no impact on the Florida Medicaid program.

Other areas that Senate Bill 280 addresses amend ss. 110.123(b)(3) and 627.0915, F.S. These additions provide specifications for the options that State employees can select for health insurance benefits and add language that encourages the state group health insurance program and workers' compensation programs to offer plans that cover telehealth services. These amendments have no impact on the Florida Medicaid program.

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

4. **DOES THE BILL DIRECT OR ALLOW THE AGENCY/BOARD/COMMISSION/DEPARTMENT TO DEVELOP, ADOPT, OR ELIMINATE RULES, REGULATIONS, POLICIES, OR PROCEDURES?** Y _x__ N ___

If yes, explain:	Existing rules will need to be amended to comply with the bill.
Is the change consistent with the agency's core mission?	Y _x__ N ___
Rule(s) impacted (provide references to F.A.C., etc.):	59G-1.057, F.A.C., and 59G-4.002, F.A.C. (Provider Reimbursement Schedules and Billing Codes)

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

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

6. ARE THERE ANY REPORTS OR STUDIES REQUIRED BY THIS BILL? Y ___ N _X_

If yes, provide a description:	N/A
Date Due:	N/A
Bill Section Number(s):	N/A

7. ARE THERE ANY GUBERNATORIAL APPOINTMENTS OR CHANGES TO EXISTING BOARDS, TASK FORCES, COUNCILS, COMMISSION, ETC.? REQURIED BY THIS BILL? Y ___ N _X_

Board:	N/A
Board Purpose:	N/A
Who Appointments:	N/A
Appointee Term:	N/A
Changes:	N/A
Bill Section Number(s):	N/A

FISCAL ANALYSIS

1. DOES THE BILL HAVE A FISCAL IMPACT TO LOCAL GOVERNMENT? Y ___ N _X_

Revenues:	N/A
Expenditures:	N/A
Does the legislation increase local taxes or fees? If yes, explain.	N/A
If yes, does the legislation provide for a local referendum or local governing body public vote prior to implementation of the tax or fee increase?	N/A

2. DOES THE BILL HAVE A FISCAL IMPACT TO STATE GOVERNMENT? Y ___ N _x__

Revenues:	N/A
Expenditures:	N/A
Does the legislation contain a State Government appropriation?	No

If yes, was this appropriated last year?	N/A

3. DOES THE BILL HAVE A THE FISCAL IMPACT TO THE PRIVATE SECTOR? Y ___ N _X_

Revenues:	N/A
Expenditures:	N/A
Other:	N/A

4. DOES THE BILL INCREASE OR DECREASE TAXES, FEES, OR FINES? Y ___ N _X_

If yes, explain impact.	N/A
Bill Section Number:	N/A

TECHNOLOGY IMPACT

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

If yes, describe the anticipated impact to the agency including any fiscal impact.	The Agency will need to update the Florida Medicaid Management Information System to reflect additional provider types and places of service for telehealth.

FEDERAL IMPACT

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

If yes, describe the anticipated impact including any fiscal impact.	To maintain uniform naming conventions and practice standards throughout the State's policies, the Agency will need to amend the state plan. This requires federal approval.

ADDITIONAL COMMENTS

N/A

LEGAL – GENERAL COUNSEL'S OFFICE REVIEW

Issues/concerns/comments:	None.

THE FLORIDA SENATE

APPEARANCE RECORD

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

03/25/2019
Meeting Date

1526
Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name Paul Sanford

Job Title _____

Address 106 S. Monroe St
Street

Tallahassee, FL 32301
City *State* *Zip*

Phone 850.222-7200

Email _____

Speaking: ☐ For ☐ Against ☒ Information

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

Representing Florida Ins. Council + Florida Blue

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

Meeting Date

H 526

Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic TELEHEALTH

Name RAMON MACRY

Job Title MANAGING PARTNER

Address P.O. BOX 10245 Street

Phone 850 222 1568

TALL FL 32302 City State Zip

Email RME RAMONMACRY.COM

Speaking: ☐ For ☐ Against ☐ Information

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

Representing MARY RAWLINGS BROWARD

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

3/25/19
Meeting Date

SB1526
Bill Number (if applicable)

Topic Telehealth

Amendment Barcode (if applicable)

Name Alison Dudley

Job Title President, AB Dudley: ASC

Address P.O. Box 4208
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Email alison@dudleyandassociates.com

Speaking: ☑ For ☐ Against ☐ Information

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

Representing The Florida Radiological Society

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

3-25-2019
Meeting Date

SB 1526
Bill Number (if applicable)

Topic TELEHEALTH

Amendment Barcode (if applicable)

Name JACK HEBERT

Job Title Govt Affairs Dir.

Address 2861 Executive Dr, #100
Street
Clearwater, FL 33762
City *State* *Zip*

Phone 727-560-3323

Email jack@fcachiro.org

Speaking: ☑ For ☐ Against ☐ Information

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

Representing Florida Chiropractic Assn.

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

3-25
Meeting Date

1526
Bill Number (if applicable)

Topic Telehealth

Amendment Barcode (if applicable)

Name COREY HOWARD, MD

Job Title President, Florida Medical Association

Address 1430 Piedmont Drive E
Street

Tallahassee FL 32308
City *State* *Zip*

Phone 239 821-6325

Email CoreyFMA@gmail.com

Speaking: ☑ For ☐ Against ☐ Information

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

Representing FMA

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

March 25, 2019
Meeting Date

SB 1526
Bill Number (if applicable)

Topic Telehealth

Amendment Barcode (if applicable)

Name Diego Echeverri - "Dee-yay-Goh Etch-uh-very"

Job Title Director of Coalitions

Address 200 W College
Street

Tallahassee FL
City *State* *Zip*

Phone 813-767-2084

Email decheverri@afphq.org

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

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

Representing Americans For Prosperity

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

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

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

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

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

3/25/19
Meeting Date

1526
Bill Number (if applicable)

Topic Telehealth

Amendment Barcode (if applicable)

Name Ron Watson

Job Title Lobbyist

Address 3738 Mirdor Way
Street

Tallahassee FL 32309
City *State* *Zip*

Phone 850 567 1202

Email watsonstrategies@comcast.net

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Renal Coalition

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

3/25/19
Meeting Date

1526
Bill Number (if applicable)

Topic Telehealth

Amendment Barcode (if applicable)

Name Stephen Winn

Job Title Exec. Director

Address 2544 Blairstone Pines Dr
Street

Phone 878-7364

Tall. FL 32301
City *State* *Zip*

Email winnsr@earthlink.net

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Osteopathic Medical Association

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

3/25/2019
Meeting Date

1526
Bill Number (if applicable)

Topic Telehealth

Amendment Barcode (if applicable)

Name Victoria Zepp

Job Title Chief Policy and Research Officer

Address 411 E. College Avenue
Street

Tallahassee FL 32301
City *State* *Zip*

Phone 850/561-1102

Email Victoria@flchildren.org

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Coalition for Children (FCC)

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

3/25/19
Meeting Date

SB 1526
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic Telehealth

Name Dorene Barker

Job Title Associate State Director - Advocacy

Address 200 W. College Ave, Ste 304 A
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City *State* *Zip*

Phone 850-228-6387

Email dobarker@aarp.org

Speaking: ☐ For ☐ Against ☐ Information

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

Representing AARP Florida

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

3/25/19
Meeting Date

1526
Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

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

Representing Florida Chapter, American College of Physicians

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

3/25/19
Meeting Date

1526
Bill Number (if applicable)

Topic Telehealth

Amendment Barcode (if applicable)

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

Representing FL Chapter, American College of Cardiology

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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S-001 (10/14/14)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	CS/SB 1650
INTRODUCER:	Health Policy Committee and Senator Albritton
SUBJECT:	Child Welfare
DATE:	March 25, 2019
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Williams	Brown	HP	**Fav/CS**
2.			CF	
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1650 makes a number of changes to the Florida child welfare laws primarily to ensure compliance with federal regulations for implementation of the federal Family First Prevention Services Act and to align with the Title IV-E and Guardianship Assistance Program (GAP) requirements. Specifically, the bill:

- Amends provisions relating to the Relative Caregiver Program (RCP) to authorize relatives and nonrelatives who are caring for a child and who do not meet the eligibility requirement for Level I licensure under child placement criteria to apply for the RCP.
- Provides that guardianship assistance benefits under the GAP will be terminated if the guardian is no longer providing support for the child.
- Clarifies provisions relating to the extended foster care program, including requiring a young adult participating in the program to provide specified documentation of eligibility and granting the Department of Children and Families (DCF) rulemaking authority.
- Amends provisions relating to judicial reviews for young adults who are leaving and re-entering extended care.
- Clarifies provisions relating to financial assistance and other benefits available to children and young adults.
- Amends requirements relating to the licensure of family foster homes, residential child-caring agencies, and child-placing agencies, to either meet federal requirements or to streamline requirements for Level I licensing.
- Reduces from three months to 60 days the period of time for a court review following a child's placement in a residential treatment program.

The bill provides that, in questions regarding whether the DCF may provide psychotropic medications to a child in its custody, an advanced practice registered nurse whose specialty is psychiatric nursing and who has prescribing authority under a supervisory protocol established with a physician as provided pursuant to the Nurse Practice Act, may perform certain medical, psychiatric, and psychological examinations of and provide treatment to children in care, and may perform physical, mental, and substance abuse examinations of a person with or requesting child custody services. Under current law, such services must be performed by a physician.

The DCF estimates the bill to have no fiscal impact.

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

II. Present Situation:

Child Welfare

Chapter 39, F.S., is specific to judicial proceedings relating to children and is divided into multiple parts under this topic. Part IV is specific to the process of taking children into the state's custody and corresponding shelter hearings under that process.

Relative and Nonrelative Caregivers

When children cannot remain safely with their parents, placement with relatives is preferred over placement in foster care with nonrelatives. Caseworkers try to identify and locate a relative or relatives who can safely care for the children while parents receive services to help them address the issues that brought the children to the attention of child welfare. Placement with relatives – or kinship care – provides permanency for children and helps them maintain family connections. Kinship care is the raising of children by grandparents, other extended family members, and adults with whom they have a close family-like relationship, such as godparents and close family friends.[1, 2]

Kinship care may be formal and involve a training and licensure process for the caregivers, monthly payments to help defray the costs of caring for the child, and support services. Kinship care also may be informal and involve only an assessment process to ensure the safety and suitability of the home along with supportive services for the child and caregivers. Approximately 25 percent of the children in out-of-home care are living with relatives.[3]

[1] "Fictive kin" is a term used to refer to individuals that are unrelated by either birth or marriage, but have an emotionally significant relationship with another individual that would take on the characteristics of a family relationship.
[2] U.S. Department of Health & Human Services, Administration for Children & Families, Children's Bureau, Child Welfare Information Gateway, About Kinship Care, *available at* https://www.childwelfare.gov/topics/outofhome/kinship/about/ (last visited March 17, 2019).
[3] Id.

In Florida, a point-in-time count as of January 1, 2019, showed there were 23,726 children in out of-home care. Of those children, 13,449 were in kinship care foster care placements (56.7 percent) and 10,277 were in licensed foster care placements (43.3 percent).[4]

Relative Caregiver Program (RCP)

The Relative Caregiver Program was established in 1998[5] for the purpose of recognizing the importance of family relationships and providing additional placement options and incentives to help achieve permanency and stability for many children who are otherwise at risk of foster care placement. The program provides financial assistance to qualified relatives. Within available funding, the Relative Caregiver Program is also required to provide caregivers with family support and preservation services, school readiness assistance, and other available services in order to support the child's safety, growth, and healthy development. Children living with caregivers who are receiving assistance under the program are also eligible for Medicaid coverage.[6]

In 2014, the Legislature expanded the program to include nonrelatives who a child may have a close relationship with but who are not a blood relative or a relative by marriage. Those nonrelatives are eligible for financial assistance if they are able and willing to care for the child and provide a safe, stable home environment. Before such placement is made, a court must find that the proposed placement is in the best interest of the child.[7]

Current law provides that the statewide average monthly rate for children placed by a court with relatives or nonrelatives who are not licensed as foster homes may not exceed 82 percent of the statewide average foster care rate, and the cost of providing the assistance to any caregiver in the program may not exceed the cost of providing out-of-home care in emergency shelter or foster care.[8]

This program provides monthly cash assistance to relatives who meet eligibility rules and have custody of a child under age 18 who has been declared dependent by a Florida court and placed in their home by the Department of Children and Families (DCF) or a Community Based Care (CBC) contracted provider. The monthly cash assistance amount is higher than the Temporary Cash Assistance for one child but less than the amount paid for a child in the foster care program.

Fostering Connections to Success and Increasing Adoptions Act

The Fostering Connections to Success and Increasing Adoptions Act of 2008 (Fostering Connections) was enacted into federal law in October 2008. Among its many provisions, it gave

[4] Foster care includes all children who have been removed from their homes due to abuse, neglect or abandonment. Kinship foster care is a subset that includes children who are placed with relatives or other person(s) deemed to be a significant person in the child's life. Licensed foster care is a subset that includes traditional family foster homes, therapeutic foster homes, group homes, residential placements and other settings requiring a license.
[5] Chapter 98-78, L.O.F.
[6] Chapter 2014-224, L.O.F.
[7] Section 39.5085, F.S.
[8] Id.

states for the first time the option to use funds through federal Title IV-E of the Social Security Act (Title IV-E) for financing guardianship assistance programs (GAP). Otherwise known as subsidized guardianship, the programs enabled children in the care of grandparents and other relatives to exit foster care into permanent homes.[9]

Guardianship Assistance Program (GAP)

Florida established its GAP program in law in 2018,[10] and the program will begin on July 1, 2019. The GAP allows DCF to provide caregivers who establish legal guardianship with a larger monthly stipend compared to existing state programs.

Under the federal requirements, if a child meets select Title IV-E eligibility standards, the child's caregiver may also be eligible for a GAP subsidy if:

- The child has been removed from his or her family's home pursuant to a voluntary placement agreement or as a result of a judicial determination that allowing the child to remain in the home would be contrary to the child's welfare;
- The child is eligible for federal foster care maintenance payments under Title IV-E of the Social Security Act for at least six consecutive months while residing in the home of the prospective relative guardian who is licensed or approved as meeting the licensure requirements as a foster family home;
- Returning home or adoption are not appropriate permanency options for the child;
- The guardian demonstrates a strong commitment to caring permanently for the child; and,
- The child has been consulted regarding the guardianship arrangement (applicable to children age 14 and older).[11]

A prospective guardian must meet certain conditions to qualify for a GAP subsidy. He or she must:

- Be the eligible child's relative or close fictive kin;
- Have undergone fingerprint-based criminal record checks and child abuse and neglect registry checks;
- Be a licensed foster parent and approved for guardianship assistance by the relevant state department;
- Display a strong commitment to caring permanently for the child; and,
- Have obtained legal guardianship of the child after the guardianship assistance agreement has been negotiated and finalized with the state.

Nonrelative caregivers currently receive monthly assistance supported by the state General Revenue Fund. Until the Legislature authorized the GAP effective July 1, 2019, the RCP provided the only financial assistance available to relative and nonrelative caregivers who have children placed with them. The RCP and GAP programs will run concurrently starting July 1, 2019, and relative and nonrelative caregivers must first fail to meet the requirements of GAP before being admitted into the RCP.

[9] Public Law No. 110-351.
[10] Section 39.6225, F.S.
[11] 42 U.S.C. s. 673(d)(3)(A).

Title IV-E Waivers

In 1994, the U.S. Department of Health and Human Services (HHS) was authorized to approve state demonstration projects made possible by waiving certain provisions of Title IV-E. This provided states flexibility in using federal funds for services promoting safety, well-being, and permanency for children in the child welfare system.[12] HHS may waive compliance with standard Title IV-E requirements and instead allow states to establish projects that allow them to serve children and provide services that are not typically eligible. To do so, states must enter into an agreement with the federal government outlining the terms and conditions to which the state will adhere in using the federal funds. Currently, 26 states have approved projects, including Florida.

Florida's Title IV-E Waiver

Florida's original Title IV-E waiver was effective October 1, 2006, with a 5-year duration. Key features of the waiver were:

- A capped allocation of funds, similar to a block grant, distributed to CBCs for service provision;
- Flexibility to use funds for a broader array of services beyond out-of-home care; and
- Ability to serve children who did not meet Title IV-E criteria.

The original waiver tested the hypotheses that under this approach:

- An expanded array of CBC services would become available;
- Fewer children would need to enter out-of-home care;
- Child outcomes would improve; and
- Out-of-home care costs would decrease while expenditures for in-home and preventive services would increase.

Florida's waiver is due to end September 30, 2019. Florida will revert to the more restrictive Title IV-E federal funding requirements beginning the next day. When the waiver expires, the state will be required to revert to a traditional Title IV-E service model, which will both eliminate federal support for many current services, forcing the state to either end those services or pay for them without federal funds. DCF estimates that under the latter option, expiration of the waiver will lead to an operating deficit of roughly $70-90 million per year over the next five fiscal years.

Family First Prevention Services Act

The Family First Prevention Services Act (Family First) was signed into law as part of the Bipartisan Budget Act on February 9, 2018.[13] Family First amended Title IV-E and Title IV-B of the Social Security Act to make significant changes to child welfare laws to help keep children safely with their families and avoid the experience of entering the foster care system, to

[12] Amy C Vargo et al., *IV-E Waiver Demonstration Evaluation, Final Evaluation Report, SFY 11-12*, (March 15, 2012), *available at* http://centerforchildwelfare.org/kb/LegislativeMandatedRpts/IV-EWaiverFinalReport3-28-12.pdf (last visited March 19, 2019).

[13] Public Law No. 115–123

emphasize the importance of children growing up in families, and to help ensure children are placed in the least restrictive, most family-like setting appropriate to their special needs when out-of-home care is needed.[14] The effective date coincides with the expiration of the Title IV-E waiver that Florida has been operating under since 2006. Family First includes:

- Federal prevention funds for children at risk of entering foster care. Family First provides federal funds under Title IV-E of the Social Security Act, beginning in FY 2020, to support evidence-based prevention efforts for:
  - Mental health and substance abuse prevention and treatment services and
  - In-home parent skill-based services.

  Such services may be provided for not more than 12 months for children who are at imminent risk of entering foster care, their parents and relatives to assist the children, and pregnant or parenting teens.
- Federal funds targeted for children in foster family homes, or in qualified residential treatment programs, or other special settings. Federal funding is limited to children in family foster homes, qualified residential treatment programs, and special treatment settings for pregnant or parenting teens, youth 18 and over preparing to transition from foster care to adulthood, and youth who have been found to be – or are at risk of becoming – sex trafficking victims.

Family First requires timely assessments and periodic reviews of children with special needs who are placed in qualified residential treatment programs to ensure their continued need for such care. After FY 2020 (unless the state opts to delay until 2022), Title IV-E reimbursement will be provided only for administrative costs for children in other group care settings, and not for room and board.

The new funding for preventing children from entering foster care and restricting federal funds for group care takes effect in FY 2020 (or 2022 at a state's option) so that states can make necessary accommodations. Family First recognizes adjustments will be needed to establish prevention services to keep children safely in families and in care that meets their special treatment needs. States have flexibility in defining the safety services they provide to children and families and how they will ensure quality residential treatment for children with emotional and behavioral needs.[15]

Florida has asked for the 2-year extension in implementing Family First.

Regulation of Nursing

As authorized under s. 20.43, F.S., the Department of Health (DOH) and its Division of Medical Quality Assurance is responsible for regulating 30 health care professions. Among those is nursing and the Board of Nursing (BON), as created under Part I of Ch. 464, F.S., the Nurse Practice Act, which governs the licensure and regulation of nurses in Florida. Nurses are licensed

[14] Children's Defense Fund, *Family First Prevention Services Act*, available at https://www.childrensdefense.org/policy/policy-priorities/child-welfare/family-first/ (last visited March 19. 2019).
[15] Id.

by the DOH[16] and regulated by the BON.[17] A person desiring to practice nursing in Florida must obtain a Florida license by examination,[18] endorsement,[19] or hold an active multistate license pursuant to s. 464.0095, F.S., the Nurse Licensure Compact.[20]

Advanced Practice Registered Nurses

An "Advanced Practice Registered Nurse" (APRN) is a person licensed in this state to practice professional nursing and certified in advanced or specialized nursing practice, such as certified registered nurse anesthetists (CRNAs), psychiatric nurses, certified nurse midwives (CNM), and nurse practitioners.[21] The term "advanced or specialized nursing practice" is also defined.[22]

Advanced or specialized nursing practice means, in addition to the practice of professional nursing, the performance of advanced-level nursing acts approved by the BON, which, by virtue of specialized education, training, and experience, are appropriately performed by an APRN. Within the context of advanced or specialized nursing practice, the APRN may perform acts of nursing diagnosis and nursing treatment of alterations of the health status. The APRN may also perform acts of medical diagnosis and treatment, prescription, and operation as authorized within the framework of an established protocol under the supervision of a physician.[23] In addition, within a supervisory protocol, an APRN may:

- Prescribe, dispense, administer, or order any drug; however, an APRN must have graduated from a program leading to a master's or doctoral degree in a clinical nursing specialty area with training in specialized practitioner skills before being allowed to prescribe controlled substances;
- Order diagnostic tests and physical and occupational therapy;
- Order any medication for administration in a hospital, ambulatory surgical center, or nursing home; and
- Perform additional acts within his or her specialty.[24]

[16] Section 464.008, F.S.
[17] The Board of Nursing (BON) is comprised of 13 members appointed by the Governor and confirmed by the Senate who serve 4-year terms. All members must be residents of the state. Seven members must be registered nurses who are representative of the diverse areas of practice within the nursing profession. Three members must be licensed practical nurses and three members must be laypersons. At least one member of the BON must be 60 years of age or older. *See* s. 464.004, F.S.
[18] An individual must pass the National Council Licensure Examination (NCLEX), have graduated from an approved nursing education program, and pass applicable background screening. *See* s. 464.008, F.S.
[19] Licensed in another state or territory, actively practiced nursing for two of the previous 3 years prior to application without discipline, and meet the equivalent educational and examination qualifications.
[20] In 2016, the Legislature created s. 464.0095, F.S., which adopts the revised Nurse Licensure Compact (NLC) in its entirety into state law. This legislation allows licensed practical and professional nurses to practice in all member states by maintaining a single license in the nurse's primary state of residence. The effective date of s. 464.0095, F.S., was December 31, 2018, or upon enactment of the revised NLC into law by 26 states, whichever occurs first. At least 26 states have enacted the revised NLC into law and the Enhanced Nurse Licensure Compact Interstate Commission set the implementation date as January 19, 2018. The DOH and the Florida BON have implemented the NLC. *See* http://floridasnursing.gov/latest-news/the-enlc-was-implemented-on-january-19-2018 (last visited Jan. 25, 2018).
[21] *See* ss. 464.003(3) and 464.012(1)(a), F.S.
[22] Section 464.003(2), F.S.
[23] Section 464.003(2), F.S.
[24] Section 464.012(3) and (4), F.S.

Subsection (6) of s. 464.012, F.S., directs the BON to establish a committee to recommend a formulary of controlled substances that an APRN may not prescribe or prescribe only for specific uses or limited quantities. The language goes on to indicate that the formulary must restrict the prescribing of psychiatric mental health controlled substances for children younger than 18 years of age to advanced practice registered nurses who also are psychiatric nurses as defined in s. 394.455, F.S. The formulary must also limit the prescribing of Schedule II controlled substances as listed in s. 893.03, F.S., to a 7-day supply, except that such restriction does not apply to controlled substances that are psychiatric medications prescribed by psychiatric nurses as defined in s. 394.455, F.S.

An APRN must maintain medical malpractice insurance or provide proof of financial responsibility, unless exempt.[25]

Any nurse desiring to obtain Florida certification as an APRN must submit to the DOH, among other information, proof that he or she holds a current Florida professional nursing license as registered nurse or holds an active multistate license to practice professional nursing, and meets at least one of the following additional requirements:

- Certification by an appropriate specialty board such as a registered nurse anesthetist, psychiatric nurse, or nurse midwife; or
- Graduation from a nursing program leading to a master's degree in a nursing clinical specialty area with preparation in specialized practitioner skills. An applicant graduating on or after October 1, 1998, must meet this requirement for initial certification as a nurse practitioner. An applicant graduating on or after October 1, 2001, must meet this requirement for initial certification as a Certified Registered Nurse Anesthetist (CRNA).[26]

The Florida Mental Health Act

Chapter 394, F.S., is specific to mental health. Part I of ch. 394, F.S., is "The Florida Mental Health Act." Consisting of ss. 394.451-394.47892, F.S., this part provides the statutory basis under which the DCF plans for, evaluates, and implements a statewide program of mental health, including community services, receiving and treatment facilities, child services, research, and training, as authorized and approved by the Legislature, based on the annual program budget of the DCF.

The DCF also coordinates its efforts with other departments and divisions of the state government, county and municipal governments, and private agencies concerned with and providing mental health services. The DCF establishes standards, provides technical assistance, and exercises supervision of mental health programs of, and the treatment of patients at, community facilities, other facilities for persons who have a mental illness, and any agency or facility providing services to patients pursuant to part I of ch. 394, F.S.

Section 394.455, F.S., provides the definitions of 48 applicable terms used in part I of ch. 394, F.S. Subsection (35) defines "psychiatric nurse" to mean an advanced practice registered nurse licensed under s. 464.012, F.S., who has a master's or doctoral degree in psychiatric nursing,

[25] Section 456.048, F.S.
[26] Section 464.012(1), F.S., as amended by chapter 2017-134, Laws of Fla.

holds a national advanced practice certification as a psychiatric mental health advanced practice nurse, and has 2 years of post-master's clinical experience under the supervision of a physician.

Child Welfare: Treating Practitioners

Section 39.407, F.S., provides for the medical, psychiatric, and psychological examination and treatment of children in care and the physical, mental, and substance abuse examination of a person with or requesting child custody. Under these provisions, the determination of the use or continued use of a psychotropic medication in the treatment of a child in custody may be determined only by a prescribing physician. This must be done only after an attempt to obtain express and informed consent as defined in s. 394.455(15), F.S., and as described in s. 394.459(3)(a), F.S., from the child's parent or legal guardian. In instances where parental rights have been terminated or a parent cannot be located or is unknown, or the parent declines to provide consent, the DCF may, after consultation with a prescribing physician, seek court authorization to provide psychotropic medications to the child.

III. Effect of Proposed Changes:

Section 1 amends s. 39.01, F.S., relating to definitions. The definition of the term "institutional child abuse or neglect" is amended to clarify that employees of public schools, as well as private schools, are part of the definition for institutional child abuse or neglect to bring the definition into agreement with s. 39.01(54), F.S., which provides the definition of "other person responsible for a child's welfare."

Section 2 amends s. 39.4015, F.S., to delete the definition of fictive kin. The definition of fictive kin in s. 39.01, F.S., meets the Title IV-E requirements, and a duplicative definition is unnecessary.

Section 3 amends s. 39.402, F.S., relating to placement in a shelter, to require the order for placement of a child in shelter care contain a statement that the DCF has placement and care responsibility for any child who is not placed in the care of a parent at the conclusion of the shelter hearing. This brings the state into compliance with federal requirements.

Section 4 amends s. 39.407, F.S., relating to whether the DCF may provide psychotropic medications to a child in its custody. The bill provides that, in the process for making that determination, an advanced practice registered nurse whose specialty is psychiatric nursing and who has prescribing authority under a supervisory protocol established with a physician as provided pursuant to the Nurse Practice Act, may perform certain medical, psychiatric, and psychological examinations of and provide treatment to children in care, and may perform physical, mental, and substance abuse examinations of a person with or requesting child custody services. Under current law, such services must be performed by a physician.

The bill reduces from 3 months to 60 days the period of time for a court review following a child's placement in a residential treatment program.

Section 5 amends s. 39.5085, F. S., relating to the Relative Caregiver Program, to authorize relatives and nonrelatives who are caring for a child and who do not meet the eligibility

requirement for Level I licensure under s. 409.175, F.S., to apply for the Relative Caregiver Program.

Section 6 amends s. 39.5086, F.S., relating to kinship navigator programs, to delete the unnecessary definition for the term "fictive kin".

Section 7 amends s. 39.6225, F.S., relating to the Guardianship Assistance Program (GAP), to provide that guardianship assistance benefits under the GAP will be terminated if the guardian is no longer providing support for the child. This change was suggested by the Children's Bureau, Administration for Children and Families, U.S. Department of Health and Human Services.[27]

The bill also provides that the case plan must describe information regarding permanent guardianship if the guardian is *pursuing* guardianship assistance payments. Current statute requires the case plan to include information regarding permanent guardianship if the guardian is *receiving* guardianship assistance payments.

Section 8 amends s. 39.6251, F.S., relating to extended foster care for young adults, to make a number of changes, including:

- Requiring a young adult in the extended foster care program to either furnish documentation of participation in one of the required activities or execute a consent for release of records to the DCF or CBC to obtain the documentation.
- Amending the permanency goal for a young adult who chooses to remain in the extended foster care program past his or her 18th birthday to transition to independence.
- Allowing a young adult who is between the ages of 18 and 21 and who has left the program, to apply with the CBC for readmission through the execution of a voluntary placement agreement. This change allows the state to request Title IV-E reimbursement.
- Providing the DCF with rulemaking authority to administer the extended foster care program. The DCF is authorized to develop rules to establish processes and procedures for the program. This change will help provide consistent application of the program statewide.

Section 9 amends s. 39.701, F.S., relating to judicial review, to make a number of changes including:

- Replacing the current provision that requires the court to return the child to the custody of the parent(s) if it is determined that the parent(s) have substantially complied with the case plan.
- Requiring that if the court determines at any judicial review that the child will remain in out-of-home care in a placement other than with a parent, the court must order that the DCF has placement and care responsibility for the child.
- Addressing additional ways to enter extended foster care while expanding the DCF's ability to seek reimbursement of Title IV-E funds. Section 39.701(4)(f), F.S., allows a young adult to elect to voluntarily leave extended foster care for the sole purpose of ending a removal episode and immediately executes a voluntary placement agreement with the DCF to reenroll in extended foster care, the court must enter an order finding that the prior removal episode ended. Under these circumstances, the court does not lose its jurisdiction and no petition to reinstate jurisdiction is required.

[27] Department of Children and Families, *Senate Bill 1650 Analysis* (February 16, 2019) (on file with the Senate Committee on Health Policy).

- Creating s. 39.701(4)(g), F.S., to require that when a youth enters extended foster care by executing a voluntary placement agreement, the court must enter an order within 180 days of the agreement that determines whether the supervised living arrangement is in the best interest of the youth. The supervised living arrangement may include a licensed foster home, licensed group home, college dormitory, shared housing, apartment or another housing arrangement if approved by the CBC and is acceptable to the young adult. In addition, when a youth is in extended foster care, the court must include in each judicial review order that the DCF has placement and care responsibility for the youth. Lastly, when a youth is in extended foster care, the court must enter an order at a minimum of every 12 months that includes a finding of whether the DCF has made reasonable efforts to finalize the permanency plan currently in effect.

Section 10 amends s. 409.1451, F.S., relating to the Road-to-Independence Program, to clarify that financial assistance to young adults receiving independent living services including Postsecondary Education Services and Support (PESS), Title IV-E EFC, and Aftercare services may be disregarded for purposes of determining eligibility for, or the amount of, any other federal or federally supported assistance. This will ensure that young adults have access to all assistance programs, if they meet the other eligibility criteria, regardless of their participation in independent living services pursuant to ss. 39.6251 and 409.1451, F.S.

Section 11 amends s. 409.175, F.S., relating to the licensure of family foster homes, residential child-caring agencies, and child-placing agencies, to either meet federal requirements or to streamline requirements for Level I licensing. Changes made to meet federal requirements in order to receive Title IV-E reimbursement related to licensure include:

- Clarifying that a family foster home is a home licensed by the DCF.
- Screening household members in the renewal process for licensure if they have worked or resided on a continuous basis in the home since fingerprints were submitted to the DCF.
- Adding the ability to extend a license up to, but no more than, 30 days.
- Deleting the DCF's ability to provide a provisional license.

Changes made to streamline Level I licensure include:

- Clarifying that the term "personnel" does not include a family foster home.
- Clarifying that background "screening" of personnel applies to Level II through Level V family foster home licensing.
- Adding foster family homes in the screening requirements for good moral character.
- Adding actions by a family foster home or household members to the list of who the DCF may deny, suspend, or revoke a license due to removing family foster home from the definition of personnel.
- Adding family foster homes and household members to the list of those who willfully or intentionally fail to comply with the requirements for background screening.
- Deleting the specified number of preservice and in-service training hours and allowing the DCF to establish the hours by rule.

Section 12 amends s. 409.903, F.S., relating to mandatory payments for medical assistance and related services to eligible individuals, to include children who receive GAP benefits as eligible

for Medicaid. Changes to this section will bring the DCF into compliance with federal requirements.

Section 13 amends s. 409.991, F.S., relating to allocation of funds for community-based care lead agencies. Core services funds are all funds allocated to community-based care lead agencies with a number of exceptions. The bill excludes GAP funding from core services funds in determining the allocations for the CBC lead agencies. This means that funding for GAP is not eligible for distribution according to the equity formula and allows the funds to be distributed based on the projected population and GAP payments made by the CBC lead agencies.

Section 14 amends s. 414.045, F.S., relating to the cash assistance program, to add families in GAP as a "child-only" case, which can be funded through TANF. Families in the Relative Caregiver Program are currently considered child-only cases.

Section 15 amends s. 1009.25, F.S., relating to postsecondary fee exemptions.
Section 1009.25(1)(d), F.S., currently provides a tuition fee exemption to a student who is or was at the time he or she reached 18 years of age, in the custody of a relative or nonrelative. The change clarifies that children who are permanently placed with a relative have access to tuition exemptions until the age of 28, whether they are eligible for GAP or the RCP.

Section 16 provides an effective date of July, 1, 2019.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

The DCF estimates the bill to have no fiscal impact.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

The bill amends the following sections of the Florida Statutes: 39.01, 39.4015, 39.402, 39.407, 39.5085, 39.5086, 39.6225, 39.6251, 39.701, 409.1451, 409.175, 409.903, 409.991, 414.045, and 1009.25.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Policy on March 25, 2019:
The CS makes the following changes to the bill:

- Retains the definition of "fictive kin" in s. 39.01, F.S. The result is that multiple sections of statute which were modified in the underlying bill to conform cross-references are no longer necessary and have been removed from the bill.
- Modifies provisions under the Relative Caregiver Program such that relatives who are caring for a child and who do not meet the eligibility requirements for Level I under s. 409.175, F.S., relating to licensure of child-placement programs, are authorized to apply for the Relative Caregiver Program. The underlying bill required such caregivers to be denied under the Guardianship Assistance Program before applying to the Relative Caregiver Program.

B. Amendments:

None.

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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/25/2019	.	
	.	
	.	
	.	

The Committee on Health Policy (Albritton) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Subsection (37) of section 39.01, Florida Statutes, is amended to read:

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

(37) "Institutional child abuse or neglect" means situations of known or suspected child abuse or neglect in which

the person allegedly perpetrating the child abuse or neglect is an employee of a public or private school, public or private day care center, residential home, institution, facility, or agency or any other person at such institution responsible for the child's care as defined in this section ~~subsection (54)~~.

Section 2. Paragraph (d) of subsection (2) of section 39.4015, Florida Statutes, is amended to read:

39.4015 Family finding.—

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

~~(d) "Fictive kin" means an individual who is unrelated to the child by either birth or marriage, but has such a close emotional relationship with the child that he or she may be considered part of the family.~~

Section 3. Paragraph (h) of subsection (8) of section 39.402, Florida Statutes, is amended to read:

39.402 Placement in a shelter.—

(8)

(h) The order for placement of a child in shelter care must identify the parties present at the hearing and must contain written findings:

1. That placement in shelter care is necessary based on the criteria in subsections (1) and (2).

2. That placement in shelter care is in the best interest of the child.

3. That continuation of the child in the home is contrary to the welfare of the child because the home situation presents a substantial and immediate danger to the child's physical, mental, or emotional health or safety which cannot be mitigated by the provision of preventive services.

4. That based upon the allegations of the petition for placement in shelter care, there is probable cause to believe that the child is dependent or that the court needs additional time, which may not exceed 72 hours, in which to obtain and review documents pertaining to the family in order to appropriately determine the risk to the child.

5. That the department has made reasonable efforts to prevent or eliminate the need for removal of the child from the home. A finding of reasonable effort by the department to prevent or eliminate the need for removal may be made and the department is deemed to have made reasonable efforts to prevent or eliminate the need for removal if:

a. The first contact of the department with the family occurs during an emergency;

b. The appraisal of the home situation by the department indicates that the home situation presents a substantial and immediate danger to the child's physical, mental, or emotional health or safety which cannot be mitigated by the provision of preventive services;

c. The child cannot safely remain at home, either because there are no preventive services that can ensure the health and safety of the child or because, even with appropriate and available services being provided, the health and safety of the child cannot be ensured; or

d. The parent or legal custodian is alleged to have committed any of the acts listed as grounds for expedited termination of parental rights in s. 39.806(1)(f)-(i).

6. That the department has made reasonable efforts to keep siblings together if they are removed and placed in out-of-home

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care unless such placement is not in the best interest of each child. It is preferred that siblings be kept together in a foster home, if available. Other reasonable efforts shall include short-term placement in a group home with the ability to accommodate sibling groups if such a placement is available. The department shall report to the court its efforts to place siblings together unless the court finds that such placement is not in the best interest of a child or his or her sibling.

7. That the court notified the parents, relatives that are providing out-of-home care for the child, or legal custodians of the time, date, and location of the next dependency hearing and of the importance of the active participation of the parents, relatives that are providing out-of-home care for the child, or legal custodians in all proceedings and hearings.

8. That the court notified the parents or legal custodians of their right to counsel to represent them at the shelter hearing and at each subsequent hearing or proceeding, and the right of the parents to appointed counsel, pursuant to the procedures set forth in s. 39.013.

9. That the court notified relatives who are providing out-of-home care for a child as a result of the shelter petition being granted that they have the right to attend all subsequent hearings, to submit reports to the court, and to speak to the court regarding the child, if they so desire.

10. That the department has placement and care responsibility for any child who is not placed in the care of a parent at the conclusion of the shelter hearing.

Section 4. Subsection (3) and paragraphs (g), (h), and (i) of subsection (6) of section 39.407, Florida Statutes, are

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amended to read:

39.407 Medical, psychiatric, and psychological examination and treatment of child; physical, mental, or substance abuse examination of person with or requesting child custody.—

(3)(a)1. Except as otherwise provided in subparagraph (b)1. or paragraph (e), before the department provides psychotropic medications to a child in its custody, the prescribing physician or the advanced practice registered nurse whose specialty is psychiatric nursing, as defined in chapter 394, and who is given prescribing authority pursuant to chapter 464 shall attempt to obtain express and informed consent, as defined in s. 394.455(15) and as described in s. 394.459(3)(a), from the child's parent or legal guardian. The department must take steps necessary to facilitate the inclusion of the parent in the child's consultation with the physician or advanced practice registered nurse. However, if the parental rights of the parent have been terminated, the parent's location or identity is unknown or cannot reasonably be ascertained, or the parent declines to give express and informed consent, the department may, after consultation with the prescribing physician or advanced practice registered nurse, seek court authorization to provide the psychotropic medications to the child. Unless parental rights have been terminated and if it is possible to do so, the department shall continue to involve the parent in the decisionmaking process regarding the provision of psychotropic medications. If, at any time, a parent whose parental rights have not been terminated provides express and informed consent to the provision of a psychotropic medication, the requirements of this section that the department seek court authorization do

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not apply to that medication until such time as the parent no longer consents.

2. Any time the department seeks a medical evaluation to determine the need to initiate or continue a psychotropic medication for a child, the department must provide to the evaluating physician or advanced practice registered nurse all pertinent medical information known to the department concerning that child.

(b)1. If a child who is removed from the home under s. 39.401 is receiving prescribed psychotropic medication at the time of removal and parental authorization to continue providing the medication cannot be obtained, the department may take possession of the remaining medication and may continue to provide the medication as prescribed until the shelter hearing, if it is determined that the medication is a current prescription for that child and the medication is in its original container.

2. If the department continues to provide the psychotropic medication to a child when parental authorization cannot be obtained, the department shall notify the parent or legal guardian as soon as possible that the medication is being provided to the child as provided in subparagraph 1. The child's official departmental record must include the reason parental authorization was not initially obtained and an explanation of why the medication is necessary for the child's well-being.

3. If the department is advised by a physician licensed under chapter 458 or chapter 459 or an advanced practice registered nurse whose specialty is psychiatric nursing, as defined in chapter 394, and who is given prescribing authority

pursuant to chapter 464 that the child should continue the psychotropic medication and parental authorization has not been obtained, the department shall request court authorization at the shelter hearing to continue to provide the psychotropic medication and shall provide to the court any information in its possession in support of the request. Any authorization granted at the shelter hearing may extend only until the arraignment hearing on the petition for adjudication of dependency or 28 days following the date of removal, whichever occurs sooner.

4. Before filing the dependency petition, the department shall ensure that the child is evaluated by a physician licensed under chapter 458 or chapter 459 or an advanced practice registered nurse whose specialty is psychiatric nursing, as defined in chapter 394, and who is given prescribing authority pursuant to chapter 464 to determine whether it is appropriate to continue the psychotropic medication. If, as a result of the evaluation, the department seeks court authorization to continue the psychotropic medication, a motion for such continued authorization shall be filed at the same time as the dependency petition, within 21 days after the shelter hearing.

(c) Except as provided in paragraphs (b) and (e), the department must file a motion seeking the court’s authorization to initially provide or continue to provide psychotropic medication to a child in its legal custody. The motion must be supported by a written report prepared by the department which describes the efforts made to enable the prescribing physician or advanced practice registered nurse whose specialty is psychiatric nursing, as defined in chapter 394, and who is given prescribing authority pursuant to chapter 464 to obtain express

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and informed consent for providing the medication to the child and other treatments considered or recommended for the child. In addition, the motion must be supported by the prescribing physician's or advanced practice registered nurse's signed medical report providing:

1. The name of the child, the name and range of the dosage of the psychotropic medication, and that there is a need to prescribe psychotropic medication to the child based upon a diagnosed condition for which such medication is being prescribed.

2. A statement indicating that the physician has reviewed all medical information concerning the child which has been provided.

3. A statement indicating that the psychotropic medication, at its prescribed dosage, is appropriate for treating the child's diagnosed medical condition, as well as the behaviors and symptoms the medication, at its prescribed dosage, is expected to address.

4. An explanation of the nature and purpose of the treatment; the recognized side effects, risks, and contraindications of the medication; drug-interaction precautions; the possible effects of stopping the medication; and how the treatment will be monitored, followed by a statement indicating that this explanation was provided to the child if age appropriate and to the child's caregiver.

5. Documentation addressing whether the psychotropic medication will replace or supplement any other currently prescribed medications or treatments; the length of time the child is expected to be taking the medication; and any

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additional medical, mental health, behavioral, counseling, or other services that the prescribing physician or advanced practice registered nurse recommends.

(d)1. The department must notify all parties of the proposed action taken under paragraph (c) in writing or by whatever other method best ensures that all parties receive notification of the proposed action within 48 hours after the motion is filed. If any party objects to the department's motion, that party shall file the objection within 2 working days after being notified of the department's motion. If any party files an objection to the authorization of the proposed psychotropic medication, the court shall hold a hearing as soon as possible before authorizing the department to initially provide or to continue providing psychotropic medication to a child in the legal custody of the department. At such hearing and notwithstanding s. 90.803, the medical report described in paragraph (c) is admissible in evidence. The prescribing physician or advanced practice registered nurse whose specialty is psychiatric nursing, as defined in chapter 394, and who is given prescribing authority pursuant to chapter 464 need not attend the hearing or testify unless the court specifically orders such attendance or testimony, or a party subpoenas the physician or advanced practice registered nurse to attend the hearing or provide testimony. If, after considering any testimony received, the court finds that the department's motion and the physician's or advanced practice registered nurse's medical report meet the requirements of this subsection and that it is in the child's best interests, the court may order that the department provide or continue to provide the psychotropic

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medication to the child without additional testimony or evidence. At any hearing held under this paragraph, the court shall further inquire of the department as to whether additional medical, mental health, behavioral, counseling, or other services are being provided to the child by the department which the prescribing physician or advanced practice registered nurse considers to be necessary or beneficial in treating the child's medical condition and which the physician or advanced practice registered nurse recommends or expects to provide to the child in concert with the medication. The court may order additional medical consultation, including consultation with the MedConsult line at the University of Florida, if available, or require the department to obtain a second opinion within a reasonable timeframe as established by the court, not to exceed 21 calendar days, after such order based upon consideration of the best interests of the child. The department must make a referral for an appointment for a second opinion with a physician within 1 working day. The court may not order the discontinuation of prescribed psychotropic medication if such order is contrary to the decision of the prescribing physician or advanced practice registered nurse unless the court first obtains an opinion from a licensed psychiatrist, if available, or, if not available, a physician licensed under chapter 458 or chapter 459, stating that more likely than not, discontinuing the medication would not cause significant harm to the child. If, however, the prescribing psychiatrist specializes in mental health care for children and adolescents, the court may not order the discontinuation of prescribed psychotropic medication unless the required opinion is also from a psychiatrist who specializes in

mental health care for children and adolescents. The court may also order the discontinuation of prescribed psychotropic medication if a child's treating physician, licensed under chapter 458 or chapter 459, states that continuing the prescribed psychotropic medication would cause significant harm to the child due to a diagnosed nonpsychiatric medical condition.

2. The burden of proof at any hearing held under this paragraph shall be by a preponderance of the evidence.

(e)1. If the child's prescribing physician or advanced practice registered nurse whose specialty is psychiatric nursing, as defined in chapter 394, and who is given prescribing authority pursuant to chapter 464 certifies in the signed medical report required in paragraph (c) that delay in providing a prescribed psychotropic medication would more likely than not cause significant harm to the child, the medication may be provided in advance of the issuance of a court order. In such event, the medical report must provide the specific reasons why the child may experience significant harm and the nature and the extent of the potential harm. The department must submit a motion seeking continuation of the medication and the physician's medical report to the court, the child's guardian ad litem, and all other parties within 3 working days after the department commences providing the medication to the child. The department shall seek the order at the next regularly scheduled court hearing required under this chapter, or within 30 days after the date of the prescription, whichever occurs sooner. If any party objects to the department's motion, the court shall hold a hearing within 7 days.

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2. Psychotropic medications may be administered in advance of a court order in hospitals, crisis stabilization units, and in statewide inpatient psychiatric programs. Within 3 working days after the medication is begun, the department must seek court authorization as described in paragraph (c).

(f)1. The department shall fully inform the court of the child's medical and behavioral status as part of the social services report prepared for each judicial review hearing held for a child for whom psychotropic medication has been prescribed or provided under this subsection. As a part of the information provided to the court, the department shall furnish copies of all pertinent medical records concerning the child which have been generated since the previous hearing. On its own motion or on good cause shown by any party, including any guardian ad litem, attorney, or attorney ad litem who has been appointed to represent the child or the child's interests, the court may review the status more frequently than required in this subsection.

2. The court may, in the best interests of the child, order the department to obtain a medical opinion addressing whether the continued use of the medication under the circumstances is safe and medically appropriate.

(g) The department shall adopt rules to ensure that children receive timely access to clinically appropriate psychotropic medications. These rules must include, but need not be limited to, the process for determining which adjunctive services are needed, the uniform process for facilitating the prescribing physician's <u>or advanced practice registered nurse's</u> ability to obtain the express and informed consent of a child's

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parent or guardian, the procedures for obtaining court authorization for the provision of a psychotropic medication, the frequency of medical monitoring and reporting on the status of the child to the court, how the child's parents will be involved in the treatment-planning process if their parental rights have not been terminated, and how caretakers are to be provided information contained in the physician's or advanced practice registered nurse's signed medical report. The rules must also include uniform forms to be used in requesting court authorization for the use of a psychotropic medication and provide for the integration of each child's treatment plan and case plan. The department must begin the formal rulemaking process within 90 days after the effective date of this act.

(6) Children who are in the legal custody of the department may be placed by the department, without prior approval of the court, in a residential treatment center licensed under s. 394.875 or a hospital licensed under chapter 395 for residential mental health treatment only pursuant to this section or may be placed by the court in accordance with an order of involuntary examination or involuntary placement entered pursuant to s. 394.463 or s. 394.467. All children placed in a residential treatment program under this subsection must have a guardian ad litem appointed.

(g)1. The department must submit, at the beginning of each month, to the court having jurisdiction over the child, a written report regarding the child's progress toward achieving the goals specified in the individualized plan of treatment.

2. The court must conduct a hearing to review the status of the child's residential treatment plan no later than 60 days ~~3~~

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~~months~~ after the child's admission to the residential treatment program. An independent review of the child's progress toward achieving the goals and objectives of the treatment plan must be completed by a qualified evaluator and submitted to the court before its 60-day ~~3-month~~ review.

3. For any child in residential treatment at the time a judicial review is held pursuant to s. 39.701, the child's continued placement in residential treatment must be a subject of the judicial review.

4. If at any time the court determines that the child is not suitable for continued residential treatment, the court shall order the department to place the child in the least restrictive setting that is best suited to meet his or her needs.

(h) After the initial 60-day ~~3-month~~ review, the court must conduct a review of the child's residential treatment plan every 90 days.

(i) The department must adopt rules for implementing timeframes for the completion of suitability assessments by qualified evaluators and a procedure that includes timeframes for completing the 60-day ~~3-month~~ independent review by the qualified evaluators of the child's progress toward achieving the goals and objectives of the treatment plan which review must be submitted to the court. The Agency for Health Care Administration must adopt rules for the registration of qualified evaluators, the procedure for selecting the evaluators to conduct the reviews required under this section, and a reasonable, cost-efficient fee schedule for qualified evaluators.

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Section 5. Present paragraphs (a) through (h) of subsection (2) of section 39.5085, Florida Statutes, are redesignated as paragraphs (b) through (i), respectively, paragraph (a) of subsection (1) is amended, and a new paragraph (a) is added to subsection (2) of that section, to read:

39.5085 Relative Caregiver Program.—

(1) It is the intent of the Legislature in enacting this section to:

(a) Provide for the establishment of procedures and protocols that serve to advance the continued safety of children by acknowledging the valued resource uniquely available through grandparents, relatives of children, and specified nonrelatives of children pursuant to subparagraph (2)(b)3. ~~(2)(a)3.~~

(2)

(a) Relatives or nonrelatives who are caring for a child and do not meet the eligibility requirements for Level I licensure under s. 409.175 may apply for the Relative Caregiver Program.

Section 6. Paragraph (a) of subsection (1) of section 39.5086, Florida Statutes, is amended to read:

39.5086 Kinship navigator programs.—

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

~~(a) "Fictive kin" has the same meaning as provided in s. 39.4015(2)(d).~~

Section 7. Subsections (6) and (10) of section 39.6225, Florida Statutes, are amended to read:

39.6225 Guardianship Assistance Program.—

(6) Guardianship assistance benefits shall be terminated if the guardian is no longer providing support to the child. For

purposes of this subsection, a guardian is considered to no longer be providing support to the child if:

(a) The child is absent from the home of the guardian for a period of at least 60 consecutive calendar days, unless the child:

1. Is absent due to medical care, school attendance, runaway status, or detention in a Department of Juvenile Justice facility; and

2. Continues to be under the care and custody of the guardian.

(b) The court modifies the placement of the child and the guardian is no longer eligible to receive guardianship assistance benefits.

(10) The case plan must describe the following for each child with a permanency goal of permanent guardianship in which the guardian is pursuing ~~in receipt of~~ guardianship assistance ~~payments~~:

(a) The manner in which the child meets program eligibility requirements.

(b) The manner in which the department determined that reunification or adoption is not appropriate.

(c) Efforts to discuss adoption with the child's permanent guardian.

(d) Efforts to discuss guardianship assistance with the child's parent or the reasons why efforts were not made.

(e) The reasons why a permanent placement with the prospective guardian is in the best interest of the child.

(f) The reasons why the child is separated from his or her siblings during placement, if applicable.

(g) Efforts to consult the child, if the child is 14 years of age or older, regarding the permanent guardianship arrangement.

Section 8. Subsections (2) and (3), paragraph (a) of subsection (4), and subsection (6) of section 39.6251, Florida Statutes, are amended, and subsection (10) is added to that section, to read:

39.6251 Continuing care for young adults.—

(2) The primary goal for a child in care is permanency. A child who is living in licensed care on his or her 18th birthday and who has not achieved permanency under s. 39.621 is eligible to remain in licensed care under the jurisdiction of the court and in the care of the department. A child is eligible to remain in licensed care if he or she is:

(a) Completing secondary education or a program leading to an equivalent credential;

(b) Enrolled in an institution that provides postsecondary or vocational education;

(c) Participating in a program or activity designed to promote or eliminate barriers to employment;

(d) Employed for at least 80 hours per month; or

(e) Unable to participate in programs or activities listed in paragraphs (a)-(d) full time due to a physical, intellectual, emotional, or psychiatric condition that limits participation. Any such barrier to participation must be supported by documentation in the child’s case file or school or medical records of a physical, intellectual, or psychiatric condition that impairs the child’s ability to perform one or more life activities.

The young adult must furnish documentation to the department or lead agency of his or her participation in one of the programs or activities listed in paragraphs (a)-(d), or his or her inability to participate in one of the programs or activities as provided in paragraph (e), or authorize the release of his or her records to the department or lead agency.

(3) The permanency goal for a young adult who chooses to remain in care past his or her 18th birthday is to transition to independence ~~from licensed care to independent living~~.

(4)(a) The young adult must reside in a supervised living environment that is approved by the department or a community-based care lead agency. The young adult shall live independently, but in an environment in which he or she is provided supervision, case management, and supportive services by the department or lead agency. Such an environment must offer developmentally appropriate freedom and responsibility to prepare the young adult for adulthood. For the purposes of this subsection, a supervised living arrangement may include a licensed foster home, licensed group home, college dormitory, shared housing, apartment, or another housing arrangement if the arrangement is approved by the community-based care lead agency and is acceptable to the young adult~~, with first choice being a licensed foster home~~. A young adult may continue to reside with the same licensed foster family or group care provider with whom he or she was residing at the time he or she reached the age of 18 years.

(6) A young adult who is between the ages of 18 and 21 and who has left care may return to care by applying to the

community-based care lead agency for readmission through the execution of a voluntary placement agreement. The community-based care lead agency shall readmit the young adult if he or she continues to meet the eligibility requirements in this section.

(a) The department shall develop a standard procedure and application packet for readmission to care to be used by all community-based care lead agencies.

(b) Within 30 days after the young adult has been readmitted to care, the community-based care lead agency shall assign a case manager to update the case plan and the transition plan and to arrange for the required services. Updates to the case plan and the transition plan and arrangements for the required services shall be undertaken in consultation with the young adult. The department shall petition the court to reinstate jurisdiction over the young adult. Notwithstanding s. 39.013(2), the court shall resume jurisdiction over the young adult if the department establishes that he or she continues to meet the eligibility requirements in this section.

(10) The department shall adopt rules to administer this section.

Section 9. Paragraph (d) of subsection (2) of section 39.701, Florida Statutes, is amended, and paragraphs (f) and (g) are added to subsection (4) of that section, to read:

39.701 Judicial review.—

(2) REVIEW HEARINGS FOR CHILDREN YOUNGER THAN 18 YEARS OF AGE.—

(d) *Orders.*—

1. Based upon the criteria set forth in paragraph (c) and

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the recommended order of the citizen review panel, if any, the court shall determine whether ~~or not~~ the social service agency shall initiate proceedings to have a child declared a dependent child, return the child to the parent, continue the child in out-of-home care for a specified period of time, or initiate termination of parental rights proceedings for subsequent placement in an adoptive home. Amendments to the case plan must be prepared as provided ~~prescribed~~ in s. 39.6013. If the court finds that the prevention or reunification efforts of the department will allow the child to remain safely at home or be safely returned to the home, the court shall allow the child to remain in or return to the home after making a specific finding of fact that the reasons for the creation of the case plan have been remedied to the extent that the child's safety, well-being, and physical, mental, and emotional health will not be endangered.

2. The court shall return the child to the custody of his or her ~~the~~ parents at any time it determines that the circumstances which caused the out-of-home placement, and issues subsequently identified, have been remedied to the extent that return of the child to the home with an in-home safety plan prepared or approved by the department ~~that they have substantially complied with the case plan, if the court is satisfied that reunification~~ will not be detrimental to the child's safety, well-being, and physical, mental, and emotional health.

3. If, in the opinion of the court, the social service agency has not complied with its obligations as specified in the written case plan, the court may find the social service agency

in contempt, shall order the social service agency to submit its plans for compliance with the agreement, and shall require the social service agency to show why the child could not safely be returned to the home of the parents.

4. If, at any judicial review, the court finds that the parents have failed to substantially comply with the case plan to the degree that further reunification efforts are without merit and not in the best interest of the child, on its own motion, the court may order the filing of a petition for termination of parental rights, regardless of whether ~~or not~~ the time period as contained in the case plan for substantial compliance has expired.

5. Within 6 months after the date that the child was placed in shelter care, the court shall conduct a judicial review hearing to review the child's permanency goal as identified in the case plan. At the hearing the court shall make findings regarding the likelihood of the child's reunification with the parent or legal custodian. In making such findings, the court shall consider the level of the parent or legal custodian's compliance with the case plan and demonstrated change in protective capacities compared to that necessary to achieve timely reunification within 12 months after the removal of the child from the home. The court shall also consider the frequency, duration, manner, and level of engagement of the parent or legal custodian's visitation with the child in compliance with the case plan. If the court makes a written finding that it is not likely that the child will be reunified with the parent or legal custodian within 12 months after the child was removed from the home, the department must file with

the court, and serve on all parties, a motion to amend the case plan under s. 39.6013 and declare that it will use concurrent planning for the case plan. The department must file the motion within 10 business days after receiving the written finding of the court. The department must attach the proposed amended case plan to the motion. If concurrent planning is already being used, the case plan must document the efforts the department is taking to complete the concurrent goal.

6. The court may issue a protective order in assistance, or as a condition, of any other order made under this part. In addition to the requirements included in the case plan, the protective order may set forth requirements relating to reasonable conditions of behavior to be observed for a specified period of time by a person or agency who is before the court,~~:~~ and the order may require any person or agency to make periodic reports to the court containing such information as the court in its discretion may prescribe.

7. If, at any judicial review, the court determines that the child shall remain in out-of-home care in a placement other than with a parent, the court shall order that the department has placement and care responsibility for the child.

(4) REVIEW HEARINGS FOR YOUNG ADULTS IN FOSTER CARE.—During each period of time that a young adult remains in foster care, the court shall review the status of the young adult at least every 6 months and must hold a permanency review hearing at least annually.

(f) If the young adult elects to voluntarily leave extended foster care for the sole purpose of ending a removal episode and immediately thereafter executes a voluntary placement agreement

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with the department to reenroll in extended foster care, the court shall enter an order finding that the prior removal episode has ended. Under these circumstances, the court maintains jurisdiction and a petition to reinstate jurisdiction as provided in s. 39.6251(6)(b) is not required.

(g)1. When a young adult enters extended foster care by executing a voluntary placement agreement, the court shall enter an order within 180 days after execution of the agreement which determines whether the placement is in the best interest of the young adult. For purposes of this paragraph, a placement may include a licensed foster home, licensed group home, college dormitory, shared housing, apartment, or another housing arrangement, if the arrangement is approved by the community-based care lead agency and is acceptable to the young adult.

2. When a young adult is in extended foster care, each judicial review order shall provide that the department has placement and care responsibility for the young adult.

3. When a young adult is in extended foster care, the court shall enter an order at least every 12 months that includes a finding of whether the department has made reasonable efforts to finalize the permanency plan currently in effect.

Section 10. Present subsections (9) and (10) of section 409.1451, Florida Statutes, are redesignated as subsections (10) and (11), respectively, paragraph (b) of subsection (2) is amended, and a new subsection (9) is added to that section, to read:

409.1451 The Road-to-Independence Program.—

(2) POSTSECONDARY EDUCATION SERVICES AND SUPPORT.—

(b) The amount of the financial assistance shall be as

follows:

1. For a young adult who does not remain in foster care and is attending a postsecondary school as provided in s. 1009.533, the amount is $1,256 monthly.

2. For a young adult who remains in foster care, is attending a postsecondary school, as provided in s. 1009.533, and continues to reside in a licensed foster home, the amount is the established room and board rate for foster parents. This takes the place of the payment provided for in s. 409.145(4).

3. For a young adult who remains in foster care, but temporarily resides away from a licensed foster home for purposes of attending a postsecondary school as provided in s. 1009.533, the amount is $1,256 monthly. This takes the place of the payment provided for in s. 409.145(4).

4. For a young adult who remains in foster care, is attending a postsecondary school as provided in s. 1009.533, and continues to reside in a licensed group home, the amount is negotiated between the community-based care lead agency and the licensed group home provider.

5. For a young adult who remains in foster care, but temporarily resides away from a licensed group home for purposes of attending a postsecondary school as provided in s. 1009.533, the amount is $1,256 monthly. This takes the place of a negotiated room and board rate.

~~6. The amount of the award may be disregarded for purposes of determining the eligibility for, or the amount of, any other federal or federally supported assistance.~~

6.~~7.~~ A young adult is eligible to receive financial assistance during the months when he or she is enrolled in a

postsecondary educational institution.

(9) FINANCIAL ASSISTANCE FOR YOUNG ADULTS RECEIVING SERVICES.—Financial awards to young adults receiving services under subsections (2) and (3) and s. 39.6251 may be disregarded for purposes of determining the eligibility for, or the amount of, any other federal or federally supported assistance.

Section 11. Paragraphs (e), (j), and (m) of subsection (2), paragraph (b) of subsection (5), paragraph (c) of subsection (6), subsection (7), paragraph (b) of subsection (9), paragraphs (b) and (c) of subsection (12), and paragraphs (b) and (d) of subsection (14) of section 409.175, Florida Statutes, are amended to read:

409.175 Licensure of family foster homes, residential child-caring agencies, and child-placing agencies; public records exemption.—

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

(e) "Family foster home" means a ~~private~~ residence licensed by the department in which children who are unattended by a parent or legal guardian are provided 24-hour care. The term does not include an adoptive home that has been approved by the department or approved by a licensed child-placing agency for children placed for adoption.

(j) "Personnel" means all owners, operators, employees, and volunteers working in a child-placing agency~~, family foster home,~~ or residential child-caring agency who may be employed by or do volunteer work for a person, corporation, or agency that holds a license as a child-placing agency or a residential child-caring agency, but the term does not include those who do not work on the premises where child care is furnished and have

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no direct contact with a child or have no contact with a child outside of the presence of the child's parent or guardian. For purposes of screening, the term includes any member, over the age of 12 years, of the family of the owner or operator or any person other than a client, over the age of 12 years, residing with the owner or operator if the agency ~~or family foster home~~ is located in or adjacent to the home of the owner or operator or if the family member of, or person residing with, the owner or operator has any direct contact with the children. Members of the family of the owner or operator, or persons residing with the owner or operator, who are between the ages of 12 years and 18 years are not required to be fingerprinted, but must be screened for delinquency records. For purposes of screening, the term also includes owners, operators, employees, and volunteers working in summer day camps~~,~~ or summer 24-hour camps providing care for children. A volunteer who assists on an intermittent basis for less than 10 hours per month shall not be included in the term "personnel" for the purposes of screening if a person who meets the screening requirement of this section is always present and has the volunteer in his or her line of sight.

(m) "Screening" means the act of assessing the background of personnel or level II through level V family foster homes and includes, but is not limited to, employment history checks as provided in chapter 435, using the level 2 standards for screening set forth in that chapter.

(5) The department shall adopt and amend rules for the levels of licensed care associated with the licensure of family foster homes, residential child-caring agencies, and child-placing agencies. The rules may include criteria to approve

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waivers to licensing requirements when applying for a child-specific license.

(b) The requirements for licensure and operation of family foster homes, residential child-caring agencies, and child-placing agencies shall include:

1. The operation, conduct, and maintenance of these homes and agencies and the responsibility which they assume for children served and the evidence of need for that service.

2. The provision of food, clothing, educational opportunities, services, equipment, and individual supplies to assure the healthy physical, emotional, and mental development of the children served.

3. The appropriateness, safety, cleanliness, and general adequacy of the premises, including fire prevention and health standards, to provide for the physical comfort, care, and well-being of the children served.

4. The ratio of staff to children required to provide adequate care and supervision of the children served and, in the case of family foster homes, the maximum number of children in the home.

5. The good moral character based upon screening, education, training, and experience requirements for personnel and family foster homes.

6. The department may grant exemptions from disqualification from working with children or the developmentally disabled as provided in s. 435.07.

7. The provision of preservice and inservice training for all foster parents and agency staff.

8. Satisfactory evidence of financial ability to provide

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care for the children in compliance with licensing requirements.

9. The maintenance by the agency of records pertaining to admission, progress, health, and discharge of children served, including written case plans and reports to the department.

10. The provision for parental involvement to encourage preservation and strengthening of a child's relationship with the family.

11. The transportation safety of children served.

12. The provisions for safeguarding the cultural, religious, and ethnic values of a child.

13. Provisions to safeguard the legal rights of children served.

(6)

(c) A licensed family foster home, child-placing agency, or residential child-caring agency which applies for renewal of its license shall submit to the department a list of personnel or household members who have worked or resided on a continuous basis at the applicant family foster home or agency since submitting fingerprints to the department, identifying those for whom a written assurance of compliance was provided by the department and identifying those personnel or household members who have recently begun working or residing at the family foster home or agency and are awaiting the results of the required fingerprint check, along with the date of the submission of those fingerprints for processing. The department shall by rule determine the frequency of requests to the Department of Law Enforcement to run state criminal records checks for such personnel or household members except for those personnel or household members awaiting the results of initial fingerprint

checks for employment at the applicant family foster home or agency.

(7)~~(a)~~ The department may extend a license expiration date once for a period of up to 30 days. However, the department may not extend a license expiration date more than once during a licensure period ~~The department may issue a provisional license to an applicant who is unable to conform to the licensing requirements at the time of the study, but who is believed able to meet the licensing requirements within the time allowed by the provisional license. The issuance of a provisional license shall be contingent upon the submission to the department of an acceptable written plan to overcome the deficiency by the expiration date of the provisional license~~.

~~(b) A provisional license may be issued when the applicant fails to meet licensing requirements in matters that are not of immediate danger to the children and the agency has submitted a corrective action plan which is approved by the department. A provisional license may be issued if the screening material has been timely submitted; however, a provisional license may not be issued unless the applicant is in compliance with the requirements in this section for screening of personnel.~~

~~(c) A provisional license shall not be issued for a period in excess of 1 year and shall not be subject to renewal; and it may be suspended if periodic inspection by the department indicates that insufficient progress has been made toward compliance with the requirements.~~

(9)

(b) Any of the following actions by a family foster home or its household members or an agency or its personnel is a ground

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for denial, suspension, or revocation of a license:

1. An intentional or negligent act materially affecting the health or safety of children in the home or agency.

2. A violation of ~~the provisions of~~ this section or of licensing rules adopted ~~promulgated~~ pursuant to this section.

3. Noncompliance with the requirements for good moral character as specified in paragraph (5)(b).

4. Failure to dismiss personnel or a household member found in noncompliance with requirements for good moral character.

5. Failure to comply with the requirements of ss. 63.0422 and 790.335.

(12)

(b) It is unlawful for any person, agency, family foster home, summer day camp, or summer 24-hour camp providing care for children to:

1. Willfully or intentionally fail to comply with the requirements for the screening of personnel and family foster homes or the dismissal of personnel or household members found not to be in compliance with the requirements for good moral character as specified in paragraph (5)(b).

2. Use information from the criminal records obtained under this section for any purpose other than screening a person for employment as specified in this section or to release such information to any other person for any purpose other than screening for employment as specified in this section.

(c) It is unlawful for any person, agency, family foster home, summer day camp, or summer 24-hour camp providing care for children to use information from the juvenile records of any person obtained under this section for any purpose other than

screening for employment as specified in this section or to release information from such records to any other person for any purpose other than screening for employment as specified in this section.

(14)

(b) As a condition of licensure, foster parents shall successfully complete ~~a minimum of 21 hours of~~ preservice training. The preservice training shall be uniform statewide and shall include, but not be limited to, such areas as:

1. Orientation regarding agency purpose, objectives, resources, policies, and services;

2. Role of the foster parent as a treatment team member;

3. Transition of a child into and out of foster care, including issues of separation, loss, and attachment;

4. Management of difficult child behavior that can be intensified by placement, by prior abuse or neglect, and by prior placement disruptions;

5. Prevention of placement disruptions;

6. Care of children at various developmental levels, including appropriate discipline; and

7. Effects of foster parenting on the family of the foster parent.

(d) Before ~~prior to~~ licensure renewal, each ~~level II through level V~~ foster parent must ~~shall~~ successfully complete ~~8 hours of~~ inservice training. ~~Each level I foster parent shall successfully complete 4 hours of inservice training.~~ Periodic time-limited training courses shall be made available for selective use by foster parents. Such inservice training shall include subjects affecting the daily living experiences of

foster parenting as a foster parent. For a foster parent participating in the required inservice training, the department shall reimburse such parent for travel expenditures and, if both parents in a home are attending training or if the absence of the parent would leave the children without departmentally approved adult supervision, the department shall make provision for child care or shall reimburse the foster parents for child care purchased by the parents for children in their care.

Section 12. Subsection (4) of section 409.903, Florida Statutes, is amended to read:

409.903 Mandatory payments for eligible persons.—The agency shall make payments for medical assistance and related services on behalf of the following persons who the department, or the Social Security Administration by contract with the Department of Children and Families, determines to be eligible, subject to the income, assets, and categorical eligibility tests set forth in federal and state law. Payment on behalf of these Medicaid eligible persons is subject to the availability of moneys and any limitations established by the General Appropriations Act or chapter 216.

(4) A child who is eligible under Title IV-E of the Social Security Act for subsidized board payments, foster care, or adoption subsidies, and a child for whom the state has assumed temporary or permanent responsibility and who does not qualify for Title IV-E assistance but is in foster care, shelter or emergency shelter care, or subsidized adoption. This category includes:

(a) A young adult who is eligible to receive services under s. 409.1451, until the young adult reaches 21 years of age,

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without regard to any income, resource, or categorical eligibility test that is otherwise required.

(b) ~~This category also includes~~ A person who as a child was eligible under Title IV-E of the Social Security Act for foster care or the state-provided foster care and who is a participant in the Road-to-Independence Program.

(c) A child who is eligible for the Guardianship Assistance Program as provided in s. 39.6225.

Section 13. Paragraph (a) of subsection (1) of section 409.991, Florida Statutes, is amended to read:

409.991 Allocation of funds for community-based care lead agencies.—

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

(a) "Core services funds" means all funds allocated to community-based care lead agencies operating under contract with the department pursuant to s. 409.987, with the following exceptions:

1. Funds appropriated for independent living;

2. Funds appropriated for maintenance adoption subsidies;

3. Funds allocated by the department for protective investigations training;

4. Nonrecurring funds;

5. Designated mental health wrap-around services funds; ~~and~~

6. Funds for special projects for a designated community-based care lead agency; and

7. Funds appropriated for the Guardianship Assistance Program under s. 39.6225.

Section 14. Paragraph (b) of subsection (1) of section 414.045, Florida Statutes, is amended to read:

414.045 Cash assistance program.—Cash assistance families include any families receiving cash assistance payments from the state program for temporary assistance for needy families as defined in federal law, whether such funds are from federal funds, state funds, or commingled federal and state funds. Cash assistance families may also include families receiving cash assistance through a program defined as a separate state program.

(1) For reporting purposes, families receiving cash assistance shall be grouped into the following categories. The department may develop additional groupings in order to comply with federal reporting requirements, to comply with the data-reporting needs of the board of directors of CareerSource Florida, Inc., or to better inform the public of program progress.

(b) *Child-only cases.*—Child-only cases include cases that do not have an adult or teen head of household as defined in federal law. Such cases include:

1. Children in the care of caretaker relatives, if the caretaker relatives choose to have their needs excluded in the calculation of the amount of cash assistance.

2. Families in the Relative Caregiver Program as provided in s. 39.5085.

3. Families in which the only parent in a single-parent family or both parents in a two-parent family receive supplemental security income (SSI) benefits under Title XVI of the Social Security Act, as amended. To the extent permitted by federal law, individuals receiving SSI shall be excluded as household members in determining the amount of cash assistance,

and such cases shall not be considered families containing an adult. Parents or caretaker relatives who are excluded from the cash assistance group due to receipt of SSI may choose to participate in work activities. An individual whose ability to participate in work activities is limited who volunteers to participate in work activities shall be assigned to work activities consistent with such limitations. An individual who volunteers to participate in a work activity may receive child care or support services consistent with such participation.

4. Families in which the only parent in a single-parent family or both parents in a two-parent family are not eligible for cash assistance due to immigration status or other limitation of federal law. To the extent required by federal law, such cases shall not be considered families containing an adult.

5. To the extent permitted by federal law and subject to appropriations, special needs children who have been adopted pursuant to s. 409.166 and whose adopting family qualifies as a needy family under the state program for temporary assistance for needy families. Notwithstanding any provision to the contrary in s. 414.075, s. 414.085, or s. 414.095, a family shall be considered a needy family if:

a. The family is determined by the department to have an income below 200 percent of the federal poverty level;

b. The family meets the requirements of s. 414.095(2) and (3) related to residence, citizenship, or eligible noncitizen status; and

c. The family provides any information that may be necessary to meet federal reporting requirements specified under

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Part A of Title IV of the Social Security Act.

6. Families in the Guardianship Assistance Program as provided in s. 39.6225.

Families described in subparagraph 1., subparagraph 2., or subparagraph 3. may receive child care assistance or other supports or services so that the children may continue to be cared for in their own homes or in the homes of relatives. Such assistance or services may be funded from the temporary assistance for needy families block grant to the extent permitted under federal law and to the extent funds have been provided in the General Appropriations Act.

Section 15. Paragraph (d) of subsection (1) of section 1009.25, Florida Statutes, is amended to read:

1009.25 Fee exemptions.—

(1) The following students are exempt from the payment of tuition and fees, including lab fees, at a school district that provides workforce education programs, Florida College System institution, or state university:

(d) A student who is or was at the time he or she reached 18 years of age in the custody of a relative or nonrelative under s. 39.5085 or s. 39.6225 or who was adopted from the Department of Children and Families after May 5, 1997. Such exemption includes fees associated with enrollment in applied academics for adult education instruction. The exemption remains valid until the student reaches 28 years of age.

Section 16. This act shall take effect July 1, 2019.

========== T I T L E A M E N D M E N T ==========

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And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled

An act relating to child welfare; amending ss. 39.01 and 39.4015, F.S.; revising definitions; amending s. 39.402, F.S.; requiring that the order for placement of a child in shelter care contain a written finding specifying that the Department of Children and Families has placement and care responsibility for certain children; amending s. 39.407, F.S.; authorizing certain advanced practice registered nurses to prescribe psychotropic medications to certain children; revising the time period within which a court must review a child's residential treatment plan; amending s. 39.5085, F.S.; revising eligibility for the Relative Caregiver Program; amending s. 39.5086, F.S.; deleting the term "fictive kin"; amending s. 39.6225, F.S.; providing for the termination of guardianship assistance benefits under certain circumstances; conforming provisions to changes made by the act; amending s. 39.6251, F.S.; requiring a young adult in extended foster care to provide certain documentation or authorize release of certain records; revising permanency goals for young adults in extended foster care; requiring execution of a voluntary placement agreement under certain circumstances; requiring the department to adopt rules; amending s. 39.701, F.S.; revising when a court

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must return a child to the custody of his or her parents after making certain determinations; requiring the court to enter certain orders if a young adult enters extended foster care; amending s. 409.1451, F.S.; authorizing certain financial awards to be disregarded when a young adult is applying for other federal assistance; amending s. 409.175, F.S.; revising definitions; revising provisions related to the licensure of family foster homes and certain child-caring and child-placing agencies; deleting required numbers of training hours for foster parents; amending s. 409.903, F.S.; revising eligibility for Medicaid coverage; amending s. 409.991, F.S.; revising a definition; amending s. 414.045, F.S.; revising eligibility for child-only funding; amending s. 1009.25, F.S.; revising eligibility for tuition fee exemptions; providing an effective date.

By Senator Albritton

26-01284-19 20191650__

A bill to be entitled

An act relating to child welfare; amending ss. 39.01 and 39.4015, F.S.; revising definitions; conforming cross-references; amending s. 39.402, F.S.; requiring that the order for placement of a child in shelter care contain a written finding specifying that the Department of Children and Families has placement and care responsibility for certain children; amending s. 39.407, F.S.; authorizing certain advanced practice registered nurses to prescribe psychotropic medications to certain children; revising the time period within which a court must review a child's residential treatment plan; amending s. 39.5085, F.S.; revising eligibility for the Relative Caregiver Program; amending s. 39.5086, F.S.; deleting the term "fictive kin"; amending s. 39.6225, F.S.; providing for the termination of guardianship assistance benefits under certain circumstances; conforming provisions to changes made by the act; amending s. 39.6251, F.S.; requiring a young adult in extended foster care to provide certain documentation or authorize release of certain records; revising permanency goals for young adults in extended foster care; requiring execution of a voluntary placement agreement under certain circumstances; requiring the department to adopt rules; amending s. 39.701, F.S.; revising when a court must return a child to the custody of his or her parents after making certain determinations; requiring the court to make certain

orders relating to extended foster care; amending s. 409.1451, F.S.; authorizing certain financial awards to be disregarded when applying for other federal assistance; amending s. 409.175, F.S.; revising definitions; revising provisions related to the licensure of family foster homes and certain child-caring and child-placing agencies; deleting required numbers of training hours for foster parents; amending s. 409.903, F.S.; revising eligibility for Medicaid coverage; amending s. 409.991, F.S.; revising a definition; amending s. 414.045, F.S.; revising eligibility for child-only funding; amending s. 1009.25, F.S.; revising eligibility for tuition fee exemptions; amending ss. 39.302, 39.521, 39.523, 39.6012, 322.09, 394.495, 627.746, 934.255, and 960.065, F.S.; conforming cross-references; providing an effective date.

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

Section 1. Present subsections (30) through (87) of section 39.01, Florida Statutes, are redesignated as subsections (29) through (86), respectively, and present subsections (10), (29), (31), and (37) of that section are amended, to read:

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

(10) "Caregiver" means the parent, legal custodian, permanent guardian, adult household member, or other person responsible for a child's welfare as defined in subsection (53)

~~(54)~~.

~~(29) "Fictive kin" means a person unrelated by birth, marriage, or adoption who has an emotionally significant relationship, which possesses the characteristics of a family relationship, to a child.~~

(30)~~(31)~~ "Guardian" means a relative, nonrelative, or next of kin~~, or fictive kin~~ who is awarded physical custody of a child in a proceeding brought pursuant to this chapter.

(36)~~(37)~~ "Institutional child abuse or neglect" means situations of known or suspected child abuse or neglect in which the person allegedly perpetrating the child abuse or neglect is an employee of a public or private school, public or private day care center, residential home, institution, facility, or agency or any other person at such institution responsible for the child's care as defined in this section ~~subsection (54)~~.

Section 2. Subsection (1) of section 39.302, Florida Statutes, is amended to read:

39.302 Protective investigations of institutional child abuse, abandonment, or neglect.—

(1) The department shall conduct a child protective investigation of each report of institutional child abuse, abandonment, or neglect. Upon receipt of a report that alleges that an employee or agent of the department, or any other entity or person covered by s. 39.01(36) or (53) ~~s. 39.01(37) or (54)~~, acting in an official capacity, has committed an act of child abuse, abandonment, or neglect, the department shall initiate a child protective investigation within the timeframe established under s. 39.201(5) and notify the appropriate state attorney, law enforcement agency, and licensing agency, which shall

immediately conduct a joint investigation, unless independent investigations are more feasible. When conducting investigations or having face-to-face interviews with the child, investigation visits shall be unannounced unless it is determined by the department or its agent that unannounced visits threaten the safety of the child. If a facility is exempt from licensing, the department shall inform the owner or operator of the facility of the report. Each agency conducting a joint investigation is entitled to full access to the information gathered by the department in the course of the investigation. A protective investigation must include an interview with the child's parent or legal guardian. The department shall make a full written report to the state attorney within 3 working days after making the oral report. A criminal investigation shall be coordinated, whenever possible, with the child protective investigation of the department. Any interested person who has information regarding the offenses described in this subsection may forward a statement to the state attorney as to whether prosecution is warranted and appropriate. Within 15 days after the completion of the investigation, the state attorney shall report the findings to the department and shall include in the report a determination of whether or not prosecution is justified and appropriate in view of the circumstances of the specific case.

Section 3. Paragraphs (a), (c), and (d) of subsection (2) and paragraphs (a) and (b) of subsection (3) of section 39.4015, Florida Statutes, are amended to read:

39.4015 Family finding.—

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

(a) "Diligent efforts" means the use of methods and

techniques, including, but not limited to, interviews with immediate and extended family ~~and fictive kin~~, genograms, eco-mapping, case mining, cold calls, and specialized computer searches.

(c) "Family group decisionmaking" is a generic term that includes a number of approaches in which family members ~~and fictive kin~~ are brought together to make decisions about how to care for their children and develop a plan for services. The term includes family team conferencing, family team meetings, family group conferencing, family team decisionmaking, family unity meetings, and team decisionmaking, which may consist of several phases and employ a trained facilitator or coordinator.

~~(d) "Fictive kin" means an individual who is unrelated to the child by either birth or marriage, but has such a close emotional relationship with the child that he or she may be considered part of the family.~~

(3) FAMILY-FINDING PROGRAM.—Subject to available resources, the department, in collaboration with sheriffs' offices that conduct child protective investigations and community-based care lead agencies, may develop a formal family-finding program to be implemented by child protective investigators and community-based care lead agencies as resources permit.

(a) Family finding may begin as soon as a child is taken into custody of the department, pursuant to s. 39.401, and throughout the duration of the case as necessary, finding and engaging with as many family members ~~and fictive kin~~ as possible for each child who may help with care or support for the child. The department or community-based care lead agency must specifically document strategies taken to locate and engage

relatives ~~and fictive kin~~. Strategies of engagement may include, but are not limited to, asking the relatives ~~and fictive kin~~ to:

1. Participate in a family group decisionmaking conference, family team conferencing, or other family meetings aimed at developing or supporting the family service plan;

2. Attend visitations with the child;

3. Assist in transportation of the child;

4. Provide respite or child care services; or

5. Provide actual kinship care.

(b) The family finding program shall provide the department and the community-based care lead agencies with best practices for identifying family ~~and fictive kin~~. The family finding program must use diligent efforts in family finding, must continue those efforts until multiple relatives ~~and fictive kin~~ are identified, and must go beyond basic searching tools by exploring alternative tools and methodologies. Family finding efforts by the department and the community-based care lead agency may include, but are not limited to:

1. Searching for and locating adult relatives ~~and fictive kin~~.

2. Identifying and building positive connections between the child and the child's relatives ~~and fictive kin~~.

3. Supporting the engagement of relatives ~~and fictive kin~~ in social service planning and delivery of services and creating a network of extended family support to assist in remedying the concerns that led to the child becoming involved with the child welfare system, when appropriate.

4. Maintaining family connections, when possible.

5. Keeping siblings together in care, when in the best

interest of each child and when possible.

Section 4. Paragraph (h) of subsection (8) of section 39.402, Florida Statutes, is amended to read:

39.402 Placement in a shelter.—

(8)

(h) The order for placement of a child in shelter care must identify the parties present at the hearing and must contain written findings:

1. That placement in shelter care is necessary based on the criteria in subsections (1) and (2).

2. That placement in shelter care is in the best interest of the child.

3. That continuation of the child in the home is contrary to the welfare of the child because the home situation presents a substantial and immediate danger to the child's physical, mental, or emotional health or safety which cannot be mitigated by the provision of preventive services.

4. That based upon the allegations of the petition for placement in shelter care, there is probable cause to believe that the child is dependent or that the court needs additional time, which may not exceed 72 hours, in which to obtain and review documents pertaining to the family in order to appropriately determine the risk to the child.

5. That the department has made reasonable efforts to prevent or eliminate the need for removal of the child from the home. A finding of reasonable effort by the department to prevent or eliminate the need for removal may be made and the department is deemed to have made reasonable efforts to prevent or eliminate the need for removal if:

a. The first contact of the department with the family occurs during an emergency;

b. The appraisal of the home situation by the department indicates that the home situation presents a substantial and immediate danger to the child's physical, mental, or emotional health or safety which cannot be mitigated by the provision of preventive services;

c. The child cannot safely remain at home, either because there are no preventive services that can ensure the health and safety of the child or because, even with appropriate and available services being provided, the health and safety of the child cannot be ensured; or

d. The parent or legal custodian is alleged to have committed any of the acts listed as grounds for expedited termination of parental rights in s. 39.806(1)(f)-(i).

6. That the department has made reasonable efforts to keep siblings together if they are removed and placed in out-of-home care unless such placement is not in the best interest of each child. It is preferred that siblings be kept together in a foster home, if available. Other reasonable efforts shall include short-term placement in a group home with the ability to accommodate sibling groups if such a placement is available. The department shall report to the court its efforts to place siblings together unless the court finds that such placement is not in the best interest of a child or his or her sibling.

7. That the court notified the parents, relatives that are providing out-of-home care for the child, or legal custodians of the time, date, and location of the next dependency hearing and of the importance of the active participation of the parents,

relatives that are providing out-of-home care for the child, or legal custodians in all proceedings and hearings.

8. That the court notified the parents or legal custodians of their right to counsel to represent them at the shelter hearing and at each subsequent hearing or proceeding, and the right of the parents to appointed counsel, pursuant to the procedures set forth in s. 39.013.

9. That the court notified relatives who are providing out-of-home care for a child as a result of the shelter petition being granted that they have the right to attend all subsequent hearings, to submit reports to the court, and to speak to the court regarding the child, if they so desire.

10. That the department has placement and care responsibility for any child who is not placed in the care of a parent at the conclusion of the shelter hearing.

Section 5. Subsection (3) and paragraphs (g), (h), and (i) of subsection (6) of section 39.407, Florida Statutes, are amended to read:

39.407 Medical, psychiatric, and psychological examination and treatment of child; physical, mental, or substance abuse examination of person with or requesting child custody.—

(3)(a)1. Except as otherwise provided in subparagraph (b)1. or paragraph (e), before the department provides psychotropic medications to a child in its custody, the prescribing physician or the advanced practice registered nurse whose specialty is psychiatric nursing, as defined in chapter 394, and who is given prescribing authority under chapter 464 shall attempt to obtain express and informed consent, as defined in s. 394.455(15) and as described in s. 394.459(3)(a), from the child's parent or

legal guardian. The department must take steps necessary to facilitate the inclusion of the parent in the child's consultation with the physician or advanced practice registered nurse. However, if the parental rights of the parent have been terminated, the parent's location or identity is unknown or cannot reasonably be ascertained, or the parent declines to give express and informed consent, the department may, after consultation with the prescribing physician or advanced practice registered nurse, seek court authorization to provide the psychotropic medications to the child. Unless parental rights have been terminated and if it is possible to do so, the department shall continue to involve the parent in the decisionmaking process regarding the provision of psychotropic medications. If, at any time, a parent whose parental rights have not been terminated provides express and informed consent to the provision of a psychotropic medication, the requirements of this section that the department seek court authorization do not apply to that medication until such time as the parent no longer consents.

2. Any time the department seeks a medical evaluation to determine the need to initiate or continue a psychotropic medication for a child, the department must provide to the evaluating physician or advanced practice registered nurse all pertinent medical information known to the department concerning that child.

(b)1. If a child who is removed from the home under s. 39.401 is receiving prescribed psychotropic medication at the time of removal and parental authorization to continue providing the medication cannot be obtained, the department may take

possession of the remaining medication and may continue to provide the medication as prescribed until the shelter hearing, if it is determined that the medication is a current prescription for that child and the medication is in its original container.

2. If the department continues to provide the psychotropic medication to a child when parental authorization cannot be obtained, the department shall notify the parent or legal guardian as soon as possible that the medication is being provided to the child as provided in subparagraph 1. The child's official departmental record must include the reason parental authorization was not initially obtained and an explanation of why the medication is necessary for the child's well-being.

3. If the department is advised by a physician licensed under chapter 458 or chapter 459 or an advanced practice registered nurse whose specialty is psychiatric nursing, as defined in chapter 394, and who is given prescribing authority under chapter 464 that the child should continue the psychotropic medication and parental authorization has not been obtained, the department shall request court authorization at the shelter hearing to continue to provide the psychotropic medication and shall provide to the court any information in its possession in support of the request. Any authorization granted at the shelter hearing may extend only until the arraignment hearing on the petition for adjudication of dependency or 28 days following the date of removal, whichever occurs sooner.

4. Before filing the dependency petition, the department shall ensure that the child is evaluated by a physician licensed under chapter 458 or chapter 459 or an advanced practice

registered nurse whose specialty is psychiatric nursing, as defined in chapter 394, and who is given prescribing authority under chapter 464 to determine whether it is appropriate to continue the psychotropic medication. If, as a result of the evaluation, the department seeks court authorization to continue the psychotropic medication, a motion for such continued authorization shall be filed at the same time as the dependency petition, within 21 days after the shelter hearing.

(c) Except as provided in paragraphs (b) and (e), the department must file a motion seeking the court's authorization to initially provide or continue to provide psychotropic medication to a child in its legal custody. The motion must be supported by a written report prepared by the department which describes the efforts made to enable the prescribing physician or advanced practice registered nurse whose specialty is psychiatric nursing, as defined in chapter 394, and who is given prescribing authority under chapter 464 to obtain express and informed consent for providing the medication to the child and other treatments considered or recommended for the child. In addition, the motion must be supported by the prescribing physician's or advanced practice registered nurse's signed medical report providing:

1. The name of the child, the name and range of the dosage of the psychotropic medication, and that there is a need to prescribe psychotropic medication to the child based upon a diagnosed condition for which such medication is being prescribed.

2. A statement indicating that the physician has reviewed all medical information concerning the child which has been

provided.

3. A statement indicating that the psychotropic medication, at its prescribed dosage, is appropriate for treating the child's diagnosed medical condition, as well as the behaviors and symptoms the medication, at its prescribed dosage, is expected to address.

4. An explanation of the nature and purpose of the treatment; the recognized side effects, risks, and contraindications of the medication; drug-interaction precautions; the possible effects of stopping the medication; and how the treatment will be monitored, followed by a statement indicating that this explanation was provided to the child if age appropriate and to the child's caregiver.

5. Documentation addressing whether the psychotropic medication will replace or supplement any other currently prescribed medications or treatments; the length of time the child is expected to be taking the medication; and any additional medical, mental health, behavioral, counseling, or other services that the prescribing physician or advanced practice registered nurse recommends.

(d)1. The department must notify all parties of the proposed action taken under paragraph (c) in writing or by whatever other method best ensures that all parties receive notification of the proposed action within 48 hours after the motion is filed. If any party objects to the department's motion, that party shall file the objection within 2 working days after being notified of the department's motion. If any party files an objection to the authorization of the proposed psychotropic medication, the court shall hold a hearing as soon

as possible before authorizing the department to initially provide or to continue providing psychotropic medication to a child in the legal custody of the department. At such hearing and notwithstanding s. 90.803, the medical report described in paragraph (c) is admissible in evidence. The prescribing physician or advanced practice registered nurse whose specialty is psychiatric nursing, as defined in chapter 394, and who is given prescribing authority under chapter 464 need not attend the hearing or testify unless the court specifically orders such attendance or testimony, or a party subpoenas the physician or advanced practice registered nurse to attend the hearing or provide testimony. If, after considering any testimony received, the court finds that the department's motion and the physician's or advanced practice registered nurse's medical report meet the requirements of this subsection and that it is in the child's best interests, the court may order that the department provide or continue to provide the psychotropic medication to the child without additional testimony or evidence. At any hearing held under this paragraph, the court shall further inquire of the department as to whether additional medical, mental health, behavioral, counseling, or other services are being provided to the child by the department which the prescribing physician or advanced practice registered nurse considers to be necessary or beneficial in treating the child's medical condition and which the physician or advanced practice registered nurse recommends or expects to provide to the child in concert with the medication. The court may order additional medical consultation, including consultation with the MedConsult line at the University of Florida, if available, or require the department

to obtain a second opinion within a reasonable timeframe as established by the court, not to exceed 21 calendar days, after such order based upon consideration of the best interests of the child. The department must make a referral for an appointment for a second opinion with a physician within 1 working day. The court may not order the discontinuation of prescribed psychotropic medication if such order is contrary to the decision of the prescribing physician or advanced practice registered nurse unless the court first obtains an opinion from a licensed psychiatrist, if available, or, if not available, a physician licensed under chapter 458 or chapter 459, stating that more likely than not, discontinuing the medication would not cause significant harm to the child. If, however, the prescribing psychiatrist specializes in mental health care for children and adolescents, the court may not order the discontinuation of prescribed psychotropic medication unless the required opinion is also from a psychiatrist who specializes in mental health care for children and adolescents. The court may also order the discontinuation of prescribed psychotropic medication if a child's treating physician, licensed under chapter 458 or chapter 459, states that continuing the prescribed psychotropic medication would cause significant harm to the child due to a diagnosed nonpsychiatric medical condition.

2. The burden of proof at any hearing held under this paragraph shall be by a preponderance of the evidence.

(e)1. If the child's prescribing physician or advanced practice registered nurse whose specialty is psychiatric nursing, as defined in chapter 394, and who is given prescribing

authority under chapter 464 certifies in the signed medical report required in paragraph (c) that delay in providing a prescribed psychotropic medication would more likely than not cause significant harm to the child, the medication may be provided in advance of the issuance of a court order. In such event, the medical report must provide the specific reasons why the child may experience significant harm and the nature and the extent of the potential harm. The department must submit a motion seeking continuation of the medication and the physician's medical report to the court, the child's guardian ad litem, and all other parties within 3 working days after the department commences providing the medication to the child. The department shall seek the order at the next regularly scheduled court hearing required under this chapter, or within 30 days after the date of the prescription, whichever occurs sooner. If any party objects to the department's motion, the court shall hold a hearing within 7 days.

2. Psychotropic medications may be administered in advance of a court order in hospitals, crisis stabilization units, and in statewide inpatient psychiatric programs. Within 3 working days after the medication is begun, the department must seek court authorization as described in paragraph (c).

(f)1. The department shall fully inform the court of the child's medical and behavioral status as part of the social services report prepared for each judicial review hearing held for a child for whom psychotropic medication has been prescribed or provided under this subsection. As a part of the information provided to the court, the department shall furnish copies of all pertinent medical records concerning the child which have

been generated since the previous hearing. On its own motion or on good cause shown by any party, including any guardian ad litem, attorney, or attorney ad litem who has been appointed to represent the child or the child's interests, the court may review the status more frequently than required in this subsection.

2. The court may, in the best interests of the child, order the department to obtain a medical opinion addressing whether the continued use of the medication under the circumstances is safe and medically appropriate.

(g) The department shall adopt rules to ensure that children receive timely access to clinically appropriate psychotropic medications. These rules must include, but need not be limited to, the process for determining which adjunctive services are needed, the uniform process for facilitating the prescribing physician's or advanced practice registered nurse's ability to obtain the express and informed consent of a child's parent or guardian, the procedures for obtaining court authorization for the provision of a psychotropic medication, the frequency of medical monitoring and reporting on the status of the child to the court, how the child's parents will be involved in the treatment-planning process if their parental rights have not been terminated, and how caretakers are to be provided information contained in the physician's or advanced practice registered nurse's signed medical report. The rules must also include uniform forms to be used in requesting court authorization for the use of a psychotropic medication and provide for the integration of each child's treatment plan and case plan. The department must begin the formal rulemaking

process within 90 days after the effective date of this act.

(6) Children who are in the legal custody of the department may be placed by the department, without prior approval of the court, in a residential treatment center licensed under s. 394.875 or a hospital licensed under chapter 395 for residential mental health treatment only pursuant to this section or may be placed by the court in accordance with an order of involuntary examination or involuntary placement entered pursuant to s. 394.463 or s. 394.467. All children placed in a residential treatment program under this subsection must have a guardian ad litem appointed.

(g)1. The department must submit, at the beginning of each month, to the court having jurisdiction over the child, a written report regarding the child's progress toward achieving the goals specified in the individualized plan of treatment.

2. The court must conduct a hearing to review the status of the child's residential treatment plan no later than 60 days ~~3 months~~ after the child's admission to the residential treatment program. An independent review of the child's progress toward achieving the goals and objectives of the treatment plan must be completed by a qualified evaluator and submitted to the court before its 60-day ~~3-month~~ review.

3. For any child in residential treatment at the time a judicial review is held pursuant to s. 39.701, the child's continued placement in residential treatment must be a subject of the judicial review.

4. If at any time the court determines that the child is not suitable for continued residential treatment, the court shall order the department to place the child in the least

restrictive setting that is best suited to meet his or her needs.

(h) After the initial 60-day ~~3-month~~ review, the court must conduct a review of the child's residential treatment plan every 90 days.

(i) The department must adopt rules for implementing timeframes for the completion of suitability assessments by qualified evaluators and a procedure that includes timeframes for completing the 60-day ~~3-month~~ independent review by the qualified evaluators of the child's progress toward achieving the goals and objectives of the treatment plan which review must be submitted to the court. The Agency for Health Care Administration must adopt rules for the registration of qualified evaluators, the procedure for selecting the evaluators to conduct the reviews required under this section, and a reasonable, cost-efficient fee schedule for qualified evaluators.

Section 6. Present paragraphs (a) through (h) of subsection (2) of section 39.5085, Florida Statutes, are redesignated as paragraphs (b) through (i), respectively, paragraph (a) of subsection (1) is amended, and a new paragraph (a) is added to subsection (2) of that section, to read:

39.5085 Relative Caregiver Program.—

(1) It is the intent of the Legislature in enacting this section to:

(a) Provide for the establishment of procedures and protocols that serve to advance the continued safety of children by acknowledging the valued resource uniquely available through grandparents, relatives of children, and specified nonrelatives

of children pursuant to subparagraph (2)(b)3. ~~(2)(a)3.~~

(2)

(a) Relatives and nonrelatives who are caring for a child must be denied for the Guardianship Assistance Program under s. 39.6225 before applying for the Relative Caregiver Program.

Section 7. Section 39.5086, Florida Statutes, is amended to read:

39.5086 Kinship navigator programs.—

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

~~(a) "Fictive kin" has the same meaning as provided in s. 39.4015(2)(d).~~

(a)~~(b)~~ "Kinship care" means the full-time care of a child placed in out-of-home care by the court in the home of a relative ~~or fictive kin~~.

(b)~~(c)~~ "Kinship navigator program" means a program designed to ensure that kinship caregivers are provided with necessary resources for the preservation of the family.

(c)~~(d)~~ "Relative" means an individual who is caring full time for a child placed in out-of-home care by the court and who:

1. Is related to the child within the fifth degree by blood or marriage to the parent or stepparent of the child; or

2. Is related to a half-sibling of that child within the fifth degree by blood or marriage to the parent or stepparent.

(2) PURPOSE AND SERVICES.—

(a) The purpose of a kinship navigator program is to help relative caregivers ~~and fictive kin~~ in the child welfare system to navigate the broad range of services available to them and the children from public, private, community, and faith-based

organizations.

(b) Subject to available resources, each community-based care lead agency may establish a kinship navigator program that:

1. Coordinates with other state or local agencies that promote service coordination or provide information and referral services, including any entities that participate in the Florida 211 Network, to avoid duplication or fragmentation of services to kinship care families;

2. Is planned and operated in consultation with kinship caregivers and organizations representing them, youth raised by kinship caregivers, relevant governmental agencies, and relevant community-based or faith-based organizations;

3. Has a toll-free telephone hotline to provide information to link kinship caregivers, kinship support group facilitators, and kinship service providers to:

a. One another;

b. Eligibility and enrollment information for federal, state, and local benefits;

c. Relevant training to assist kinship caregivers in caregiving and in obtaining benefits and services; and

d. Relevant knowledge related to legal options available for child custody, other legal assistance, and help in obtaining legal services.

4. Provides outreach to kinship care families, including by establishing, distributing, and updating a kinship care website, or other relevant guides or outreach materials; and

5. Promotes partnerships between public and private agencies, including schools, community-based or faith-based organizations, and relevant governmental agencies, to increase

their knowledge of the needs of kinship care families to promote better services for those families.

(3) RULEMAKING.—The department may adopt rules to implement this section.

Section 8. Paragraph (c) of subsection (1) of section 39.521, Florida Statutes, is amended to read:

39.521 Disposition hearings; powers of disposition.—

(1) A disposition hearing shall be conducted by the court, if the court finds that the facts alleged in the petition for dependency were proven in the adjudicatory hearing, or if the parents or legal custodians have consented to the finding of dependency or admitted the allegations in the petition, have failed to appear for the arraignment hearing after proper notice, or have not been located despite a diligent search having been conducted.

(c) When any child is adjudicated by a court to be dependent, the court having jurisdiction of the child has the power by order to:

1. Require the parent and, when appropriate, the legal guardian or the child to participate in treatment and services identified as necessary. The court may require the person who has custody or who is requesting custody of the child to submit to a mental health or substance abuse disorder assessment or evaluation. The order may be made only upon good cause shown and pursuant to notice and procedural requirements provided under the Florida Rules of Juvenile Procedure. The mental health assessment or evaluation must be administered by a qualified professional as defined in s. 39.01, and the substance abuse assessment or evaluation must be administered by a qualified

professional as defined in s. 397.311. The court may also require such person to participate in and comply with treatment and services identified as necessary, including, when appropriate and available, participation in and compliance with a mental health court program established under chapter 394 or a treatment-based drug court program established under s. 397.334. Adjudication of a child as dependent based upon evidence of harm as defined in s. 39.01(34)(g) ~~s. 39.01(35)(g)~~ demonstrates good cause, and the court shall require the parent whose actions caused the harm to submit to a substance abuse disorder assessment or evaluation and to participate and comply with treatment and services identified in the assessment or evaluation as being necessary. In addition to supervision by the department, the court, including the mental health court program or the treatment-based drug court program, may oversee the progress and compliance with treatment by a person who has custody or is requesting custody of the child. The court may impose appropriate available sanctions for noncompliance upon a person who has custody or is requesting custody of the child or make a finding of noncompliance for consideration in determining whether an alternative placement of the child is in the child's best interests. Any order entered under this subparagraph may be made only upon good cause shown. This subparagraph does not authorize placement of a child with a person seeking custody of the child, other than the child's parent or legal custodian, who requires mental health or substance abuse disorder treatment.

2. Require, if the court deems necessary, the parties to participate in dependency mediation.

3. Require placement of the child either under the

protective supervision of an authorized agent of the department in the home of one or both of the child's parents or in the home of a relative of the child or another adult approved by the court, or in the custody of the department. Protective supervision continues until the court terminates it or until the child reaches the age of 18, whichever date is first. Protective supervision shall be terminated by the court whenever the court determines that permanency has been achieved for the child, whether with a parent, another relative, or a legal custodian, and that protective supervision is no longer needed. The termination of supervision may be with or without retaining jurisdiction, at the court's discretion, and shall in either case be considered a permanency option for the child. The order terminating supervision by the department must set forth the powers of the custodian of the child and include the powers ordinarily granted to a guardian of the person of a minor unless otherwise specified. Upon the court's termination of supervision by the department, further judicial reviews are not required if permanency has been established for the child.

4. Determine whether the child has a strong attachment to the prospective permanent guardian and whether such guardian has a strong commitment to permanently caring for the child.

Section 9. Paragraph (a) of subsection (2) of section 39.523, Florida Statutes, is amended to read:

39.523 Placement in out-of-home care.—

(2) ASSESSMENT AND PLACEMENT.—When any child is removed from a home and placed into out-of-home care, a comprehensive placement assessment process shall be completed to determine the level of care needed by the child and match the child with the

most appropriate placement.

(a) The community-based care lead agency or subcontracted agency with the responsibility for assessment and placement must coordinate a multidisciplinary team staffing with any available individual currently involved with the child including, but not limited to, a representative from the department and the case manager for the child; a therapist, attorney ad litem, guardian ad litem, teachers, coaches, Children's Medical Services; and other community providers of services to the child or stakeholders as applicable. The team may also include clergy and~~,~~ relatives~~, and fictive kin~~ if appropriate. Team participants must gather data and information on the child which is known at the time including, but not limited to:

1. Mental, medical, behavioral health, and medication history;

2. Community ties and school placement;

3. Current placement decisions relating to any siblings;

4. Alleged type of abuse or neglect including sexual abuse and trafficking history; and

5. The child's age, maturity, strengths, hobbies or activities, and the child's preference for placement.

Section 10. Paragraph (c) of subsection (1) of section 39.6012, Florida Statutes, is amended to read:

39.6012 Case plan tasks; services.—

(1) The services to be provided to the parent and the tasks that must be completed are subject to the following:

(c) If there is evidence of harm as defined in s. 39.01(34)(g) ~~s. 39.01(35)(g)~~, the case plan must include as a required task for the parent whose actions caused the harm that

the parent submit to a substance abuse disorder assessment or evaluation and participate and comply with treatment and services identified in the assessment or evaluation as being necessary.

Section 11. Subsections (1), (6), (10), and (12) of section 39.6225, Florida Statutes, are amended to read:

39.6225 Guardianship Assistance Program.—

(1) The department shall establish and operate the Guardianship Assistance Program to provide guardianship assistance payments to relatives and~~,~~ next of kin~~, and fictive kin~~ who meet the eligibility requirements established in this section. For purposes of administering the program, the term:

(a) "Child" means an individual who has not attained 21 years of age.

(b) "Young adult" means an individual who has attained 18 years of age but who has not attained 21 years of age.

(6) Guardianship assistance benefits shall be terminated if the guardian is no longer providing support to the child. For purposes of this subsection, a guardian is considered to no longer be providing support to the child if:

(a) The child is absent from the home of the guardian for a period of at least 60 consecutive calendar days, unless the child:

1. Is absent due to medical care, school attendance, runaway status, or detention in a Department of Juvenile Justice facility; and

2. Continues to be under the care and custody of the guardian.

(b) The court modifies the placement of the child and the

guardian is no longer eligible to receive guardianship assistance benefits.

(10) The case plan must describe the following for each child with a permanency goal of permanent guardianship in which the guardian is pursuing ~~in receipt of~~ guardianship assistance ~~payments~~:

(a) The manner in which the child meets program eligibility requirements.

(b) The manner in which the department determined that reunification or adoption is not appropriate.

(c) Efforts to discuss adoption with the child's permanent guardian.

(d) Efforts to discuss guardianship assistance with the child's parent or the reasons why efforts were not made.

(e) The reasons why a permanent placement with the prospective guardian is in the best interest of the child.

(f) The reasons why the child is separated from his or her siblings during placement, if applicable.

(g) Efforts to consult the child, if the child is 14 years of age or older, regarding the permanent guardianship arrangement.

(12) The department shall develop and implement a comprehensive communications strategy in support of relatives ~~and fictive kin~~ who are prospective caregivers. This strategy shall provide such prospective caregivers with information on supports and services available under state law. At a minimum, the department's communication strategy shall involve providing prospective caregivers with information about:

(a) Eligibility criteria, monthly payment rates, terms of

payment, and program or licensure requirements for the Relative Caregiver Program, the Guardianship Assistance Program, and licensure as a Level I or Level II family foster home as provided in s. 409.175.

(b) A detailed description of the process for licensure as a Level I or Level II family foster home and for applying for the Relative Caregiver program.

(c) Points of contact for addressing questions or obtaining assistance in applying for programs or licensure.

Section 12. Subsections (2) and (3), paragraph (a) of subsection (4), and subsection (6) of section 39.6251, Florida Statutes, are amended, and subsection (10) is added to that section, to read:

39.6251 Continuing care for young adults.—

(2) The primary goal for a child in care is permanency. A child who is living in licensed care on his or her 18th birthday and who has not achieved permanency under s. 39.621 is eligible to remain in licensed care under the jurisdiction of the court and in the care of the department. A child is eligible to remain in licensed care if he or she is:

(a) Completing secondary education or a program leading to an equivalent credential;

(b) Enrolled in an institution that provides postsecondary or vocational education;

(c) Participating in a program or activity designed to promote or eliminate barriers to employment;

(d) Employed for at least 80 hours per month; or

(e) Unable to participate in programs or activities listed in paragraphs (a)-(d) full time due to a physical, intellectual,

emotional, or psychiatric condition that limits participation. Any such barrier to participation must be supported by documentation in the child's case file or school or medical records of a physical, intellectual, or psychiatric condition that impairs the child's ability to perform one or more life activities.

The young adult must furnish documentation to the department or lead agency of his or her participation in one of the programs or activities listed in paragraphs (a)-(d), or his or her inability to participate in one of the programs or activities as provided in paragraph (e), or authorize the release of his or her records to the department or lead agency.

(3) The permanency goal for a young adult who chooses to remain in licensed care past his or her 18th birthday is to transition to independence ~~from licensed care to independent living~~.

(4)(a) The young adult must reside in a supervised living environment that is approved by the department or a community-based care lead agency. The young adult shall live independently, but in an environment in which he or she is provided supervision, case management, and supportive services by the department or lead agency. Such an environment must offer developmentally appropriate freedom and responsibility to prepare the young adult for adulthood. For the purposes of this subsection, a supervised living arrangement may include a licensed foster home, licensed group home, college dormitory, shared housing, apartment, or another housing arrangement if the arrangement is approved by the community-based care lead agency

and is acceptable to the young adult~~, with first choice being a licensed foster home~~. A young adult may continue to reside with the same licensed foster family or group care provider with whom he or she was residing at the time he or she reached the age of 18 years.

(6) A young adult who is between the ages of 18 and 21 and who has left care may return to care by applying to the community-based care lead agency for readmission <u>through the execution of a voluntary placement agreement</u>. The community-based care lead agency shall readmit the young adult if he or she continues to meet the eligibility requirements in this section.

(a) The department shall develop a standard procedure and application packet for readmission to care to be used by all community-based care lead agencies.

(b) Within 30 days after the young adult has been readmitted to care, the community-based care lead agency shall assign a case manager to update the case plan and the transition plan and to arrange for the required services. Updates to the case plan and the transition plan and arrangements for the required services shall be undertaken in consultation with the young adult. The department shall petition the court to reinstate jurisdiction over the young adult. Notwithstanding s. 39.013(2), the court shall resume jurisdiction over the young adult if the department establishes that he or she continues to meet the eligibility requirements in this section.

<u>(10) The department shall adopt rules to administer this section.</u>

Section 13. Paragraph (d) of subsection (2) of section

39.701, Florida Statutes, is amended, and paragraphs (f) and (g) are added to subsection (4) of that section, to read:

39.701 Judicial review.—

(2) REVIEW HEARINGS FOR CHILDREN YOUNGER THAN 18 YEARS OF AGE.—

(d) *Orders.*—

1. Based upon the criteria set forth in paragraph (c) and the recommended order of the citizen review panel, if any, the court shall determine whether ~~or not~~ the social service agency shall initiate proceedings to have a child declared a dependent child, return the child to the parent, continue the child in out-of-home care for a specified period of time, or initiate termination of parental rights proceedings for subsequent placement in an adoptive home. Amendments to the case plan must be prepared as provided ~~prescribed~~ in s. 39.6013. If the court finds that the prevention or reunification efforts of the department will allow the child to remain safely at home or be safely returned to the home, the court shall allow the child to remain in or return to the home after making a specific finding of fact that the reasons for the creation of the case plan have been remedied to the extent that the child's safety, well-being, and physical, mental, and emotional health will not be endangered.

2. The court shall return the child to the custody of his or her ~~the~~ parents at any time it determines that the circumstances which caused the out-of-home placement, and issues subsequently identified, have been remedied to the extent that return of the child to the home with an in-home safety plan prepared or approved by the department ~~that they have~~

~~substantially complied with the case plan, if the court is satisfied that reunification~~ will not be detrimental to the child's safety, well-being, and physical, mental, and emotional health.

3. If, in the opinion of the court, the social service agency has not complied with its obligations as specified in the written case plan, the court may find the social service agency in contempt, shall order the social service agency to submit its plans for compliance with the agreement, and shall require the social service agency to show why the child could not safely be returned to the home of the parents.

4. If, at any judicial review, the court finds that the parents have failed to substantially comply with the case plan to the degree that further reunification efforts are without merit and not in the best interest of the child, on its own motion, the court may order the filing of a petition for termination of parental rights, regardless of whether ~~or not~~ the time period as contained in the case plan for substantial compliance has expired.

5. Within 6 months after the date that the child was placed in shelter care, the court shall conduct a judicial review hearing to review the child's permanency goal as identified in the case plan. At the hearing the court shall make findings regarding the likelihood of the child's reunification with the parent or legal custodian. In making such findings, the court shall consider the level of the parent or legal custodian's compliance with the case plan and demonstrated change in protective capacities compared to that necessary to achieve timely reunification within 12 months after the removal of the

child from the home. The court shall also consider the frequency, duration, manner, and level of engagement of the parent or legal custodian's visitation with the child in compliance with the case plan. If the court makes a written finding that it is not likely that the child will be reunified with the parent or legal custodian within 12 months after the child was removed from the home, the department must file with the court, and serve on all parties, a motion to amend the case plan under s. 39.6013 and declare that it will use concurrent planning for the case plan. The department must file the motion within 10 business days after receiving the written finding of the court. The department must attach the proposed amended case plan to the motion. If concurrent planning is already being used, the case plan must document the efforts the department is taking to complete the concurrent goal.

6. The court may issue a protective order in assistance, or as a condition, of any other order made under this part. In addition to the requirements included in the case plan, the protective order may set forth requirements relating to reasonable conditions of behavior to be observed for a specified period of time by a person or agency who is before the court, ~~;~~ and the order may require any person or agency to make periodic reports to the court containing such information as the court in its discretion may prescribe.

7. If, at any judicial review, the court determines that the child shall remain in out-of-home care, the court shall order that the department has placement and care responsibility for the child.

(4) REVIEW HEARINGS FOR YOUNG ADULTS IN FOSTER CARE.—During

each period of time that a young adult remains in foster care, the court shall review the status of the young adult at least every 6 months and must hold a permanency review hearing at least annually.

(f) If the young adult elects to voluntarily leave extended foster care for the sole purpose of ending a removal episode and immediately thereafter executes a voluntary placement agreement with the department to reenroll in extended foster care, the court shall enter an order finding that the prior removal episode has ended. Under these circumstances, the court maintains jurisdiction and a petition to reinstate jurisdiction as provided in s. 39.6251(6)(b) is not required.

(g)1. When a young adult enters extended foster care by executing a voluntary placement agreement, the court shall enter an order within 180 days after execution of the agreement that determines whether the placement is in the best interests of the young adult. For purposes of this paragraph, a placement may include a licensed foster home, licensed group home, college dormitory, shared housing, apartment, or another housing arrangement, if the arrangement is approved by the community-based care lead agency and is acceptable to the young adult.

2. When a young adult is in extended foster care, each judicial review order shall provide that the department has placement and care responsibility for the young adult.

3. When a young adult is in extended foster care, the court shall enter an order at least every 12 months that includes a finding of whether the department has made reasonable efforts to finalize the permanency plan currently in effect.

Section 14. Subsection (4) of section 322.09, Florida

Statutes, is amended to read:

322.09 Application of minors; responsibility for negligence or misconduct of minor.—

(4) Notwithstanding subsections (1) and (2), if a caregiver of a minor who is under the age of 18 years and is in out-of-home care as defined in s. 39.01 ~~s. 39.01(49)~~, an authorized representative of a residential group home at which such a minor resides, the caseworker at the agency at which the state has placed the minor, or a guardian ad litem specifically authorized by the minor's caregiver to sign for a learner's driver license signs the minor's application for a learner's driver license, that caregiver, group home representative, caseworker, or guardian ad litem does not assume any obligation or become liable for any damages caused by the negligence or willful misconduct of the minor by reason of having signed the application. Before signing the application, the caseworker, authorized group home representative, or guardian ad litem shall notify the caregiver or other responsible party of his or her intent to sign and verify the application.

Section 15. Paragraph (p) of subsection (4) of section 394.495, Florida Statutes, is amended to read:

394.495 Child and adolescent mental health system of care; programs and services.—

(4) The array of services may include, but is not limited to:

(p) Trauma-informed services for children who have suffered sexual exploitation as defined in s. 39.01(76)(g) ~~s. 39.01(77)(g)~~.

Section 16. Present subsections (9) and (10) of section

409.1451, Florida Statutes, are redesignated as subsections (10) and (11), respectively, paragraph (b) of subsection (2) is amended, and a new subsection (9) is added to that section, to read:

409.1451 The Road-to-Independence Program.—

(2) POSTSECONDARY EDUCATION SERVICES AND SUPPORT.—

(b) The amount of the financial assistance shall be as follows:

1. For a young adult who does not remain in foster care and is attending a postsecondary school as provided in s. 1009.533, the amount is $1,256 monthly.

2. For a young adult who remains in foster care, is attending a postsecondary school, as provided in s. 1009.533, and continues to reside in a licensed foster home, the amount is the established room and board rate for foster parents. This takes the place of the payment provided for in s. 409.145(4).

3. For a young adult who remains in foster care, but temporarily resides away from a licensed foster home for purposes of attending a postsecondary school as provided in s. 1009.533, the amount is $1,256 monthly. This takes the place of the payment provided for in s. 409.145(4).

4. For a young adult who remains in foster care, is attending a postsecondary school as provided in s. 1009.533, and continues to reside in a licensed group home, the amount is negotiated between the community-based care lead agency and the licensed group home provider.

5. For a young adult who remains in foster care, but temporarily resides away from a licensed group home for purposes of attending a postsecondary school as provided in s. 1009.533,

the amount is $1,256 monthly. This takes the place of a negotiated room and board rate.

~~6. The amount of the award may be disregarded for purposes of determining the eligibility for, or the amount of, any other federal or federally supported assistance.~~

6.~~7.~~ A young adult is eligible to receive financial assistance during the months when he or she is enrolled in a postsecondary educational institution.

(9) FINANCIAL ASSISTANCE FOR YOUNG ADULTS RECEIVING SERVICES.—Financial awards to young adults receiving services under subsections (2) and (3) and s. 39.6251 may be disregarded for purposes of determining the eligibility for, or the amount of, any other federal or federally supported assistance.

Section 17. Paragraphs (e), (j), and (m) of subsection (2), paragraph (b) of subsection (5), paragraph (c) of subsection (6), subsection (7), paragraph (b) of subsection (9), paragraphs (b) and (c) of subsection (12), and paragraphs (b) and (d) of subsection (14) of section 409.175, Florida Statutes, are amended to read:

409.175 Licensure of family foster homes, residential child-caring agencies, and child-placing agencies; public records exemption.—

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

(e) "Family foster home" means a ~~private~~ residence licensed by the department in which children who are unattended by a parent or legal guardian are provided 24-hour care. The term does not include an adoptive home that has been approved by the department or approved by a licensed child-placing agency for children placed for adoption.

(j) "Personnel" means all owners, operators, employees, and volunteers working in a child-placing agency~~, family foster home,~~ or residential child-caring agency who may be employed by or do volunteer work for a person, corporation, or agency that holds a license as a child-placing agency or a residential child-caring agency, but the term does not include those who do not work on the premises where child care is furnished and have no direct contact with a child or have no contact with a child outside of the presence of the child's parent or guardian. For purposes of screening, the term includes any member, over the age of 12 years, of the family of the owner or operator or any person other than a client, over the age of 12 years, residing with the owner or operator if the agency ~~or family foster home~~ is located in or adjacent to the home of the owner or operator or if the family member of, or person residing with, the owner or operator has any direct contact with the children. Members of the family of the owner or operator, or persons residing with the owner or operator, who are between the ages of 12 years and 18 years are not required to be fingerprinted, but must be screened for delinquency records. For purposes of screening, the term also includes owners, operators, employees, and volunteers working in summer day camps~~,~~ or summer 24-hour camps providing care for children. A volunteer who assists on an intermittent basis for less than 10 hours per month shall not be included in the term "personnel" for the purposes of screening if a person who meets the screening requirement of this section is always present and has the volunteer in his or her line of sight.

(m) "Screening" means the act of assessing the background of personnel <u>or Level II through Level V family foster homes</u> and

includes, but is not limited to, employment history checks as provided in chapter 435, using the level 2 standards for screening set forth in that chapter.

(5) The department shall adopt and amend rules for the levels of licensed care associated with the licensure of family foster homes, residential child-caring agencies, and child-placing agencies. The rules may include criteria to approve waivers to licensing requirements when applying for a child-specific license.

(b) The requirements for licensure and operation of family foster homes, residential child-caring agencies, and child-placing agencies shall include:

1. The operation, conduct, and maintenance of these homes and agencies and the responsibility which they assume for children served and the evidence of need for that service.

2. The provision of food, clothing, educational opportunities, services, equipment, and individual supplies to assure the healthy physical, emotional, and mental development of the children served.

3. The appropriateness, safety, cleanliness, and general adequacy of the premises, including fire prevention and health standards, to provide for the physical comfort, care, and well-being of the children served.

4. The ratio of staff to children required to provide adequate care and supervision of the children served and, in the case of <u>family</u> foster homes, the maximum number of children in the home.

5. The good moral character based upon screening, education, training, and experience requirements for personnel

and family foster homes.

6. The department may grant exemptions from disqualification from working with children or the developmentally disabled as provided in s. 435.07.

7. The provision of preservice and inservice training for all foster parents and agency staff.

8. Satisfactory evidence of financial ability to provide care for the children in compliance with licensing requirements.

9. The maintenance by the agency of records pertaining to admission, progress, health, and discharge of children served, including written case plans and reports to the department.

10. The provision for parental involvement to encourage preservation and strengthening of a child's relationship with the family.

11. The transportation safety of children served.

12. The provisions for safeguarding the cultural, religious, and ethnic values of a child.

13. Provisions to safeguard the legal rights of children served.

(6)

(c) A licensed family foster home, child-placing agency, or residential child-caring agency which applies for renewal of its license shall submit to the department a list of personnel or household members who have worked or resided on a continuous basis at the applicant family foster home or agency since submitting fingerprints to the department, identifying those for whom a written assurance of compliance was provided by the department and identifying those personnel or household members who have recently begun working or residing at the family foster

home or agency and are awaiting the results of the required fingerprint check, along with the date of the submission of those fingerprints for processing. The department shall by rule determine the frequency of requests to the Department of Law Enforcement to run state criminal records checks for such personnel or household members except for those personnel or household members awaiting the results of initial fingerprint checks for employment at the applicant family foster home or agency.

(7) ~~(a)~~ The department may extend a license expiration date once for a period of up to 30 days. However, the department may not extend a license expiration date more than once. ~~The department may issue a provisional license to an applicant who is unable to conform to the licensing requirements at the time of the study, but who is believed able to meet the licensing requirements within the time allowed by the provisional license. The issuance of a provisional license shall be contingent upon the submission to the department of an acceptable written plan to overcome the deficiency by the expiration date of the provisional license.~~

~~(b) A provisional license may be issued when the applicant fails to meet licensing requirements in matters that are not of immediate danger to the children and the agency has submitted a corrective action plan which is approved by the department. A provisional license may be issued if the screening material has been timely submitted; however, a provisional license may not be issued unless the applicant is in compliance with the requirements in this section for screening of personnel.~~

~~(c) A provisional license shall not be issued for a period~~

~~in excess of 1 year and shall not be subject to renewal; and it may be suspended if periodic inspection by the department indicates that insufficient progress has been made toward compliance with the requirements.~~

(9)

(b) Any of the following actions by a family foster home or its household members or an agency or its personnel is a ground for denial, suspension, or revocation of a license:

1. An intentional or negligent act materially affecting the health or safety of children in the home or agency.

2. A violation of ~~the provisions of~~ this section or of licensing rules adopted ~~promulgated~~ pursuant to this section.

3. Noncompliance with the requirements for good moral character as specified in paragraph (5)(b).

4. Failure to dismiss personnel or a household member found in noncompliance with requirements for good moral character.

5. Failure to comply with the requirements of ss. 63.0422 and 790.335.

(12)

(b) It is unlawful for any person, agency, family foster home, summer day camp, or summer 24-hour camp providing care for children to:

1. Willfully or intentionally fail to comply with the requirements for the screening of personnel and family foster homes or the dismissal of personnel or household members found not to be in compliance with the requirements for good moral character as specified in paragraph (5)(b).

2. Use information from the criminal records obtained under this section for any purpose other than screening a person for

employment as specified in this section or to release such information to any other person for any purpose other than screening for employment as specified in this section.

(c) It is unlawful for any person, agency, family foster home, summer day camp, or summer 24-hour camp providing care for children to use information from the juvenile records of any person obtained under this section for any purpose other than screening for employment as specified in this section or to release information from such records to any other person for any purpose other than screening for employment as specified in this section.

(14)

(b) As a condition of licensure, foster parents shall successfully complete ~~a minimum of 21 hours of~~ preservice training. The preservice training shall be uniform statewide and shall include, but not be limited to, such areas as:

1. Orientation regarding agency purpose, objectives, resources, policies, and services;

2. Role of the foster parent as a treatment team member;

3. Transition of a child into and out of foster care, including issues of separation, loss, and attachment;

4. Management of difficult child behavior that can be intensified by placement, by prior abuse or neglect, and by prior placement disruptions;

5. Prevention of placement disruptions;

6. Care of children at various developmental levels, including appropriate discipline; and

7. Effects of foster parenting on the family of the foster parent.

(d) Before ~~prior to~~ licensure renewal, each ~~level II through level V~~ foster parent must ~~shall~~ successfully complete ~~8 hours of~~ inservice training. ~~Each level I foster parent shall successfully complete 4 hours of inservice training.~~ Periodic time-limited training courses shall be made available for selective use by foster parents. Such inservice training shall include subjects affecting the daily living experiences of foster parenting as a foster parent. For a foster parent participating in the required inservice training, the department shall reimburse such parent for travel expenditures and, if both parents in a home are attending training or if the absence of the parent would leave the children without departmentally approved adult supervision, the department shall make provision for child care or shall reimburse the foster parents for child care purchased by the parents for children in their care.

Section 18. Subsection (4) of section 409.903, Florida Statutes, is amended to read:

409.903 Mandatory payments for eligible persons.—The agency shall make payments for medical assistance and related services on behalf of the following persons who the department, or the Social Security Administration by contract with the Department of Children and Families, determines to be eligible, subject to the income, assets, and categorical eligibility tests set forth in federal and state law. Payment on behalf of these Medicaid eligible persons is subject to the availability of moneys and any limitations established by the General Appropriations Act or chapter 216.

(4) A child who is eligible under Title IV-E of the Social Security Act for subsidized board payments, foster care, or

adoption subsidies, and a child for whom the state has assumed temporary or permanent responsibility and who does not qualify for Title IV-E assistance but is in foster care, shelter or emergency shelter care, or subsidized adoption. This category includes:

(a) A young adult who is eligible to receive services under s. 409.1451, until the young adult reaches 21 years of age, without regard to any income, resource, or categorical eligibility test that is otherwise required.

(b) ~~This category also includes~~ A person who as a child was eligible under Title IV-E of the Social Security Act for foster care or the state-provided foster care and who is a participant in the Road-to-Independence Program.

(c) A child who is eligible for the Guardianship Assistance Program as provided in s. 39.6225.

Section 19. Paragraph (a) of subsection (1) of section 409.991, Florida Statutes, is amended to read:

409.991 Allocation of funds for community-based care lead agencies.—

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

(a) "Core services funds" means all funds allocated to community-based care lead agencies operating under contract with the department pursuant to s. 409.987, with the following exceptions:

1. Funds appropriated for independent living;

2. Funds appropriated for maintenance adoption subsidies;

3. Funds allocated by the department for protective investigations training;

4. Nonrecurring funds;

5. Designated mental health wrap-around services funds; ~~and~~

6. Funds for special projects for a designated community-based care lead agency; and

7. Funds appropriated for the Guardianship Assistance Program under s. 39.6225.

Section 20. Paragraph (b) of subsection (1) of section 414.045, Florida Statutes, is amended to read:

414.045 Cash assistance program.—Cash assistance families include any families receiving cash assistance payments from the state program for temporary assistance for needy families as defined in federal law, whether such funds are from federal funds, state funds, or commingled federal and state funds. Cash assistance families may also include families receiving cash assistance through a program defined as a separate state program.

(1) For reporting purposes, families receiving cash assistance shall be grouped into the following categories. The department may develop additional groupings in order to comply with federal reporting requirements, to comply with the data-reporting needs of the board of directors of CareerSource Florida, Inc., or to better inform the public of program progress.

(b) *Child-only cases.*—Child-only cases include cases that do not have an adult or teen head of household as defined in federal law. Such cases include:

1. Children in the care of caretaker relatives, if the caretaker relatives choose to have their needs excluded in the calculation of the amount of cash assistance.

2. Families in the Relative Caregiver Program as provided

in s. 39.5085.

3. Families in which the only parent in a single-parent family or both parents in a two-parent family receive supplemental security income (SSI) benefits under Title XVI of the Social Security Act, as amended. To the extent permitted by federal law, individuals receiving SSI shall be excluded as household members in determining the amount of cash assistance, and such cases shall not be considered families containing an adult. Parents or caretaker relatives who are excluded from the cash assistance group due to receipt of SSI may choose to participate in work activities. An individual whose ability to participate in work activities is limited who volunteers to participate in work activities shall be assigned to work activities consistent with such limitations. An individual who volunteers to participate in a work activity may receive child care or support services consistent with such participation.

4. Families in which the only parent in a single-parent family or both parents in a two-parent family are not eligible for cash assistance due to immigration status or other limitation of federal law. To the extent required by federal law, such cases shall not be considered families containing an adult.

5. To the extent permitted by federal law and subject to appropriations, special needs children who have been adopted pursuant to s. 409.166 and whose adopting family qualifies as a needy family under the state program for temporary assistance for needy families. Notwithstanding any provision to the contrary in s. 414.075, s. 414.085, or s. 414.095, a family shall be considered a needy family if:

a. The family is determined by the department to have an income below 200 percent of the federal poverty level;

b. The family meets the requirements of s. 414.095(2) and (3) related to residence, citizenship, or eligible noncitizen status; and

c. The family provides any information that may be necessary to meet federal reporting requirements specified under Part A of Title IV of the Social Security Act.

6. Families in the Guardianship Assistance Program as provided in s. 39.6225.

Families described in subparagraph 1., subparagraph 2., or subparagraph 3. may receive child care assistance or other supports or services so that the children may continue to be cared for in their own homes or in the homes of relatives. Such assistance or services may be funded from the temporary assistance for needy families block grant to the extent permitted under federal law and to the extent funds have been provided in the General Appropriations Act.

Section 21. Section 627.746, Florida Statutes, is amended to read:

627.746 Coverage for minors who have a learner's driver license; additional premium prohibited.—An insurer that issues an insurance policy on a private passenger motor vehicle to a named insured who is a caregiver of a minor who is under the age of 18 years and is in out-of-home care as defined in s. 39.01 ~~s. 39.01(49)~~ may not charge an additional premium for coverage of the minor while the minor is operating the insured vehicle, for the period of time that the minor has a learner's driver

license, until such time as the minor obtains a driver license.

Section 22. Paragraph (c) of subsection (1) of section 934.255, Florida Statutes, is amended to read:

934.255 Subpoenas in investigations of sexual offenses.—

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

(c) "Sexual abuse of a child" means a criminal offense based on any conduct described in s. 39.01 ~~s. 39.01(71)~~.

Section 23. Subsection (5) of section 960.065, Florida Statutes, is amended to read:

960.065 Eligibility for awards.—

(5) A person is not ineligible for an award pursuant to paragraph (2)(a), paragraph (2)(b), or paragraph (2)(c) if that person is a victim of sexual exploitation of a child as defined in s. 39.01(76)(g) ~~s. 39.01(77)(g)~~.

Section 24. Paragraph (d) of subsection (1) of section 1009.25, Florida Statutes, is amended to read:

1009.25 Fee exemptions.—

(1) The following students are exempt from the payment of tuition and fees, including lab fees, at a school district that provides workforce education programs, Florida College System institution, or state university:

(d) A student who is or was at the time he or she reached 18 years of age in the custody of a relative or nonrelative under s. 39.5085 or s. 39.6225 or who was adopted from the Department of Children and Families after May 5, 1997. Such exemption includes fees associated with enrollment in applied academics for adult education instruction. The exemption remains valid until the student reaches 28 years of age.

Section 25. This act shall take effect July 1, 2019.

The Florida Senate

Committee Agenda Request

To: Senator Gayle Harrell, Chair
Committee on Health Policy

Subject: Committee Agenda Request

Date: March 13, 2019

I respectfully request that **Senate Bill #1650**, relating to Child Welfare, be placed on the:

☒ committee agenda at your earliest possible convenience.

☐ next committee agenda.

Senator Ben Albritton
Florida Senate, District 26

File signed original with committee office

S-020 (03/2004)

2019 AGENCY LEGISLATIVE BILL ANALYSIS
Department of Children and Families

BILL INFORMATION	
BILL NUMBER:	SB 1650
BILL TITLE:	**Child Welfare**
BILL SPONSOR:	N/A
EFFECTIVE DATE:	July 1, 2019

COMMITTEES OF REFERENCE
1) NA
2)
3)
4)
5)

CURRENT COMMITTEE
N/A

SIMILAR BILLS	
BILL NUMBER:	N/A
SPONSOR:	N/A

PREVIOUS LEGISLATION	
BILL NUMBER:	N/A
SPONSOR:	N/A
YEAR:	N/A
LAST ACTION:	N/A

IDENTICAL BILLS	
BILL NUMBER:	N/A
SPONSOR:	N/A

Is this bill part of an agency package?
Yes

BILL ANALYSIS INFORMATION	
DATE OF ANALYSIS:	February 26, 2019 For further information, please contact John Paul Fiore at (850) 488-9410
LEAD AGENCY ANALYST:	Courtney Smith, OCW
ADDITIONAL ANALYST(S):	
LEGAL ANALYST:	Kelly McGrath, OGC
FISCAL ANALYST:	Sue Zwirz, Budget

POLICY ANALYSIS

1. EXECUTIVE SUMMARY

The bill is seeking authority for the Department of Children and Families (Department) to adopt rules for the establishment of processes and procedures for the implementation of the Title IV-E Extended Foster Care program (EFC) and to allow financial assistance provided to young adults receiving independent living services be disregarded for other federal or federally supported programs. In addition, the bill addresses the federal methods for entry into EFC and the judicial requirements. Several sections of Florida Statutes are amended to align with the Title IV-E and GAP requirements. Lastly, to ensure compliance with federal regulations for the Family First Prevention Services Act, changes were made regarding judicial requirements for reviewing a child's placement in certain placement types.

2. SUBSTANTIVE BILL ANALYSIS

1. PRESENT SITUATION:

Section 1

Section 39.01(37), F.S., provides the definition of institutional child abuse or neglect to mean situations of known or suspected child abuse or neglect in which the person allegedly perpetrating the child abuse or neglect is an employee of a private school, public or private day care center, residential home, institution, facility, or agency or any other person at such institution responsible for the child's care as defined in subsection (54). Subsection (37) only includes employees of private schools but subsection (54) references an employee of any school which would appear to be inclusive of public schools. The Department does investigate employees of public schools, but the definitions can be confusing to individuals outside the Department.

Section 39.01(29), F.S., defines fictive kin as a person unrelated by birth, marriage, or adoption who has an emotionally significant relationship, which possesses the characteristics of a family relationship, to a child. This definition varies slightly from the definition of fictive kin in s. 39.4015, F.S.

Section 2.

(See Additional Comments section)

Section 3.

The inclusion of the definition of fictive kin in s. 39.4015, F.S., does not entirely align with the definition of fictive kin in s. 39.01, F.S., which meets the Title IV-E requirement. Two slightly different definitions for fictive kin can lead to confusion and misinterpretation by the feds and other child welfare advocates. Currently, child protective investigators, community-based care lead agencies (CBCs), and case management organizations, search for family members and fictive kin who may help with care or support for a child who has been removed from his/her home due to abuse or neglect.

Section 4.

Section 39.402(8)(h), F.S., addresses that the court order for placement of a child in shelter care must identify the parties present at the hearing and must contain written findings:

- That placement in shelter care is necessary;
- That placement in shelter care is in the best interest of the child;
- That continuation of the child in the home is contrary to the welfare of the child;
- That based upon the allegations of the petition for placement in shelter care, there is probable cause to believe that the child is dependent or that the court needs additional time, which may not exceed 72 hours, in which to obtain and review additional documents;
- That the Department has made reasonable efforts to prevent or eliminate the need for removal;
- That the Department has made reasonable efforts to keep siblings together if they are removed and placed in out-of-home care unless such placement is not in the best interest of each child;
- That the court notified the parents, relatives that are providing out-of-home care for the child, or legal custodians of the hearing and their right to counsel; and
- That the court notified relatives who are providing out-of-home care for a child as a result of the shelter petition being granted that they have the right to attend all subsequent hearings, to submit reports to the court, and to speak to the court regarding the child, if they so desire.

To be reimbursed for the care of a child, federal guidelines require that the Department has placement and care responsibility for any child who is not placed in the care of a parent at the conclusion of the shelter hearing. Florida statutes do not address that the Department has placement and care responsibility.

Section 5.

Section 39.407(3), F.S., only authorizes physicians licensed under Chapters 458 and 459, F.S., to prescribe psychotropic medications to children in out-of-home care. Two years ago, the legislature amended s. 464.012(4)(e), F.S., authorizing advance practice registered nurses whose specialty is Psychiatric Nursing to prescribe psychotropic medications to children in out-of-home care which creates a conflict between ss. 39.407 and 464.012, F.S. In the regions there is a demand for physicians who can prescribe psychotropic medications and will accept Medicaid for payment.

Section 39.407(6), F.S., authorizes the Department to place a child who is in its custody in a residential treatment center or a hospital for residential mental health treatment under certain circumstances and allows the court to place the child in a residential treatment center or a hospital for residential mental health treatment. Before the child is admitted, the child shall be assessed for suitability for residential treatment by a qualified evaluator and a personal examination and assessment must be made. The court must conduct a hearing to review the status of the child's residential treatment plan no later than three months after the child's admission to the residential treatment program and subsequently must conduct a review of the child's residential treatment plan every 90 days. Federal guidelines require the court to conduct an initial hearing to review the child's residential treatment plan within 60 days after the child's admission to the residential treatment program putting state statute in conflict with federal requirements.

Section 6.
The Relative Caregiver Program including Nonrelative Financial Assistance provides monthly assistance to relatives through the Temporary Assistance for Needy Families (TANF) federal funding and nonrelatives through general revenue. Until the legislature authorized implementation of GAP effective July 1, 2019, the Relative Caregiver Program provided the only financial assistance available to relatives and nonrelatives who have children placed with them who were in the custody of the Department. These two programs effective July 1, 2019 will run concurrently, and relatives and nonrelatives can choose to apply for either program. To be eligible to apply for GAP, the applicant must be licensed as a level I foster parent for six months under a streamlined process that allows licensing requirements that aren't safety or health related to be waived. In addition, GAP pays a higher monthly payment through Title IV-E reimbursement. Payments can continue even if the family moves out of the state, Title IV-E payments can continue until the child is 21 if a guardianship assistance agreement was established when the child was 16 or 17 years old, establishment and enforcement of child support is not a part of Title IV-E GAP eligibility requirements, and GAP redetermination guidelines are simpler, only requiring the guardian to attest to whether they are still supporting the child.

Section 7.
Kinship navigator programs are designed to ensure that relatives and fictive kin are provided necessary resources for the preservation of the family. The purpose of a kinship navigator program is to help relative caregivers and fictive kin in the child welfare system to navigate the broad range of services available to them and the children from public, private, community, and faith-based organizations.

Section 8.
(See Additional Comments section)

Section 9.
(See Additional Comments section)

Section 10.
(See Additional Comments section)

Section 11.
Section 39.6225(6), F.S., provides examples of when guardianship assistance benefits shall be terminated including:

- The child is absent from the home of the guardian for a period of at least 60 consecutive days and not due to medical care, school attendance, runaway status, or detention in a Department of Juvenile Justice facility and the child continues to be under the care and custody of the guardian; or
- The court modifies the placement of the child and the guardian is no longer eligible to receive payments.

Federal requirements state that guardianship assistance benefits shall be terminated if the guardian is no longer providing support to the child, causing state statutes to be in conflict with federal requirements as the statute does not state that termination is based on whether the guardian is no longer supporting the child, but includes examples of reasons for termination.

Section 39.6225(10), F.S., requires the case plan to include information regarding permanent guardianship if the guardian is receiving guardianship assistance payments. Once the guardian begins receiving guardianship assistance payments, the case is closed. This results in information not being included in the case plan regarding guardianship assistance payments resulting in the state not being able to receive federal reimbursement.

Section 39.6225(12), F.S.,
(See Additional Comments section)

Section 12.Sections 39.6251(2), (3), (4), and (6), F.S., establishes eligibility requirements to participate in Title IV-E EFC program including:

- When a child is living in licensed care on his or her 18th birthday and has not achieved permanency, he or she must participate in one of several activities;
- The statutory permanency goal for a young adult who chooses to remain in care is transition from licensed care to independent living; and
- The young adult must reside in a supervised living environment that is approved by the Department or a community-based care lead agency (CBC) with the first choice being a licensed foster home; or
- If a young adult who is between the ages of 18 and 21 and who has left care may return to care by applying to the CBC for readmission and shall be readmitted if he or she meets the eligibility requirements.

Section 13.
Section 39.701(2)(d), F.S., outlines the six actions the court can take during review hearings for children younger than 18 years of age. This section does not address the federal requirement that at any judicial review where the court determines that the child shall remain in out-of-home care in a placement other than with a parent, the court shall order that the Department has placement and care responsibility for the child.

Section 39.701(2)(d)2., F.S., requires the court to return the child to the custody of the parents at any time it determines that they have substantially complied with the case plan, if reunification will not be detrimental to the child's safety, well-being, and physical, mental, and emotional health. This conflicts with the current child welfare practice model which no longer looks at returning a child when the case plan has been substantially complied with but rather looks at whether the circumstances that caused the out-of-home placement and any issues subsequently identified have been remedied to the extent that the child can be returned to the home with an in-home safety plan and it will not be detrimental to the child's safety, well-being, and physical, mental, and emotional health.

Section 39.701(4), F.S., outlines the actions the court may take or require to be taken at review hearings for young adults in foster care. This section does not address federal options available for a young adult to enter into Title IV-E EFC and other federal requirements regarding the Department having placement and care responsibility and the court entering an order at a minimum of every 12 months including a finding of whether the Department has made reasonable efforts to finalize the permanency plan.

Section 14.
(See Additional Comments section)

Section 15.
(See Additional Comments section)

Section 16.
In 2014, the Nancy C. Detert Common Sense and Compassion Independent Living Act allowed the disregard of financial assistance for purposes of determining the eligibility for, or the amount of, any other federal or federally supported assistance. Section 409.1451(2), F.S., addresses Postsecondary Education Services and Support (PESS) and allows the PESS funding to be disregarded but does not address Title IV-E EFC or Aftercare Services.

Section 17.
Section 409.175(2), F.S., defines terms used in licensing placements and provides for the same Level 2 background screening and good moral character requirements for all owners, operators, employees and volunteers for foster homes, child-placing agencies and residential child-caring agencies.

Section 409.175(7), F.S., authorizes the Department to issue a provisional license to an applicant who is unable to conform to certain licensing requirements that are not of immediate danger to the children and the agency has

submitted a corrective action plan. The provisional license cannot be issued for a period in excess of one year and is not subject to renewal.

Section 409.175(9), F.S., authorizes the Department to deny, suspend or revoke licenses based on:
- Intentional or negligent act that affects the health or safety of children;
- A violation of the provisions of statutory licensing requirements or rules regarding licensing;
- Noncompliance with the requirements for good moral character; and
- Failure to dismiss personnel found in noncompliance with requirements for good moral character.

Section 409.175(12), F.S., outlines unlawful actions including operating a home or facility without a license, willfully or intentionally failing to comply with requirements for screening personnel, using information from the criminal records obtained for any purpose other than screening or to release such information, using information from juvenile records for any purpose other than screening or releasing the information. Section 409.175(12)(d), F.S., lists the charges for committing violations listed above.

Section 409.175(14), F.S., provides training requirements for foster parents as a condition of licensure to include a minimum of 21 hours of preservice training and eight hours of inservice training for level II through level V foster parent licensure renewal and four hours of inservice training for level I foster parents.

Section 18.
Section 409.903(4), F.S., addresses children who are categorically eligible for Medicaid coverage. While children who receive TANF funded Relative Caregiver and general revenue funded Nonrelative Caregiver Financial Assistant, the Title IV-E GAP program is not included in the list of children who are categorically eligible for Medicaid coverage.

Section 19.
Section 409.991(1) provides exceptions to what is considered in the core services funds; and therefore, would not be included in the equity formula in allocated funds to the CBCs

Section 20.
Section 414.045(1)(b), F.S., provides examples of child-only cases that can be funded through TANF federal funding.

Section 21.
(See Additional Comments section)

Section 22.
(See Additional Comments section)

Section 23.
(See Additional Comments section)

Section 24.
Section 1009.25(1)(d), F.S., addresses educational fee exemptions for children who turned 18 in the Relative Caregiver Program or who were adopted from the Department after May 5, 1997. The exemption remains valid until the student reaches 28 years of age.

EFFECT OF THE BILL:
Section 1.

Section 39.01(36), F.S., clarifies that employees of public schools along with private schools are part of the definition for institutional child abuse or neglect to agree with s. 39.01(54), F.S.

Section 39.01(29) – definition of fictive kin deleted by mistake.

Section 2.
(See Additional Comments section)

Section 3.
Section 39.4015(2)(d), F.S., deletes the definition of fictive kin; the definition of fictive kin in s. 39.01, F.S., meets the Title IV-E requirements, and a duplicative definition is unnecessary.

Section 4.
Section 39.402(8)(h), F.S., addresses that the order for placement of a child in shelter care must contain a statement that the Department has placement and care responsibility for any child who is not placed in the care of a parent at the conclusion of the shelter hearing. This brings the state into compliance with federal requirements.

Section 5.
Sections 39.407(3)(a)1. and 39.407(b)3. and 4., F.S., allow an advanced practice registered nurse whose specialty is psychiatric nursing as defined in s. 394.455, F.S., and authorized in s. 464.012(6)(a), F.S., to prescribe psychotropic medications to children younger than 18 years of age in out-of-home care. This change will address the conflict between ss. 39.407 and 464.012, F.S., and will help provide children in out-of-home care timely and appropriate mental health care. In addition. ARNPs with specialty in psychiatric nursing will take the necessary steps to facilitate the inclusion of the parent in the child's consultation with the physician.

Section 39.407 (6), F.S., requires the court to conduct an initial hearing to review the child's residential treatment plan within 60 days instead of three months after the child's admission to the residential treatment program putting state statutes in compliance with federal requirements.

Section 6.
Section 39.5085, F.S., requires a family to start the licensure process for GAP and be denied licensure, prior to applying for the Relative Caregiver Program. This will ensure that all relatives who are eligible for the higher payment through GAP and a more streamlined redetermination, take advantage of GAP. These changes would allow the state to claim federal Title IV-A (TANF) reimbursement for children served by GAP who do not meet Tittle IV-E criteria. This will allow the Department to use TANF funds instead of general revenue funds to support children ineligible for Title IV-E GAP.

Section 7.
(See Additional Comments section)

Section 8.
(See Additional Comments section)

Section 9.
(See Additional Comments section)

Section 10.
(See Additional Comments section)

Section 11.

Section 39.6225(6), F.S., clarifies that the reasons for terminating a guardianship assistance payment is due to a guardian no longer providing support to the child and that the examples included in statute define that the guardian is no longer providing support. This clarifies that the reasons for termination currently in statute are part of the definition of a guardian no longer providing support. This change was suggested by the Children's Bureau, Administration for Children and Families, U.S. Department of Health and Human Services.

Section 39.6225(10), F.S., clarifies that the case plan must describe information regarding permanent guardianship if the guardian is pursuing guardianship assistance payments. Current statute requires the case plan to include information regarding permanent guardianship if the guardian is receiving guardianship assistance payments. Once the guardian begins receiving guardianship assistance payments, the case is closed. This results in information not being included in the case plan regarding guardianship assistance payments. This change would require the information regarding permanent guardianship to be included in the case plan if the guardian is pursuing the payments.

Section 12.
Section 39.6251(2), F.S., amends how the young adult will document participation in one of several activities listed in this section. The young adult is required to either furnish documentation of participation in one of the activities listed or execute a consent for release of records to the Department or CBC to obtain the documentation.

Section 39.6251(3), F.S., amends the permanency goal for a young adult who chooses to remain in the care and custody of the state past his/her 18th birthday to transition to independence.

Section 39.6251(6), F.S., allows a young adult who is between the ages of 18 and 21 and who has left care, to apply with the CBC for readmission through the execution of a voluntary placement agreement. This change allows the state to request Title IV-E reimbursement.

Section 39.6251(10), F.S., provides the Department with rulemaking authority to administer the continuing care for young adults program (EFC). The Department is authorized to develop rules to establish processes and procedures for the Title IV-E EFC program. This change will help provide consistent application of the program statewide.

Section 13.
Section 39.701(2)(d)2., F.S., replaces the current statute that requires the court to return the child to the custody of the parent(s) if it is determined that the parent(s) have substantially complied with the case plan. The new language looks at whether the circumstances that caused the out-of-home placement and any issues subsequently identified have been remedied to the extent that the child can be returned to the home with an in-home safety plan and it will not be detrimental to the child's safety, well-being, and physical, mental, and emotional health. This new language reflects the Department's child welfare practice model.

Section 39.701(2)(d)7., F.S., adds a new subparagraph 7 requiring that if the court determines at any judicial review that the child shall remain in out-of-home care, the court shall order that the Department has placement and care responsibility for the child. This would bring the statutes into compliance with federal requirements. *(See Additional Comments section)*

Section 39.701(4)(f), F.S., addresses additional ways to enter EFC while expanding the Department's ability to seek reimbursement of Title IV-E funds. Section 39.701(4)(f), F.S., allows a young adult to elect to voluntarily leave EFC for the sole purpose of ending a removal episode and immediately executes a voluntary placement agreement with the Department to reenroll in EFC, the court shall enter an order finding that the prior removal episode ended. Under these circumstances, the court does not lose its jurisdiction and no petition to reinstate jurisdiction is required.

Section 39.701(4)(g), F.S., requires when a youth enters EFC by executing a voluntary placement agreement, the court shall enter an order within 180 days of the agreement that determines whether the supervised living arrangement is in the best interest of the youth. The supervised living arrangement may include a licensed foster home, licensed group home, college dormitory, shared housing, apartment or another housing arrangement if approved by the CBC and is acceptable to the young adult. In addition, when a youth is in EFC, the court shall include in each judicial review order that the Department has placement and care responsibility for the youth. Lastly, when a youth is in EFC, the court shall enter an order at a minimum of every 12 months that includes a finding of whether the Department has made reasonable efforts to finalize the permanency plan currently in effect. federal requirements.

Section 14.
(See Additional Comments section)

Section 15.
(See Additional Comments section)

Section 16.

Section 409.1451, F.S., provides clarification that financial assistance to young adults receiving independent living services including PESS, Title IV-E EFC, and Aftercare services may be disregarded for purposes of determining eligibility for, or the amount of, any other federal or federally supported assistance. This will ensure that young adults have access to all assistance programs, if they meet the other eligibility criteria, regardless of their participation in independent living services pursuant to ss. 39.6251 and 409.1451, F.S.

Section 17.

Section 409.175 – numerous changes are made to this section to either meet federal requirements or to allow for the streamlining of requirements for Level I licensing as follows:

- Section 409.175(2)(e), F.S., clarifies that a family foster home is a home licensed by the Department. This is a federal requirement that mandates in order to receive Title IV-E reimbursement for foster care board rate, the foster home must be licensed.

- Section 409.175(2)(j), F.S., clarifies that "Personnel" does not include family foster home. This change will allow the Department to simplify the screening for a Level I licensee.
- Section 409.175(2)(m), F.S., clarifies that background "screening" of personnel applies to Level II through Level V family foster home licensing. This change will also allow the Department to simplify the screening for a Level I licensee.
- Section 409.175(5)(b)(5), F.S., adds foster family homes in the screening requirements for good moral character. By removing foster family homes from the definition of personnel, the intent was not to remove them from screening for good moral character, so the foster family homes must specifically be added to this section.
- Section 409.175(6)(c), F.S., includes screening of household members in the renewal process for licensure if they have worked or resided on a continuous basis in the home since fingerprints were submitted to the Department. This is a federal requirement that must be added to this section since a Level I foster parent licensees may be required to renew his/her license before being approved for GAP and new household members will have to pass background screening before the Level I license can be removed.
- Section 409.175(7), F.S., adds the ability to extend a license up to, but no more than, 30 days. Federal requirements only allow a one-time extension of a license, so this change will bring the Department into compliance with federal requirements.
- Section 409.175(7)(a) – (c), F.S., deletes the Department's ability to provide a provisional license. Federal requirements do not allow for a provisional license. Deletion of a provisional license will bring the Department into compliance with federal requirements.
- Section 409.175(9)(b), F.S., adds actions by a family foster home or household members to the list of who the Department may deny, suspend, or revoke a license due to removing family foster home from the definition of personnel.
- Section 409.175(12)(b), F.S., adds family foster homes and household members to the list of those who willfully or intentionally fail to comply with the requirements for background screening. These actions are considered unlawful.
- Section 409.175(14)(b) and (d), F.S., deletes the specified number of preservice and inservice training hours respectively, allowing the Department to streamline the licensing requirements for training and establish the hours by rule.

Section 18.
Section 409.903(4), F.S., includes children who receive GAP as categorically eligible for Medicaid. Changes to this section bring the Department into compliance with federal requirements.

Section 19.
Section 409.991(1)(a), F.S., includes GAP funding as an exemption from core services funds. This section excludes GAP funding from core services funds in determining the allocations for the CBC Lead Agencies. Similar to the current exclusion of Maintenance Adoption Subsidy from core services, this change exempts the funding for GAP from being eligible for distribution according to the equity formula and allows the funds to be distributed based on the projected population and GAP payments made by the CBC Lead Agencies.

Section 20.
Section 414.045(1)(b), F.S., adds families in GAP as a "child-only" case, which can be funded through TANF.

Section 21.
(See Additional Comments section)

Section 22.
(See Additional Comments section)

Section 23.
(See Additional Comments section)

Section 24.

Section 1009.251(d) F.S., provides a tuition fee exemption to youth eligible for GAP. The change gives children who are permanently placed with a relative access to tuition exemptions whether they are eligible for GAP or the Relative Caregiver Program

2. DOES THE LEGISLATION DIRECT OR ALLOW THE AGENCY/BOARD/COMMISSION/DEPARTMENT TO DEVELOP, ADOPT, OR ELIMINATE RULES, REGULATIONS, POLICIES, OR PROCEDURES? YES

If yes, explain:	Section 39.6251, F.S., provides the Department with rulemaking authority to administer the continuing care for young adults' program
What is the expected impact to the agency's core mission?	N/A
Rule(s) impacted (provide references to F.A.C., etc.):	Chapters 65C-13, 65C-14, 65C-28, F.A.C,

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

List any known proponents and opponents:	Unknown
Provide a summary of the proponents' and opponents' positions:	Unknown

4. ARE THERE ANY REPORTS OR STUDIES REQUIRED BY THIS BILL? NO

If yes, provide a description:	N/A
Date Due:	N/A
Bill Section Number(s):	N/A

5. ARE THERE ANY GUBERNATORIAL APPOINTMENTS OR CHANGES TO EXISTING BOARDS, TASK FORCES, COUNCILS, COMMISSION, ETC. REQUIRED BY THIS BILL? NO

Board:	N/A
Board Purpose:	N/A
Who Appoints:	N/A
Appointee Term:	N/A
Changes:	N/A
Bill Section Number(s):	N/A

FISCAL ANALYSIS

1. WHAT IS THE FISCAL IMPACT TO LOCAL GOVERNMENT?

Revenues:	None
Expenditures:	None
Does the legislation increase local taxes or fees?	No
If yes, does the legislation provide for a local referendum or local	N/A

governing body public vote prior to implementation of the tax or fee increase?	

2. WHAT IS THE FISCAL IMPACT TO STATE GOVERNMENT?

Revenues:	None
Expenditures:	None
Does the legislation contain a State Government appropriation?	No
If yes, was this appropriated last year?	N/A

3. WHAT IS THE FISCAL IMPACT TO THE PRIVATE SECTOR?

Revenues:	None
Expenditures:	None
Other:	None

4. DOES THE BILL INCREASE OR DECREASE TAXES, FEES, OR FINES?

Does the bill increase taxes, fees or fines?	No
Does the bill decrease taxes, fees or fines?	No
What is the impact of the increase or decrease?	N/A
Bill Section Number:	N/A

TECHNOLOGY IMPACT

Does the legislation impact the agency's technology systems (i.e., IT support, licensing software, data storage, etc.)?	No
If yes, describe the anticipated impact to the agency including any fiscal impact.	N/A

FEDERAL IMPACT

Does the legislation have a federal impact (i.e. federal compliance, federal funding, federal agency involvement, etc.)?	Yes
If yes, describe the anticipated impact including any fiscal impact.	Several changes to Title IV-E EFC, GAP, and judicial reviews align state statutes with federal requirements. There is no fiscal impact in aligning state statutes with federal requirements.

ADDITIONAL COMMENTS

The following sections have been added to the bill as the sections have site references to s. 39.01, F.S., because all subsections of s. 39.01, F.S., have been renumbered starting with subsection (30) as the definition of fictive kin was deleted in error.
Section 2., s. 39.302, F.S.;
Section 8., s. 39.521, F.S.;
Section 10., s. 39.6012, F.S.;
Section 14., s. 322.09, F.S.;
Section 15., s. 394.495, F.S.;
Section 21., s. 627.746, F.S.;
Section 22., s. 934.255, F.S.; and
Section 23., s. 960.065, F.S.;

Sections 1 (lines 60-63) and 3 (lines 129-132) delete the definitions of *fictive kin.* The Department must have a definition of fictive kin due to federal requirements and the definition in lines 60-63 meets the federal requirements. In addition, in Section 3, s. 39.4015, F.S., regarding family finder, all references to fictive kin have been removed. The family finding program must include locating fictive kin as well as relatives, to meet federal requirements and provide individuals who may help with care or support of a child.

The following sections referencing fictive kin were originally included in the bill, but all reference to fictive kin were deleted in error including:
Section 3., s. 39.4015, F.S.;
Section 7., s. 39.5086, F.S.;
Section 9., s. 39.523, F.S.; and
Section 11., s. 39.6225(12), F.S.

Section 5 – s. 39.407, F.S. There are a number of references to an advanced practice registered nurse. Several references indicate the advance practice registered nurse must have a specialty as a psychiatric nurse which is true when prescribing psychotropic controlled substances for the treatment of mental disorders. Is it understood that the advance practice registered nurse must have a specialty as a psychiatric nurse; and therefore, does not require that the specialty be included each time the reference is made to the advanced practice registered nurse?

Section 6 – s. 39.5085(2)(a), F.S., (lines 554-556) states that a relative or nonrelative who is caring for a child must be denied GAP before applying for the Relative Caregiver Program. The first step in becoming eligible to apply for GAP is to become licensed as a level I foster parent for six months. The majority of individuals who become licensed will ultimately be approved for GAP. The individuals who cannot be licensed, are the relatives and nonrelatives who will need the option of applying for the Relative Caregiver Program. Suggest the wording be amended to read: *Relatives and nonrelatives who are caring for children, must start the process of licensure to be eligible to apply for the Guardianship Assistance Program under s. 39.6225 and be denied before applying for the Relative Caregiver Program.*

Technical Changes to the Department's version of the bill:
Line 827 – delete *licensed* as young adults' placements are not named *licensed* care instead they are named *supervised independent living.*

Line 953-956 – need to add the following language that is in bold: 7. If, at any judicial review, the court determines that the child shall remain in out-of-home care **in a placement other than with a parent**, the court shall order that the Department has placement and care responsibility for the child. The Department does not have placement and care responsibility for a child if the child is placed with a parent.

Line 1102 – *Level II through Level V* should be changed to *level II through level V to agree with the rest of the section.*

Line 1172 – To clarify that the Department may extend a license for a period of up to 30 days once during the current licensing period, add the following language to the end of the sentence: ***during the current licensing period.***

LEGAL - GENERAL COUNSEL'S OFFICE REVIEW

Issues/concerns/comments and recommended action:	

THE FLORIDA SENATE

APPEARANCE RECORD

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

3/25/2019
Meeting Date

1650
Bill Number (if applicable)

234018
Amendment Barcode (if applicable)

Topic Child Welfare

Name Victoria Zepp

Job Title Chief Policy and Research Officer

Address 411 E. College Avenue
Street

Tallahassee FL 32301
City *State* *Zip*

Phone 850/561-1102

Email Victoria@flchildren.org

Speaking: ☑ For ☐ Against ☐ Information

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

Representing Florida Coalition for Children (FCC)

Appearing at request of Chair: ☑ Yes ☐ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

3-25-19
Meeting Date

SB 1650 STRIKE
Bill Number (if applicable)

234018
Amendment Barcode (if applicable)

Topic Child Welfare

Name Michael Wickersheim

Job Title Legislative Affairs Director

Address _____
Street

Phone 850-488-7410

_____
City *State* *Zip*

Email _____

Speaking: ☐ For ☐ Against ☐ Information

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

Representing DCF

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

3-25-19
Meeting Date

SB 1650
Bill Number (if applicable)

(As Amended)
Amendment Barcode (if applicable)

Topic Child Welfare

Name Michael Wickersheim

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Tallahasseee FL 32399
City *State* *Zip*

Email michael.wickersheim@myflfamilies.com

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Department of Children and Families

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

3/25/2019
Meeting Date

1650
Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic Child Welfare

Name Victoria Zepp

Job Title Chief Policy and Research Officer

Address 411 E. College Avenue
Street
Tallahassee FL 32301
City *State* *Zip*

Phone 850/561-1102

Email Victoria@flchildren.org

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Coalition for Children (FCC)

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

3/26/2019 (Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting) 1650

Meeting Date *Bill Number (if applicable)*

Topic Child Welfare *Amendment Barcode (if applicable)*

Name Georgia McKeown

Job Title Consultant

Address 501 E Park Ave Phone

Street

Tallahassee FL 32301 Email

City *State* *Zip*

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

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

Representing Florida Coalition for Children

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

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

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

S-001 (10/14/14)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	SB 630
INTRODUCER:	Senators Perry and Baxley
SUBJECT:	Nonopioid Directives
DATE:	March 22, 2019
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Brown	HP	**Pre-meeting**
2.			JU	
3.			RC	

I. Summary:

SB 630 amends s. 456.44, F.S., to require the Department of Health (DOH) to establish a form that a patient may execute and file with a physician, physician assistant, or advanced practice registered nurse who is registered to treat chronic nonmalignant pain (registrant) in order to inform the registrant that he or she may not be prescribed opioid drugs, be the subject of an order for opioid drugs, or be administered an opioid drug. The registrant must provide the form to any patient who may be treated using an opioid drug prior to prescribing, ordering, or administering the opioid drug to the patient.

The bill provides exemptions from liability for pharmacists who dispense opioid medications in compliance with a valid prescription and to registrants who refuse to treat a patient with opioids based on the patient's nonopioid directive form, or who treat a patient with an opioid in a hospital's emergency department in contradiction to the patient's form, under certain circumstances.

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

II. Present Situation:

Opioid Abuse

Both nationally and in Florida, opioid addiction and abuse has become an epidemic. The Florida Department of Law Enforcement (FDLE) reported that, when compared to 2016, 2017 saw:

- 6,178 (8 percent more) opioid-related deaths;
- 6,932 (4 percent more) individuals died with one or more prescription drugs in their system;[1]

[1] The drugs were identified as either the cause of death or merely present in the decedent. These drugs may have also been mixed with illicit drugs and/or alcohol. These drugs were not necessarily opioids.

- 3,684 (4 percent more) individuals died with at least one prescription drug in their system that was identified as the cause of death;
- Occurrences of heroin increased by 3 percent and deaths caused by heroin increased by 1 percent;
- Occurrences of fentanyl increased by 27 percent and deaths caused by fentanyl increased by 25 percent;
- Occurrences hydrocodone increased by 6 percent while deaths caused by hydrocodone decreased by 8 percent;
- Occurrences of buprenorphine and deaths caused by buprenorphine increased by 19 percent.[2]

The federal Centers for Disease Control and Prevention (CDC) estimates that the nationwide cost of opioid misuse at $78.5 billion per year.[3]

History of the Opioid Crisis in Florida

In the late 1990s, pharmaceutical companies reassured the medical community that patients would not become addicted to prescription opioid pain relievers, and health care providers began to prescribe them at greater rates. This subsequently led to widespread diversion and misuse of these medications before it became clear that these medications could indeed be highly addictive.[4] Between the early 2000s and the early 2010s, Florida was infamous as the "pill mill capital" of the country. At the peak of the pill mill crisis, doctors in Florida bought 89 percent of all the oxycodone sold in the county.[5]

Between 2009 and 2011, the Legislature enacted a series of reforms to combat prescription drug abuse. These reforms included strict regulation of pain management clinics; creating the Prescription Drug Monitoring Program (PDMP); and stricter regulation on selling, distributing, and dispensing controlled substances.[6] In 2016, the opioid prescription rate was 75 per 100 persons in Florida. This rate was down from a high of 83 per 100.

Drug overdose is now the leading cause of non-injury related death in the United States. Since 2000, drug overdose death rates increased by 137 percent, including a 200 percent increase in the rate of overdose deaths involving opioids. In 2015, over 52,000 deaths in the U.S. were attributed to drug poisoning, and over 33,000 (63 percent) involved an opioid. In 2015, 3,535 deaths occurred in Florida where at least one drug was identified as the cause of death. More specifically, 2,535 deaths were caused by at least one opioid in 2015. Stated differently, seven lives per day were lost to opioids in Florida in 2015. Overall the state had a rate of opioid-caused deaths of 13 per 100,000. The three counties with the highest opioid death rate were Manatee

[2] FDLE, *Drugs Identified in Deceased Persons by Florida Medical Examiners 2017 Annual Report* (Nov. 2018) http://www.fdle.state.fl.us/MEC/Publications-and-Forms/Documents/Drugs-in-Deceased-Persons/2017-Annual-Drug-Report.aspx (last visited on Mar. 20, 2019).
[3] National Institute on Drug Abuse, *Opioid Overdose Crisis* (Jan. 2018) https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis (last visited on Mar. 20, 2019).
[4] Id.
[5] Lizette Alvarez, *Florida Shutting 'Pill Mill' Clinics*, The New York Times (Aug. 31, 2011), *available at* http://www.nytimes.com/2011/09/01/us/01drugs.html (last visited on Mar. 20, 2018).
[6] See chs. 2009-198, 2010-211, and 2011-141, Laws of Fla.

County (37 per 100,000), Dixie County (30 per 100,000), and Palm Beach County (22 per 100,000).[7]

Early in 2017, the CDC declared the opioid crisis an epidemic and shortly thereafter, on May 3, 2017, Governor Rick Scott signed Executive Order 17-146 declaring the opioid epidemic a public health emergency in Florida.

House Bill 21

In 2018, the Florida Legislature passed HB 21 (ch. 2018-13, L.O.F.) to combat the opioid crisis. HB 21:

- Required additional training for practitioners on the safe and effective prescribing of controlled substances;
- Restricted the length of prescriptions for Schedule II opioid medications to 3 days or up to 7 days if medically necessary;
- Reworked the PDMP statute to require that prescribing practitioners check the PDMP prior to prescribing a controlled substance and to allow the integration of PDMP data with electronic health records and the sharing of PDMP data between Florida and other states; and
- Provided for additional funding for treatment and other issues related to opioid abuse.

III. Effect of Proposed Changes:

SB 630 amends s. 456.44, F.S., to establish a voluntary nonopioid directive form. The bill:

- States legislative findings that every competent adult has the fundamental right to self-determination regarding decisions pertaining to his or her own health, including the right to refuse an opioid drug listed as a schedule II controlled substance;
- Requires the Department of Health (DOH) to establish a voluntary nonopioid directive form. The form:
  - Must inform registrants that a patient may not be prescribed opioid drugs, may not be the subject of an order for opioid drugs, and may not be administered an opioid drug; and
  - Must be posted on the DOH's website.
- Allows a patient to execute the form and file it with a registrant and requires the registrant to document the receipt of the form in the patient's medical record.
- Allows a patient to appoint and list on the form a guardian or health care proxy who may revoke the directive. Exempts such proxy from liability for revoking a directive if acting in good faith.
- Requires a registrant to provide the form to a patient before prescribing, ordering, or administering an opioid drug to the patient.
- Requires a pharmacist to presume that an electronically transmitted prescription for an opioid drug is valid and exempts such a pharmacist from civil, criminal, and administrative liability for dispensing an opioid to a patient with reasonable care.
- A registrant is not civilly, criminally, or administratively liable if the registrant:
  - Refuses to prescribe, order, or administer an opioid pursuant to a directive; or

[7] Attorney General's Opioid Working Group, *Florida's Opioid Epidemic: Recommendations and Best Practices* (March 1, 2019), *available at* https://myfloridalegal.com/webfiles.nsf/WF/TDGT-B9UTV9/$file/AG+Opioid+Working+Group+Report+Final+2-28-2019.pdf, (last visited on March 14, 2019).

  - Prescribes, orders, or administers an opioid in contradiction of a directive if the registrant is employed by a hospital's emergency department, exercises reasonable care, and had no knowledge of the directive at the time of the prescribing, ordering, or administering.
- A registrant who fails to comply with a patient's directive, or the revocation of such directive, is subject to disciplinary action pursuant to s. 456.072, F.S.

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

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

SB 630 may have an indeterminate negative fiscal impact on the DOH related to the development of the voluntary nonopioid directive form but such impact would likely be absorbed within existing resources.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 456.44 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.

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LEGISLATIVE ACTION

Senate . House

. . . . .

The Committee on Health Policy (Perry) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Subsection (7) is added to section 456.44, Florida Statutes, to read:

456.44 Controlled substance prescribing.—

(7) NONOPIOID ALTERNATIVES.—

(a) The Legislature finds that every competent adult has the fundamental right of self-determination regarding decisions

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pertaining to his or her own health, including the right to refuse an opioid drug listed as a Schedule II controlled substance in s. 893.03 or 21 U.S.C. s. 812.

(b) The department shall develop and publish on its website an educational pamphlet regarding the use of nonopioid alternatives for the treatment of pain. The pamphlet must, at a minimum, include:

1. Information on available nonopioid alternatives for the treatment of pain, including nonopioid medicinal drugs or drug products and nonpharmacological therapies; and

2. The advantages and disadvantages of the use of nonopioid alternatives.

(c) Except in the provision of emergency services and care, as defined in s. 395.002, before providing medical treatment or anesthesia or prescribing an opioid drug listed as a Schedule II controlled substance in s. 893.03 or 21 U.S.C. s. 812 for the treatment of pain, a health care practitioner shall:

1. Inform the patient of available nonopioid alternatives for the treatment of pain, which may include nonopioid medicinal drugs or drug products, acupuncture, chiropractic treatments, massage therapy, physical therapy, occupational therapy, or any other appropriate therapy as determined by the health care practitioner;

2. Discuss the advantages and disadvantages of the use of nonopioid alternatives, including whether the patient is at a high risk of, or has a history of, controlled substance abuse or misuse and the patient’s personal preferences;

3. Provide the patient with the educational pamphlet described in paragraph (b); and

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4. Document the nonopioid alternatives considered in the patient's record.

Section 2. This act shall take effect July 1, 2019.

========== T I T L E A M E N D M E N T ==========

And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled

An act relating to nonopioid alternatives; amending s. 456.44, F.S.; providing a legislative finding; requiring the Department of Health to develop and publish on its website an educational pamphlet regarding the use of nonopioid alternatives for the treatment of pain; requiring that the pamphlet include specified information, including the advantages and disadvantages of the use of such alternatives; providing requirements for health care practitioners; providing an exception; providing an effective date.

By Senator Perry

8-00755-19 2019630__

A bill to be entitled

An act relating to nonopioid directives; amending s. 456.44, F.S.; providing legislative findings; requiring the Department of Health to establish a voluntary nonopioid directive form; providing requirements for the form; requiring the form to be posted on the department website; requiring certain registrants to document receipt of the form in a patient's medical record; authorizing a patient to appoint a duly authorized guardian or health care proxy who may revoke a voluntary nonopioid directive; requiring certain registrants to provide a copy of the form to certain patients; requiring a pharmacist to presume that an electronically transmitted prescription for an opioid drug is valid; authorizing a pharmacist to dispense an opioid drug in contradiction of a voluntary nonopioid directive; providing that certain persons are not liable for damages or subject to criminal prosecution under certain circumstances; providing that certain persons may be subject to disciplinary action under certain circumstances; providing an effective date.

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

Section 1. Subsection (7) is added to section 456.44, Florida Statutes, to read:

456.44 Controlled substance prescribing.—

(7) VOLUNTARY NONOPIOID DIRECTIVE FORM.—

(a) The Legislature finds that every competent adult has the fundamental right of self-determination regarding decisions pertaining to his or her own health, including the right to refuse an opioid drug listed as a Schedule II controlled substance in s. 893.03 or 21 U.S.C. s. 812.

(b) The department shall establish a voluntary nonopioid directive form. The form shall inform registrants that a patient may not be prescribed, ordered, or administered an opioid drug. The form shall be posted on the department website. A patient may execute and file the form with a registrant. A registrant shall document receipt of the form in a patient's medical record.

(c) A patient may appoint and list on the voluntary nonopioid directive form a duly authorized guardian or health care proxy who may revoke the directive by written or verbal means at any time and for any reason. A person acting in good faith as a duly authorized guardian or health care proxy is not liable for damages in a civil action or subject to criminal prosecution for revoking a voluntary nonopioid directive.

(d) A registrant who prescribes, orders, or administers an opioid drug for the treatment of acute pain or chronic nonmalignant pain must provide a copy of the voluntary nonopioid directive form to any patient to whom an opioid drug may be prescribed, ordered, or administered in the course of treatment before prescribing, ordering, or administering the opioid drug.

(e) For purposes of this subsection, a pharmacist shall presume that an electronically transmitted prescription for an opioid drug is valid and is authorized to dispense an opioid drug in contradiction of a voluntary nonopioid directive. A

pharmacist who exercises reasonable care is not liable for damages in a civil action, subject to criminal prosecution, or deemed to have violated the standard of care for dispensing an opioid drug in contradiction of a voluntary nonopioid directive.

(f) A registrant who exercises reasonable care is not liable for damages in a civil action, subject to criminal prosecution, or deemed to have violated the standard of care for refusing to prescribe, order, or administer an opioid drug pursuant to a voluntary nonopioid directive. However, a registrant who fails to comply with a patient's voluntary nonopioid directive or the revocation thereof may be subject to disciplinary action pursuant to s. 456.072.

(g) A registrant employed by a hospital emergency department, acting either as the patient's physician or as the emergency medical services director, who exercises reasonable care is not liable for damages in a civil action, subject to criminal prosecution, or deemed to have violated the standard of care for prescribing, ordering, or administering an opioid drug to a person who has a voluntary nonopioid directive when the registrant has reasonable cause to believe that an opioid drug is necessary and the registrant had no knowledge of the patient's voluntary nonopioid directive at the time of prescribing, ordering, or administering the opioid drug.

Section 2. This act shall take effect July 1, 2019.

The Florida Senate

Committee Agenda Request

To: Senator Gayle Harrell, Chair
Committee on Health Policy

Subject: Committee Agenda Request

Date: February 18, 2019

I respectfully request that **Senate Bill #630**, relating to Nonopioid Directives, be placed on the:

☐ committee agenda at your earliest possible convenience.

☒ next committee agenda.

W. Keith Perry

Senator Keith Perry
Florida Senate, District 8

File signed original with committee office

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	SB 1170
INTRODUCER:	Senator Brandes
SUBJECT:	Automated Pharmacy Systems
DATE:	March 22, 2019
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Brown	HP	**Pre-meeting**
2.			IT	
3.			RC	

I. Summary:

SB 1170 amends s. 465.0235, F.S., to permit a licensed community pharmacy to provide outpatient pharmacy services for the dispensing of medicinal drugs through the use of an automated pharmacy system (APS) not located at the community pharmacy, if specific requirements are met.

The bill takes effect July 1, 2019.

II. Present Situation:

The Practice of Pharmacy

Pharmacy is the third largest health profession behind nursing and medicine.[1] The Board of Pharmacy (BOP), in conjunction with the Department of Health (DOH), regulates the practice of pharmacists and pharmacies pursuant to ch. 465, F.S.[2] There are seven types of pharmacies eligible for various operating permits issued by the DOH:

- Community pharmacy;
- Institutional pharmacy;[3]
- Nuclear pharmacy;[4]

[1] American Association of Colleges of Pharmacy, *About AACP*, available at https://www.aacp.org/about-aacp (last visited Mar. 18, 2019).
[2] Sections 465.004 and 465.005, F.S.
[3] *See* ss. 465.003(11)(a)2. and 465.019, F.S.
[4] The term "nuclear pharmacy" includes every location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold. The term "nuclear pharmacy" does not include hospitals licensed under ch. 395, F.S., or the nuclear medicine facilities of such hospitals. *See* ss. 465.003(11)(a)3. and 465.0193, F.S.

- Special pharmacy;[5]
- Internet pharmacy;[6]
- Non-resident sterile compounding pharmacy;[7] and
- Special sterile compounding pharmacy.[8]

Community Pharmacy

The term "community pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis.[9] A community pharmacy permit is required for every location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis.[10] Any person desiring a permit to operate a community pharmacy must apply to the DOH. If the BOP certifies that an application complies with the laws and the rules governing pharmacies, the DOH must issue the permit.

No permit shall be issued unless a licensed pharmacist is designated as the prescription department manager.[11] A registered pharmacist may not serve as the prescription department manager in more than on location unless approved by the BOP.[12] Permits issued by the DOH are not transferable.[13] Passing an on-site inspection is a prerequisite to the issuance of an initial permit or a permit for a change of location. The DOH must make the inspection within 90 days before issuance of the permit.[14]

The BOP may suspend or revoke the permit of, or may refuse to issue a permit to:
- Any person who has been disciplined or who has abandoned a permit or allowed a permit to become void after written notice that disciplinary proceedings had been or would be brought against the permit;
- Any person who is an officer, director, or person interested directly or indirectly in a person or business entity that has had a permit disciplined or abandoned or become void after written notice that disciplinary proceedings had been or would be brought against the permit; or

[5] The term "special pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold if such locations are not otherwise defined in this subsection. *See* ss. 465.003(11)(a)4., and 465.0196, F.S.
[6] The term "internet pharmacy" includes locations not otherwise licensed or issued a permit under this chapter, within or outside this state, which use the Internet to communicate with or obtain information from consumers in this state and use such communication or information to fill or refill prescriptions or to dispense, distribute, or otherwise engage in the practice of pharmacy in this state. *See* ss. 465.003(11)(a)5. and 465.0197, F.S.
[7] The term "nonresident sterile compounding pharmacy" includes a pharmacy that ships, mails, delivers, or dispenses, in any manner, a compounded sterile product into Florida, a nonresident pharmacy registered under s. 465.0156, F.S., or an outsourcing facility, must hold a nonresident sterile compounding permit *See* s. 465.0158, F.S.
[8] *See* Fla. Admin. Code Rule 64B16-2.100 and 64B16-28.802 (2019). An outsourcing facility is considered a pharmacy and needs to hold a special sterile compounding permit if it engages in sterile compounding.
[9] *See* ss. 465.003(11)(a)1. and 465.018, F.S.
[10] Fla. Admin. Code Rule 64B16-28.100(2) (2019).
[11] Section 465.018(2), F.S.
[12] Section 465.022(11)(c), F.S.
[13] Section 465.022(13), F.S.
[14] Section 465.018(6), F.S.

- Any person who is or has been an officer of a business entity, or who was interested directly or indirectly in a business entity, the permit of which has been disciplined or abandoned or become null and void after written notice that disciplinary proceedings had been or would be brought against the permit.[15]

A community pharmacy that dispenses controlled substances must maintain a record of all controlled substance dispensing consistent with the requirements of s. 893.07, F.S., and must make the record available to the DOH or law enforcement agencies upon request.[16]

Pharmacist Licensure

A person desiring to be licensed in Florida as a pharmacist must:[17]
- Complete an application and remit an examination fee;
- Be at least 18 years of age;
- Hold a degree from an accredited and approved school or college of pharmacy;[18]
- Have completed a board-approved internship; and
- Successfully complete the board-approved examination.

A pharmacist must complete at least 30 hours of board-approved continuing education during each biennial renewal period.[19] Pharmacists who are certified to administer vaccines or epinephrine autoinjections must complete a three-hour continuing education course on the safe and effective administration of vaccines and epinephrine injections as a part of the biennial licensure renewal.[20] Pharmacists who administer long-acting antipsychotic medications must complete an approved eight-hour continuing education course as a part of the continuing education for biennial licensure renewal.[21]

Pharmacist Scope of Practice

In Florida, the "practice of the profession of pharmacy" includes:[22]
- Compounding, dispensing, and consulting concerning contents, therapeutic values, and uses of a medicinal drug;
- Consulting concerning therapeutic values and interactions of patent or proprietary preparations;
- Monitoring a patient's drug therapy and assisting the patient in the management of his or her drug therapy, including the review of the patient's drug therapy and communication with the

[15] Section 465.018(3), F.S.
[16] Section 465.018(7), F.S.
[17] Section 465.007, F.S. The DOH may also issue a license by endorsement to a pharmacist who is licensed in another state upon meeting the applicable requirements set forth in law and rule. *See* s. 465.0075, F.S.
[18] If the applicant has graduated from a 4-year undergraduate pharmacy program of a school or college of pharmacy located outside the United States, the applicant must demonstrate proficiency in English, pass the board-approved Foreign Pharmacy Graduate Equivalency Examination, and complete a minimum of 500 hours in a supervised work activity program within Florida under the supervision of a DOH-licensed pharmacist. Section 465.007(1)(b)2., F.S.
[19] Section 465.009, F.S.
[20] Section 465.009(6), F.S.
[21] Section 465.1893, F.S.
[22] Section 465.003(13), F.S.

patient's prescribing health care provider or other persons specifically authorized by the patient, regarding the drug therapy;
- Transmitting information from prescribers to their patients;
- Administering vaccines to adults;[23]
- Administering epinephrine injections;[24]
- Administering antipsychotic medications by injection at the direction of a physician;[25] and,
- Other pharmaceutical services.[26,27]

A pharmacist may not alter a prescriber's directions, diagnose or treating any disease, initiate any drug therapy, or practice medicine or osteopathic medicine, unless permitted by law.[28]

Automated Pharmacy Systems (APS)

An APS is a mechanical system that delivers prescription drugs received from a Florida-licensed pharmacy and maintains related transaction information.[29] A mechanical pharmacy system performs operations or activities, other than compounding or administration, relative to storage, packaging, dispensing, or distribution of medication, and which collects, controls, and maintains all transaction information.[30]

A community pharmacy may use an automated pharmacy system provided that:
- The APS is:
  - Located within the prescription department, adjacent to the prescription department, or is located on the establishment[31] of the licensed pharmacy, and its operation under the supervision of a pharmacist;
  - Not located within the prescription department, but must be operated as an extension of the licensed pharmacy, and does not require an independent, separate community pharmacy permit;
  - Not located within the prescription department, but must have conspicuously displayed on the automated pharmacy system the name, address, contact information and the permit

[23] *See* s. 465.189, F.S.
[24] *Id.*
[25] Section 465.1893, F.S.
[26] Section 465.003(13), F.S.
[27] "Other pharmaceutical services" means the monitoring of the patient's drug therapy and assisting the patient in the management of his or her drug therapy, and includes review of the patient's drug therapy and communication with the patient's prescribing health care provider as licensed under chs. 458, 459, 461, or 466, F.S., or similar statutory provision in another jurisdiction, or such provider's agent or such other persons as specifically authorized by the patient, regarding the drug therapy. . . The "practice of the profession of pharmacy" also includes any other act, service, operation, research, or transaction incidental to, or forming a part of, any of the foregoing acts, requiring, involving, or employing the science or art of any branch of the pharmaceutical profession, study, or training, and shall expressly permit a pharmacist to transmit information from persons authorized to prescribe medicinal drugs to their patients. The practice of the profession of pharmacy also includes the administration of vaccines to adults. Section 465.003(13), F.S.
[28] *Supra* note 22.
[29] Section 465.003(17), F.S.
[30] Fla. Admin. Code Rule 64B16-28.141(1)(a) (2019).
[31] An "Establishment" is one general physical location that may extend to one or more contiguous suites, units, floors, or buildings operated and controlled exclusively by entities under common operation and control. Where multiple buildings are under common ownership, operation, and control, an intervening thoroughfare does not affect the contiguous nature of the buildings. Fla. Admin. Code Rule 64B16-28.141(1)(b) (2019).

number of the community pharmacy that is responsible for the operation of the automated pharmacy system.

- The pharmacy develops and maintains a policy and procedure manual;
- The APS ensures that each prescription is dispensed in compliance with the definition of dispense as defined by s. 465.003, F.S., and the practice of the profession of pharmacy. The system must include:
  - A mechanism to ensure that the patient has a means to communicate with a pharmacist responsible for dispensing the medical drug product, and the means of communication may include in-person, electronic, digital, or telephonic.
- The APS must maintain a readily retrievable electronic record to identify all pharmacists, pharmacy interns, registered pharmacy technicians, or other personnel involved in the dispensing of a prescription.
- The APS must provide the ability to comply with product recalls generated by the manufacturer, distributor, or pharmacy. The system must have a process in place to isolate affected lot numbers, including an intermix of drug product lot numbers.[32]

Any pharmacy may also provide pharmacy services through the use of an APS that need not be located at the same location as the pharmacy at the following locations:

- A long-term care facility;[33]
- A hospice licensed care facility;[34]or,
- A state correctional institution.[35, 36]

Medicinal drugs stored in bulk, or unit of use, in an APS servicing a long-term care facility, hospice, or correctional institution are part of the inventory of the pharmacy providing pharmacy services, and drugs delivered by the APS are considered to have been dispensed by that pharmacy.[37]

The operation of an APS must be under the supervision of a Florida-licensed pharmacist. To qualify as a supervisor for an APS, the pharmacist need not be physically present at the site of the APS and may supervise the system electronically. The Florida-licensed pharmacist is required to develop and implement policies and procedures designed to verify that the medicinal drugs delivered by the automated dispensing system are accurate and valid and that the machine is properly restocked.[38]

The BOP must adopt rules governing the use of an APS, which must specify:

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[32] Fla. Admin. Code Rule 64B16-28,141(2), (2019).
[33] A "Long-term care facility" means a nursing home facility, assisted living facility, adult family-care home, board and care facility, or any other similar residential adult care facility. Section 400.0060(6), F.S.
[34] Section 400.601(6), F.S., defines a "hospice residential unit" as a homelike living facility, and includes a facility licensed under chs. 395 or 429. F.S., that is operated by a hospice for the benefit of its patients and is considered by a patient who lives there to be his or her primary residence.
[35] A "State correctional institution" means any prison, road camp, prison industry, prison forestry camp, or any prison camp or prison farm or other correctional facility, temporary or permanent, in which prisoners are housed, worked, or maintained, under the custody and jurisdiction of the Department of Corrections. See 944.02 (8), F.S.
[36] Section 465.0235(1), F.S.
[37] Section 465.0235(2), F.S.
[38] Section 465.0235(3), F.S.

- Recordkeeping requirements;
- Security requirements; and
- Labeling requirements that permit the use of unit-dose medications if the facility, hospice, or institution maintains medication-administration records that include directions for use of the medication, and the automated pharmacy system identifies:
  - The dispensing pharmacy;
  - The prescription number;
  - The name of the patient; and
  - The name of the prescribing practitioner.[39]

III. Effect of Proposed Changes:

SB 1170 amends s. 465.0235, F.S., to permit a licensed community pharmacy[40] to provide outpatient pharmacy services for dispensing of medicinal drugs through the use of an automated pharmacy system (APS) not located at the same location as the community pharmacy if the requirements of Florida Administrative Code Rule 64B-28.141, and all of the following are met:

- The APS is under the supervision and control of the community pharmacy;
- The community pharmacy providing services through the APS notifies the BOP of the location of the APS and any changes in such location;
- The APS is under the supervision and control of a licensed pharmacist[41] who is available and accessible for patient counseling before the dispensing of any medicinal drug;
- The APS does not contain or dispense any controlled substances listed in Schedule II, Schedule III, Schedule IV, or Schedule V of s. 893.03, F.S., or 21 U.S.C. s. 812;
- The community pharmacy maintains a record of the medicinal drugs dispensed, including the identity of the pharmacist responsible for verifying the accuracy of the dosage and directions and providing patient counseling; and
- The APS ensures the confidentiality of personal health information.

The bill provides that medicinal drugs stored in bulk, or unit of use, in an APS for outpatient dispensing are part of the inventory of the community pharmacy operating the APS and considered to have been dispensed by that pharmacy.

The bill deletes obsolete language regarding the BOP adopting rules governing the use of APS's.

The bill takes effect July 1, 2019.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

[39] Section 465.0235(5), F.S.
[40] See note 9.
[41] Section 465.003(10), F.S., defines pharmacist as a person licensed under ch. 465, F.S., to practice the profession of pharmacy.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

There may be an indeterminate cost, or a savings, to the public of having medicinal drugs readily available for dispensing at various locations other than the community pharmacy location.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 465.0235 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.

916040

LEGISLATIVE ACTION

Senate . House

. . . . .

The Committee on Health Policy (Diaz) recommended the following:

Senate Amendment (with title amendment)

Before line 14
insert:
Section 1. Subsection (2) of section 381.0031, Florida Statutes, is amended to read:
381.0031 Epidemiological research; report of diseases of public health significance to department.—
(2) Any practitioner licensed in this state to practice medicine, osteopathic medicine, chiropractic medicine, naturopathy, or veterinary medicine; <u>any licensed pharmacist</u>

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authorized pursuant to a written protocol to order and evaluate laboratory and clinical tests; any hospital licensed under part I of chapter 395; or any laboratory appropriately certified by the Centers for Medicare and Medicaid Services under the federal Clinical Laboratory Improvement Amendments, and the federal rules adopted thereunder, which diagnoses or suspects the existence of a disease of public health significance shall immediately report the fact to the Department of Health.

Section 2. Subsection (13) of section 465.003, Florida Statutes, is amended to read:

465.003 Definitions.—As used in this chapter, the term:

(13) "Practice of the profession of pharmacy" includes compounding, dispensing, and consulting concerning contents, therapeutic values, and uses of any medicinal drug; consulting concerning therapeutic values and interactions of patent or proprietary preparations, whether pursuant to prescriptions or in the absence and entirely independent of such prescriptions or orders; and conducting other pharmaceutical services. For purposes of this subsection, "other pharmaceutical services" means the monitoring of the patient's drug therapy and assisting the patient in the management of his or her drug therapy, and includes review of the patient's drug therapy and communication with the patient's prescribing health care provider as licensed under chapter 458, chapter 459, chapter 461, or chapter 466, or similar statutory provision in another jurisdiction, or such provider's agent or such other persons as specifically authorized by the patient, regarding the drug therapy. However, nothing in this subsection may be interpreted to permit an alteration of a prescriber's directions, the diagnosis or

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treatment of any disease, the initiation of any drug therapy, the practice of medicine, or the practice of osteopathic medicine, unless otherwise permitted by law. "Practice of the profession of pharmacy" also includes any other act, service, operation, research, or transaction incidental to, or forming a part of, any of the foregoing acts, requiring, involving, or employing the science or art of any branch of the pharmaceutical profession, study, or training, and shall expressly permit a pharmacist to transmit information from persons authorized to prescribe medicinal drugs to their patients. The practice of the profession of pharmacy also includes the administration of vaccines to adults pursuant to s. 465.189, the testing for and treatment of influenza and streptococcus pursuant to s. 465.1895, and the preparation of prepackaged drug products in facilities holding Class III institutional pharmacy permits.

Section 3. Section 465.1895, Florida Statutes, is created to read:

465.1895 Testing for and treatment of influenza and streptococcus.—

(1) A pharmacist may test for and treat influenza and streptococcus if all of the following criteria are met:

(a) The pharmacist has entered into a written protocol with a supervising physician licensed under chapter 458 or chapter 459 and such protocol complies with the requirements as specified in subsection (5) and board rules.

(b) The pharmacist uses an instrument and a waived test, as that term is defined in 42 C.F.R. s. 493.2.

(c) The pharmacist uses a testing system that:

1. Provides automated readings in order to reduce user

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subjectivity or interpretation of results;

2. Is capable of directly or indirectly interfacing with electronic medical records systems; and

3. Is capable of electronically reporting daily de-identified test results to the appropriate agencies.

(d) The pharmacist is certified to test for and treat influenza and streptococcus pursuant to a certification program approved by the board, in consultation with the Board of Medicine and the Board of Osteopathic Medicine, within 90 days after the date this section becomes effective. The certification program must require that the pharmacist attend, on a one-time basis, 8 hours of continuing education courses approved by the board. The continuing education curriculum must be provided by an training organization approved by the Accreditation Council for Pharmacy Education and must include, at a minimum, point-of-care testing for influenza and streptococcus and the safe and effective treatment of influenza and streptococcus.

(2) A pharmacist may not enter into a written protocol under this section unless he or she maintains at least $200,000 of professional liability insurance and is certified as required in paragraph (1)(d).

(3) A pharmacist who tests for and treats influenza and streptococcus shall maintain and make available patient records using the same standards for confidentiality and maintenance of such records as those that are imposed on health care practitioners under s. 456.057. Such records must be maintained for at least 5 years.

(4) The decision by a supervising physician licensed under chapter 458 or chapter 459 to enter into a written protocol

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under this section is a professional decision on the part of the physician, and a person may not interfere with a physician's decision regarding entering into such a protocol. A pharmacist may not enter into a written protocol that is to be performed while he or she is acting as an employee without the written approval of the owner of the pharmacy.

(5) The board shall adopt rules establishing the requirements for the written protocol within 90 days after the date this section becomes effective. At a minimum, the written protocol must include:

(a) The terms and conditions as required in s. 465.189(7);

(b) Specific categories of patients for whom the supervising physician authorizes the pharmacist to test for and treat influenza and streptococcus;

(c) The supervising physician's instructions for the treatment of influenza and streptococcus, based on the patient's age, symptoms, and test results, including negative results;

(d) A process and schedule for the supervising physician to review the pharmacist's actions under the written protocol; and

(e) A process and schedule for the pharmacist to notify the supervising physician of the patient's condition, tests administered, test results, and course of treatment.

(6) A pharmacist who provides testing for or treatment of influenza and streptococcus under this section shall notify the patient's primary care provider within 2 business days after providing any such testing or treatment.

================ T I T L E A M E N D M E N T ================

And the title is amended as follows:

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Delete line 2

and insert:

An act relating to pharmacy; amending s. 381.0031, F.S.; requiring specified licensed pharmacists to report certain information to the Department of Health; amending s. 465.003, F.S.; revising the definition of the term "practice of the profession of pharmacy"; creating s. 465.1895, F.S.; authorizing pharmacists who meet certain criteria to test for and treat influenza and streptococcus; providing requirements relating thereto; specifying requirements for the certification program and for certain continuing education; requiring that the written protocol between a pharmacist and supervising physician contain certain information, terms, and conditions; requiring the Board of Pharmacy to adopt rules within a specified time; requiring that a pharmacist notify a patient's primary care provider within a specified time after providing any such testing or treatment;

By Senator Brandes

24-01749-19 20191170__

A bill to be entitled

An act relating to automated pharmacy systems; amending s. 465.0235, F.S.; authorizing a community pharmacy to use an automated pharmacy system under certain circumstances; providing that certain medicinal drugs stored in such system for outpatient dispensing are part of the inventory of the pharmacy providing services through such system; requiring the Board of Pharmacy to adopt rules; providing an effective date.

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

Section 1. Section 465.0235, Florida Statutes, is amended to read:

465.0235 Automated pharmacy systems used by long-term care facilities, hospices, or state correctional institutions or for outpatient dispensing.—

(1) A pharmacy may provide pharmacy services to a long-term care facility or hospice licensed under chapter 400 or chapter 429 or a state correctional institution operated under chapter 944 through the use of an automated pharmacy system that need not be located at the same location as the pharmacy.

(2) A community pharmacy, as defined in s. 465.003(11)(a)1. and licensed in this state, may provide pharmacy services for outpatient dispensing through the use of an automated pharmacy system that need not be located at the same location as the community pharmacy if all of the following requirements are met:

(a) The automated pharmacy system is under the supervision

and control of the community pharmacy.

(b) The community pharmacy providing services through the automated pharmacy system notifies the board of the location of the automated pharmacy system and any changes in such location.

(c) The automated pharmacy system is under the supervision and control of a pharmacist, as defined in s. 465.003 and licensed in this state, who is available and accessible for patient counseling before the dispensing of any medicinal drug.

(d) The automated pharmacy system does not contain or dispense any controlled substances listed in Schedule II, Schedule III, Schedule IV, or Schedule V of s. 893.03 or 21 U.S.C. s. 812.

(e) The community pharmacy maintains a record of the medicinal drugs dispensed, including the identity of the pharmacist responsible for verifying the accuracy of the dosage and directions and providing patient counseling.

(f) The automated pharmacy system ensures the confidentiality of personal health information.

(3)~~(2)~~ Medicinal drugs stored in bulk or unit of use in an automated pharmacy system servicing a long-term care facility, hospice, or correctional institution, or for outpatient dispensing, are part of the inventory of such ~~the~~ pharmacy ~~providing pharmacy services to that facility, hospice, or institution~~, and medicinal drugs delivered by the automated pharmacy system are considered to have been dispensed by that pharmacy.

(4)~~(3)~~ The operation of an automated pharmacy system must be under the supervision of a ~~Florida-licensed~~ pharmacist licensed in this state. To qualify as a supervisor for an

automated pharmacy system, the pharmacist need not be physically present at the site of the automated pharmacy system and may supervise the system electronically. The ~~Florida-licensed~~ pharmacist shall be required to develop and implement policies and procedures designed to verify that the medicinal drugs delivered by the automated dispensing system are accurate and valid and that the machine is properly restocked.

(5)~~(4)~~ The Legislature does not intend this section to limit the current practice of pharmacy in this state. This section is intended to allow automated pharmacy systems to enhance the ability of a pharmacist to provide pharmacy services in locations that do not employ a full-time pharmacist. This section does not limit or replace the use of a consultant pharmacist.

(6)~~(5)~~ The board shall adopt rules governing the use of ~~an~~ automated pharmacy systems ~~system by January 1, 2005~~, which must include all of the following ~~specify~~:

(a) Recordkeeping requirements.~~;~~

(b) Security requirements.~~; and~~

(c) Labeling requirements that permit the use of unit-dose medications if the facility, hospice, or institution maintains medication-administration records that include directions for use of the medication and the automated pharmacy system identifies:

1. The dispensing pharmacy.~~;~~

2. The prescription number.~~;~~

3. The name of the patient.~~; and~~

4. The name of the prescribing practitioner.

Section 2. This act shall take effect July 1, 2019.

The Florida Senate

Committee Agenda Request

To: Senator Gayle Harrell
Committee on Health Policy

Subject: Committee Agenda Request

Date: March 4, 2019

I respectfully request that **Senate Bill #1170**, relating to **Automated Pharmacy Systems** be placed on the:

☒ committee agenda at your earliest possible convenience.

☐ next committee agenda.

Senator Jeff Brandes
Florida Senate, District 24

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	SB 1436
INTRODUCER:	Senator Gibson
SUBJECT:	Closing the Gap
DATE:	March 22, 2019
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Lloyd	Brown	HP	**Favorable**
2.			AHS	
3.			AP	

I. Summary:

SB 1436 adds a priority focus area for the "Closing the Gap" grant projects to include Alzheimer's Disease and dementia. The "Closing the Gap" program provides grants for activities designed to reduce racial and ethnic disparities. The bill also removes the requirement that up to 20 percent of any grants awarded under the program be set aside for projects related to Front Porch Florida Communities.

The bill has no fiscal impact on state government.

The effective date is July 1, 2019.

II. Present Situation:

The Closing the Gap Program

In 2000, the Florida Legislature created the Reducing the Racial and Ethnic Health Disparities: "Closing the Gap" (CTG) grant program.[1] The program is administered through the Department of Health's (DOH) Office of Minority Health and Health Equity (OMHHE). The OMHHE is charged with administering the CTG program in a manner that maximizes the impact of the grants in achieving health equity.[2] The OMHHE is responsible for publicizing the availability of the program and grant funds, establishing the grant application process, providing technical assistance and a statewide meeting to showcase best practices, developing uniform data reporting requirements, creating a monitoring process to evaluate progress towards the grant's objectives, and coordinating with other state and local programs.[3]

[1] Chapter 2000-256, ss. 31-32, Laws of Fla. (2000).
[2] Section 20.43(9), F.S.
[3] Section 381.7353, F.S. (2018).

The purposes of the grant program are to positively impact racial and ethnic disparities in several key health indicators, to make meaningful improvements in the lives of those Floridians who suffer disproportionately from disease and disability, and to provide funding in the designated priority areas.

Applications for grants during the most recent award period were required to address each of the following items:[4]

- The purpose and objectives of the proposal, including identification of the particular racial or ethnic disparity the project will address, which must include one or more of the following priority areas:
  - Decreasing racial and ethnic disparities in maternal and infant mortality rates;
  - Decreasing racial and ethnic disparities in morbidity and mortality rates relating to cancer;
  - Decreasing racial and ethnic disparities in morbidity and mortality rates relating to HIV/AIDS;
  - Decreasing racial and ethnic disparities in morbidity and mortality rates relating to cardiovascular disease;
  - Decreasing racial and ethnic disparities in morbidity and mortality rates relating to diabetes;
  - Increasing adult and child immunization rates in certain racial and ethnic populations;
  - Decreasing racial and ethnic disparities in oral health care;
  - Decreasing racial and ethnic disparities in morbidity and mortality rates relating to sickle cell disease; and,
  - Decreasing racial and ethnic disparities in morbidity and mortality rates relating to lupus.[5]
- Identification and relevance of the target population;
- Methods for obtaining baseline health status data and assessment of community health needs;
- Mechanisms for mobilizing community resources and gaining local commitment;
- Development and implementation of health promotion and disease prevention interventions;
- Mechanisms and strategies for evaluating the project's objectives, procedures, and outcomes;
- A proposed work plan, including a timeline for implementing the project; and
- The likelihood that project activities will occur and continue in the absence of funding.

The grants could have also stimulated the development of community and neighborhood-based projects to impact health outcomes of racial and ethnic populations.[6] Grantees were required to identify their target population, provide a work plan for the implementation of health promotion and disease prevention interventions, and demonstrate a high level of participation by the health care community in those planned interventions.[7] Priority was given to those proposals that were:

- Submissions from areas with the greatest documented ethnic and racial health status disparities;
- Exceeded the statutory local contribution amounts;

[4] *See* s. 381.7355(3), F.S.
[5] Chapter 2018-157, Laws of Fla. Lupus was added to the list of priority areas during the 2018 Regular Legislative Session.
[6] *Supra* note 3.
[7] *Id.*

- Demonstrated broad-based local community support shown through letters of support, inter-agency agreements, or other forms of supports;
- Showed high levels of participation by the heath care community in clinical preventive services and health promotion activities;
- Submissions from counties with high levels of families living in poverty;
- Demonstrated coordinated community approaches to addressing racial and ethnic health disparities within existing publicly financed programs;
- Incorporated policy approaches that will lead to long-term sustainability and improvement.[8]

The Legislature intended the program to operate as a partnership between the state and local governments, faith-based organizations, private sector organizations, and other non-traditional partners.[9]

Grant Proposals

Grant proposals are awarded for one year through a proposal process and may be renewed annually subject to the availability of funds and the grantee's achievement of quality standards, objectives, and outcomes.[10] The DOH released the *Request for Applications* with an application deadline date of February 16, 2018, for grants beginning July 1, 2018 and ending June 30, 2019.[11] The next funding cycle will be in 2021-2022.[12]

The maximum award per applicant was estimated at $200,000 and the grant application states approximately three million dollars would be available, subject to a state general revenue appropriation.[13] Grant funds may not be used to provide medical or clinical services.[14]

The *Request for Applications* included specific submission guidelines for potential grantees. In addition to the list of criteria for priority consideration, the proposal required applications to provide:

- A statement of need – A description of the need for the proposed project that included demographic information about the focal population to be served and the justification for the requested funding for the project. The statement of need was to include information about the impact of the problem, the prevalence of the health disparities, and risk factors that existed in the county to be served.
- Program description – A narrative of the activities was required. There were to be activities which would be conducted as a result of the funding received under this grant proposal, including the how and when those activities would be implemented. The program description was to address any barriers to implementation and a list of intended outcomes and how the grantee intended to measure those outcomes.

[8] Section 381.7354, F.S. (2018).
[9] Section 381.7352, F.S. (2018).
[10] Section 381.7356(4), F.S. (2018)
[11] Florida Department of Health, Office of Minority Health and Health Equity, *Reducing Racial and Ethnic Health Disparities Closing the Gap Grant Program (CTG) Request for Applications, RFA # 17-007, FY 2018-2019,* http://www.floridahealth.gov/programs-and-services/minority-health/closing-the-gap.html, (last visited March 20, 2019).
[12] *Id.*
[13] *Id*.
[14] *Id at 13.*

- Evaluation plan – A report of how the applicant would measure and evaluate the effectiveness and results of the grant activities. The grant prohibited the use of grant funds to secure an outside evaluator.
- Project management plan – An outline of how the grantee would execute, monitor, and control the proposed plan. The project management plan also had to include how the grantee would handle any issues that arose over the grant period.
- Collaboration – A description of how the grantee would coordinate and partner with other entities within the community for the benefit of the population being served and for the benefit of the project sustainability after the grant funding ends.
- Work plan – A listing of objectives for implementation activities with action items and timelines was required.
- Budget – Inclusion of a proposed budget for the grant period with budget justification.[15]

Matching Funds for Grants

Grants could be awarded to a county or a group of adjoining counties if those counties submitted a multi-county application for a one-year period. CTG required the grantee to provide $1 in local matching funds for every $3 in state grant funds being requested, cash or in-kind contributions, at varying contribution levels.[16] The amount of a grant award was based on the county's or the neighborhood's population demographics. Table 1 below illustrates how populations may meet the match requirement through different combinations of cash and in-kind contributions.

Table 1. **Closing the Gap Matching Funds Contribution Combinations[17]**	
Grantee Type	**Matching Funds Requirements**
County Populations greater than 50,000	One dollar for every $3 grant payment 50 percent must be in cash 50 percent may be in-kind
County Population of 50,000 or less	Local matching may be provided entirely through in-kind contributions
Grantee is a Front Porch Community	No match requirement
Performance Based Allocation Funding[18]	
Diabetes Priority Area	50 percent of budget *Example: In TBA County, increase the number of convenience stores offering fresh fruit and vegetables by 70 percent.*
Oral Health Priority Area	50 percent of budget *Example: Increase by 50 percent the proportion of children and adolescents in TBA County, screened and referred for needed dental services such as sealants.*

On June 1, 2018, the DOH awarded grants under the Request for Applications process to the following vendors:

Vendors Awards Closing the Gap Contracts (2018-2019)			
BayCare Health System	Center for Change	Metropolitan Charities	Suwannee River AHEC

[15] *Id at 18-21.*
[16] Section 381.7356, F.S. (2018).
[17] *Id.*
[18] *Supra* note 14, at 12.

Big Bend Cares	Foundation for Sickle Cell Disease Research	Miami-Dade AHEC	Dept of Health – Duval County
Big Bend Rural Health	Gadsden County Healthy Start	Mother Care Network	Dept of Health – Franklin and Gulf
Brain Expansions	Healthy Mothers Healthy Babies	Prideline Youth Services	Dept of Health – Hardee County
Broward Urban League	Hebni Nutrition Consultants	Reclaiming the Land	Dept of Health – Seminole County
Caridad Center	Latino Salud	Sickle Cell Disease Foundation	Dept of Health – Highland County

Social Determinants of Health

Healthy People 2020 is an initiative of the United States Department of Health and Human Services that provides 10-year national objectives for improving the health of Americans. Its vision is a society in which all people live long, healthy lives.[19] One of the missions of *Healthy People 2020* is increase public awareness of determinants of health, disease, and disability and the opportunities for progress. The project seeks to achieve health equity, eliminate disparities, and improve the health of all groups while also attaining high-quality, longer lives, free of preventable disease, disability, injury, and premature death.[20] In Florida, the ethnic and racial disparity in some health categories is significant, as shown in Table 2 below.

Table 2.
Minority Health Profiles – Select Indicators for 2017 [21]

Indicator (per 100,000, unless noted)	**White**	**Black**	**Hispanic**	**Non-Hispanic**
Fetal Deaths[22] (per 1,000 deliveries)	5.2	10.4	5.5	7.2
Infant Deaths[23] (per 1,000 births)	4.4	11.3	5.1	6.4
Maternal Deaths[24]	13.3	24.9	10.5	19.3
Diabetes death rate	18.3	35.7	19.8	20.0
HIV Virus Disease	1.6	10.1	30.1	3.7
Coronary Heart Disease death rate	146.2	100	125.4	153.1
Stroke death rate	37.2	53.9	37.9	37.0
Alzheimer's	21.7	15.2	25.9	20.2

[19] United States Department of Health and Human Services, *Healthy People 2020 – Framework*, https://www.healthypeople.gov/sites/default/files/HP2020Framework.pdf, (last visited March 20, 2019).
[20] *Id.*
[21] Florida Department of Health, FLHealthCHARTS.com, *Resident Age Adjusted Death Rate (AADR) per 100,000 Population by Year by 50 Leading Rankable Causes of Death by Ethnicity* (chart generated on March 20, 2019).
[22] Florida Department of Health, *Supra* note 21, *Fetal Death Ratio per 100,000 Births per year* (chart generated on March 20, 2019).
[23] Florida Department of Health, *Supra* note 21, *Infant Death Ratio per 100,000 Births per year* (chart generated on March 20, 2019).
[24] Florida Department of Health, *Supra* note 21, *Maternal Death Rate per 100,000 Births per year* (chart generated on March 20, 2019).

A statistical brief from the DOH in 2017 noted that the gap between the black rate and the white rate has decreased over time. In 1995, the age-adjusted mortality rate per 100,000 population was 1,224.9 for Black race and 811.6 for White race, and in 2015, these rates had come down to 851.9 for Black race and 735.0 for White race.[25]

Dementia

Dementia is not a specific disease but is a catch-all term that is used to describe a group of symptoms associated with a decline in memory or other cognitive abilities that reduce a person's ability to perform everyday activities.[26] Symptoms of dementia vary greatly, but at least two of these core mental functions must be significantly impaired for symptoms to be attributed to dementia:

- Memory;
- Communication and language;
- Ability to focus and pay attention;
- Reasoning and judgment; and
- Visual perception.[27]

Alzheimer's disease also accounts for 60 to 80 percent of all dementia cases.[28]

Alzheimer's Disease

Alzheimer's disease is the most common cause of dementia. The disease likely develops from many factors such as genetics, lifestyle, and the environment, with age being the greatest known risk factor. Most individuals who develop the disease will do so after the age of 65.[29] The disease is a progressive disorder that causes brain cells to degenerate and die.[30]

Individuals with Alzheimer's may show symptoms such as:

- Repeating statements and questions numerous times over;
- Forgetting conversations, appointments, or events and not remembering them later;
- Misplacing possessions routinely, often putting them in illogical places;
- Getting lost in familiar places;
- Forgetting the names of family members; and
- Having trouble finding the right words to identify objects, express thoughts, or take part in conversations.[31]

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[25] Florida Department of Health, FLHealthCHARTS.com Statistical Brief, *Gap Between Black and White Death Rate Narrows*, http://www.flhealthcharts.com/Charts/documents/StatisticalBriefs/GapNarrows.pdf, (last visited March 20, 2019).
[26] Alzheimer's Association, *What is Dementia*, https://www.alz.org/alzheimers-dementia/what-is-dementia (last visited March 20, 2019).
[27] Alzheimer's Association, *Supra* note 26, *Memory loss and other symptoms of dementia.*
[28] *Id.*
[29] Alzheimer's Association, *Causes and Risk Factors*, https://www.alz.org/alzheimers-dementia/what-is-alzheimers/causes-and-risk-factors (last visited March 20, 2019).
[30] Mayo Clinic, *Alzheimer's Disease,* https://www.mayoclinic.org/diseases-conditions/alzheimers-disease/symptoms-causes/syc-20350447 (last visited March 20, 2019).
[31] *Id.*

Individuals may also have changes in behavior due to changes in their brains and they may experience depression, apathy, and social withdrawal along with mood swings and delusions.[32]

Research also shows that Latinos are about one-and-a-half times as likely as older whites to have Alzheimer's and other dementia while older African Americans are about twice as likely to have the disease as older whites.[33] While researchers are not certain of the cause of this disparity, it is theorized that the higher rates of vascular disease put these groups at higher risk.[34]

III. Effect of Proposed Changes:

The eligibility requirements for participating in the Closing the Gap grant program under s. 381.7354, F.S., are modified to:

- Eliminate the component that up to 20 percent of any grants awarded under the program be set dedicated for projects related to Front Porch Florida Communities;[35] and
- Add Alzheimer's disease and dementia as new priority focus areas for the "Closing the Gap" grant projects.

The effective date of the bill is July 1, 2019.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

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[32] *Id.*
[33] Alzheimer's Association, *Supra* note 29.
[34] *Id.*
[35] The Front Porch Florida Initiative began during Governor Jeb Bush's administration and was dedicated to revitalization efforts in some of the state's most distressed communities through the award of competitive grants to fund projects proposed by the community. Front Porch funding was used for economic development, beautification, revitalization, technical assistance, community training, and youth development. The initiative began in 1999 and received its last appropriation in the 2007 General Appropriations Act for the 2007-2008 fiscal year. During that span, the Legislature appropriated over $28 million in funding. *See:* Florida Senate Committee on Community Affairs, *Department Of Community Affairs - Review Of The Front Porch Florida Initiative*, Interim Project 2008-110 (October 2007) *available at* http://archive.flsenate.gov/data/Publications/2008/Senate/reports/interim_reports/pdf/2008-110ca.pdf (last visited March 21, 2019)

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Public and private community groups, foundations, and community partnerships that advocate for issues relating to reducing disparities in the prevalence of Alzheimer's disease and dementia among racial and ethnic populations will have a new potential opportunity to compete for grants

C. Government Sector Impact:

The annual appropriation of state funds to CTG program is subject to an annual state budget process. Funding the program is not mandated in SB 1436. The addition of a new priority does not impact the overall cost of the program.

County health departments and other local government entities will also have an opportunity to compete for funds under the program. During this current fiscal year, several local government entities received CTG grants.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 381.7354 and 381.7355.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.

By Senator Gibson

6-01246A-19 20191436__

A bill to be entitled

An act relating to Closing the Gap grant proposals; amending s. 381.7354, F.S.; removing provisions related to Front Porch Florida Communities; amending s. 381.7355, F.S.; adding a priority area that may be addressed in a Closing the Gap grant proposal; providing an effective date.

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

Section 1. Section 381.7354, Florida Statutes, is amended to read:

381.7354 Eligibility.—

(1) Any person, entity, or organization within a county may apply for a Closing the Gap grant and may serve as the lead agency to administer and coordinate project activities within the county and develop community partnerships necessary to implement the grant.

(2) Persons, entities, or organizations within adjoining counties with populations of less than 100,000, based on the annual estimates produced by the Population Program of the University of Florida Bureau of Economic and Business Research, may jointly submit a multicounty Closing the Gap grant proposal. However, the proposal must clearly identify a single lead agency with respect to program accountability and administration.

(3) ~~In addition to the grants awarded under subsections (1) and (2), up to 20 percent of the funding for the Reducing Racial and Ethnic Health Disparities: Closing the Gap grant program shall be dedicated to projects that address improving racial and~~

~~ethnic health status within specific Front Porch Florida Communities.~~

~~(4)~~ Nothing in ss. 381.7351-381.7356 shall prevent a person, entity, or organization within a county or group of counties from separately contracting for the provision of racial and ethnic health promotion, health awareness, and disease prevention services.

Section 2. Subsection (2) of section 381.7355, Florida Statutes, is amended to read:

381.7355 Project requirements; review criteria.—

(2) A proposal must include each of the following elements:

(a) The purpose and objectives of the proposal, including identification of the particular racial or ethnic disparity the project will address. The proposal must address one or more of the following priority areas:

1. Decreasing racial and ethnic disparities in maternal and infant mortality rates.

2. Decreasing racial and ethnic disparities in morbidity and mortality rates relating to cancer.

3. Decreasing racial and ethnic disparities in morbidity and mortality rates relating to HIV/AIDS.

4. Decreasing racial and ethnic disparities in morbidity and mortality rates relating to cardiovascular disease.

5. Decreasing racial and ethnic disparities in morbidity and mortality rates relating to diabetes.

6. Increasing adult and child immunization rates in certain racial and ethnic populations.

7. Decreasing racial and ethnic disparities in oral health care.

8. Decreasing racial and ethnic disparities in morbidity and mortality rates relating to sickle cell disease.

9. Decreasing racial and ethnic disparities in morbidity and mortality rates relating to Lupus.

10. Decreasing racial and ethnic disparities in morbidity and mortality rates relating to Alzheimer's disease and dementia.

11.~~10.~~ Improve neighborhood social determinants of health, such as transportation, safety, and food access, as outlined by the Centers for Disease Control and Prevention's "Tools for Putting Social Determinants of Health into Action."

(b) Identification and relevance of the target population.

(c) Methods for obtaining baseline health status data and assessment of community health needs.

(d) Mechanisms for mobilizing community resources and gaining local commitment.

(e) Development and implementation of health promotion and disease prevention interventions.

(f) Mechanisms and strategies for evaluating the project's objectives, procedures, and outcomes.

(g) A proposed work plan, including a timeline for implementing the project.

(h) Likelihood that project activities will occur and continue in the absence of funding.

Section 3. This act shall take effect July 1, 2019.

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:
Rules, *Vice Chair*
Appropriations
Innovation, Industry, and Technology
Judiciary

JOINT COMMITTEE:
Joint Legislative Budget Commission

SENATOR AUDREY GIBSON
Minority Leader
6th District

March 7, 2019

Senator Gayle Harrell, Chair
Committee on Health Policy
530 Knott Building
404 S. Monroe Street
Tallahassee, FL 32399-1100

Chair Harrell:

I respectfully request that SB 1436, relating to addressing racial and ethnic disparities in morbidity and mortality rates relating to Alzheimer's disease and Dementia, be placed on the next committee agenda.

SB 1436, adds Alzheimer's disease and Dementia a disease, which is the 6th leading cause of death to Closing the Gap grant proposals. The Closing the Gap grant program provides funding to decrease racial or ethnic disparities for a variety of diseases and illnesses, such as Cancer, HIV/AIDS and Lupus. The bill also removes Front Porch Florida Communities, a program which no longer exists and not funded.

Thank you for your time and consideration.

Sincerely,

Audrey Gibson
State Senator
District 6

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	SB 1618
INTRODUCER:	Senator Simmons
SUBJECT:	Tobacco Products
DATE:	March 22, 2019
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Williams	Brown	HP	**Favorable**
2.			IT	
3.			RC	

I. Summary:

SB 1618 increases the minimum age to lawfully possess tobacco products from 18 to 21 years of age. The provisions of the bill may be cited as the "Tobacco 21 Act."

The bill defines "tobacco products" to include electronic smoking devices, such as electronic cigarettes. The sale of tobacco products through a vending machine is also prohibited by the bill.

The bill decriminalizes the penalties for any person who sells, delivers, barters, furnishes, or gives tobacco products to a person under the age of 21. Instead of criminal penalties, the bill provides a noncriminal penalty of a fine of no more than $500 for the first offense and a fine of no more than $1,000 for a second or subsequent offense within one year of the first violation.

Additionally, the bill repeals the current prohibitions against the possession of tobacco products by persons under the minimum age of lawful possession. However, the bill maintains the current prohibition against any person who misrepresents his or her age for the purpose of inducing a retail tobacco dealer, or an agent or employee of the dealer, to sell any tobacco product or to attempt to purchase any tobacco product from a person or vending machine. The bill provides a noncriminal penalty of 20 hours of community service for a first offense and at least 40 hours of community service for subsequent offenses within one year of the first violation.

SB 1618 may have an indeterminate fiscal impact on state government, the courts, and the clerks of court. See Section V, Fiscal Impact Statement.

The effective date of the bill is October 1, 2019.

II. Present Situation:

Tobacco Products Regulation in Florida

The Division of Alcoholic Beverage and Tobacco (Division) within the Department of Business and Professional Regulation is the state agency responsible for the regulation and enforcement of the tobacco products under ch. 569, F.S.

Section 569.002(6), F.S., defines the term "tobacco products" to include:

> loose tobacco leaves, and products made from tobacco leaves, in whole or in part, and cigarette wrappers, which can be used for smoking, sniffing, or chewing.

Section 210.25(11), F.S., relating to the tax on tobacco products other than cigarettes or cigars, defines the term "tobacco products" to mean:

> loose tobacco suitable for smoking; snuff; snuff flour; Cavendish; plug and twist tobacco; fine cuts and other chewing tobaccos; shorts; refuse scraps; clippings, cuttings, and sweepings of tobacco, and other kinds and forms of tobacco prepared in such manner as to be suitable for chewing; but "tobacco products" does not include cigarettes, as defined by s. 210.01(1), F.S., or cigars.

Tobacco Products and Minors

Section 569.0075, F.S., prohibits the giving of sample tobacco products to persons under the age of 18.

Section 569.101, F.S., prohibits the sale, delivery, bartering, furnishing or giving of tobacco products to persons under the age of 18. A violation of this prohibition is a second degree misdemeanor.[1] A second or subsequent violation within one year of the first violation is a first degree misdemeanor.[2]

It is a complete defense to a person charged with a violation of s. 569.101, F.S., if the buyer or recipient falsely evidenced that he or she was 18 years of age or older, a prudent person would believe the buyer or recipient to be 18 years of age or older, and the buyer or recipient presented false identification[3] upon which the person relied in good faith.[4]

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[1] Section 775.082, F.S., provides that the penalty for a misdemeanor of the second degree is punishable by a term of imprisonment not exceeding 60 days. Section 775.083, F.S. provides that the penalty for a misdemeanor of the second degree is punishable by a fine not to exceed $500.

[2] Section 775.082, F.S., provides that the penalty for a misdemeanor of the first degree is punishable by a term of imprisonment not exceeding one year. Section 775.083, F.S. provides that the penalty for a misdemeanor of the first degree is punishable by a fine not to exceed $1,000.

[3] Identification includes carefully checking "a driver license or an identification card issued by this state or another state of the United States, a passport, or a United States armed services identification card presented by the buyer or recipient and acted in good faith and in reliance upon the representation and appearance of the buyer or recipient in the belief that the buyer or recipient was 18 years of age or older." See s. 569.101(2)(c), F.S.

[4] Section 569.101(3), F.S.

Section 569.11, F.S., prohibits persons under the age of 18 years from possessing, directly or indirectly, any tobacco products:

- A first violation of this prohibition is a non-criminal violation with a penalty of 16 hours of community service or a $25 fine, and attendance at a school-approved anti-tobacco program, if locally available.
- A second violation within 12 weeks of the first violation is punishable with a $25 fine.
- A third or subsequent violation within 12 weeks of the first violation requires that the person be punished with the suspension or revocation of his or her driver license or driving privilege, as provided in s. 322.056, F.S.[5]

However, a person "under the age of 18" does not include any person under the age of 18 who:

- Has had his or her disability of nonage removed under ch. 743, F.S.;
- Is in the military reserve or on active duty in the Armed Forces of the United States;
- Is otherwise emancipated by a court of competent jurisdiction and released from parental care and responsibility; or
- Is acting in his or her scope of lawful employment with an entity licensed under the provisions of ch. 210, F.S., relating to taxation of cigarettes and other tobacco products, or ch. 569, F.S., relating to tobacco products.[6]

Eighty percent of all civil penalties received by a county court under s. 569.11, F.S., must be remitted to the Department of Revenue for transfer to the Department of Education for teacher training and for research and evaluation to reduce and prevent the use of tobacco products, nicotine products, or nicotine dispensing devices by children. The remaining 20 percent of civil penalties received by a county court must remain with the clerk of the county court to cover administrative costs.[7]

Retail tobacco product dealers (retailers) must post a clear and conspicuous sign that the sale of tobacco products is prohibited to persons under the age of 18 and that proof of age is required for purchase. The Division is required to make the signs available to retailers. Retailers must also have instructional material in the form of a calendar or similar format to assist in determining the age of the person attempting to purchase a tobacco product.[8]

To prevent persons under 18 years of age from purchasing or receiving tobacco products, the sale or delivery of tobacco products is prohibited, except when those products are under the direct control or line of sight of the dealer or the dealer's agent or employee. If a tobacco product is sold from a vending machine, the vending machine must have:

- An operational lock-out device which is under the control of the dealer or the dealer's agent or employee who directly regulates the sale of items through the machine by triggering the lock-out device to allow the dispensing of one tobacco product;

[5] Section 322.056, F.S., requires the mandatory revocation or suspension of, or delay of eligibility for, a driver license for persons under 18 years of age found guilty of certain alcohol, drug, tobacco or nicotine product and nicotine dispensing device offenses. Penalties range from a 30-day suspension to a two-year revocation of a driver license. However, a court may, in its discretion, order a restricted driver license for business or employment purposes.
[6] Section 569.002(7), F.S.
[7] Section 569.11(6), F.S.
[8] Section 569.14, F.S.

- A mechanism on the lock-out device to prevent the machine from functioning if the power source for the lock-out device fails or if the lock-out device is disabled; and
- A mechanism to ensure that only one tobacco product is dispensed at a time.[9]

These requirements for the sale of tobacco products do not apply to an establishment that prohibits persons under 18 years of age on premises and do not apply to the sale or delivery of cigars and pipe tobacco.[10]

Section 386.212, F.S., in the Florida Clean Indoor Air Act, prohibits any person under the age of 18 from smoking tobacco within 1,000 feet of a public or private elementary, middle, or secondary school between the hours of 6 a.m. and midnight. A violation of this prohibition is punishable by a maximum noncriminal civil penalty not to exceed $25, or 50 hours of community service or, where available, successful completion of a school-approved anti-tobacco "alternative to suspension" program.

Mail Order, Internet, and Other Remote Sales of Tobacco Products

Section 210.095(5), F.S., provides requirements for the delivery of mail order, Internet, and other remote sales of tobacco products, referred to as "delivery sales." Each person who mails, ships, or otherwise delivers tobacco products in connection with an order for a delivery sale is required to:

- Include, as part of the shipping documents, in a clear and conspicuous manner, the following statement: "Tobacco Products: Florida law prohibits shipping to individuals under 18 years of age and requires the payment of all applicable taxes."
- Use a method of mailing, shipping, or delivery which obligates the delivery service to:
  - Require the signature of an adult who resides at the delivery address and obtain proof of the legal minimum purchase age of the individual accepting delivery, if the individual appears to be under 27 years of age.
  - Require proof that the individual accepting delivery is either the addressee or the adult designated by the addressee, in the form of a valid, government-issued identification card bearing a photograph of the individual who signs to accept delivery of the shipping container.
- Provide to the delivery service, if such service is used, evidence of full compliance with requirements for the collection and remittance of all taxes imposed on tobacco products by this state with respect to the delivery sale.[11]

If a person accepts a purchase order for a delivery sale and delivers the tobacco products without using a delivery service, the person must comply with all of the requirements that apply to a delivery service.[12]

[9] Section 569.007(1), F.S.
[10] Sections 569.007(2) and (3), F.S.
[11] Section 210.095(5), F.S.
[12] Id.

Section 210.095(8), F.S., currently provides that the penalty for the following violations of the delivery sale requirements is a misdemeanor of the third degree:[13]

- A delivery sale delivers tobacco products, on behalf of a delivery service, to an individual who is under 18 years of age.
- A violation of any provision in s. 210.095, F.S., by an individual who is under 18 years of age.

Florida law does not provide a criminal penalty classification for a misdemeanor of the third degree. However, the prohibitions and penalties in s. 569.101, F.S., prohibiting the sale, delivery, bartering, furnishing, or giving, directly or indirectly, to any person who is under 18 years of age, any tobacco product, and s. 569.11, F.S., prohibiting persons under 18 years of age from possessing, directly or indirectly, any tobacco products, apply to s. 210.095, F.S., related to the delivery of tobacco products to persons under the age of 18.

Nicotine Dispensing Devices

Section 877.112, F.S., provides for the regulation of nicotine dispensing devices and nicotine products, such as electronic cigarettes (e-cigarettes). This statute extends the current prohibitions related to tobacco products to the sale, gifting, possession, or use of nicotine dispensing devices and nicotine products to and by persons under 18 years of age.

A "nicotine dispensing device" is:

> any product that employs an electronic, chemical, or mechanical means to produce vapor from a nicotine product, including, but not limited to, an electronic cigarette, electronic cigar, electronic cigarillo, electronic pipe, or other similar device or product, any replacement cartridge for such device, and any other container of nicotine in a solution or other form intended to be used with or within an electronic cigarette, electronic cigar, electronic cigarillo, electronic pipe, or other similar device or product.[14]

A "nicotine product" is any product that contains nicotine, including liquid nicotine intended for human consumption, whether inhaled, chewed, absorbed, dissolved or ingested by any means. The definition does not include a tobacco product under Florida law, a drug or device under federal law, or a product that contains incidental nicotine.[15]

The sale or giving of nicotine products or nicotine dispensing devices to any person under 18 years of age is prohibited and punishable as a second degree misdemeanor.[16] It is a complete defense to a violation if an underage person falsely misrepresented his or her age, the underage

[13] Section 775.082, F.S., provides that a misdemeanor of the second degree is punishable by a term of imprisonment not to exceed 60 days. Section 775.083, F.S. provides that a misdemeanor of the second degree is punishable by a fine not to exceed $500.
[14] Section 877.112(1)(a), F.S.
[15] Section 877.112(1)(b), F.S.
[16] Section 775.082, F.S., provides that a misdemeanor of the second degree is punishable by a term of imprisonment not to exceed 60 days. Section 775.083, F.S. provides that a misdemeanor of the second degree is punishable by a fine not to exceed $500.

person had the appearance to a prudent person to 18 years of age or older, and the person carefully checked, and relied on, the driver license or identification card of the recipient.[17]

Persons under 18 years of age possessing, purchasing, or misrepresenting their age or military service to obtain nicotine products or nicotine dispensing devices commit a noncriminal violation.[18] The penalty is 16 hours of community service or a $25 fine for a first violation, and attendance at a school-approved anti-tobacco and nicotine program, if available. A second violation within 12 weeks of the first violation requires a $25 fine. A third violation within 12 weeks of the first violation requires the suspension or revocation of the person's driver license, as provided in s. 322.056, F.S.[19]

Eighty percent of civil penalties specific to possession of nicotine products or nicotine dispensing devices by minors and misrepresenting age in making such purchases are remitted to the Department of Revenue for transfer to the Department of Education for teacher training and for research and evaluation to reduce and prevent the use of tobacco products, nicotine products, or nicotine dispensing devices by children. The remaining 20 percent of civil penalties received by a county court are retained by the clerk of the county court to cover administrative costs.[20]

Section 877.112(10), F.S., requires a retail dealer of nicotine products and nicotine dispensing devices to post signs that the sale of nicotine products and nicotine dispensing devices to persons under 18 years of age is prohibited.

Nicotine products or nicotine dispensing devices may not be sold or delivered by self-service merchandising, except when such products are under the direct control of, or in the line of sight where effective control may be reasonably maintained by, the retailer or their agent or employee.[21]

To prevent persons under 18 years of age from purchasing or receiving nicotine products or nicotine dispensing devices, s. 877.112(12), F.S., requires retailers to comply with restrictions identical to the restrictions on the sale of tobacco products in s. 569.007(1), F.S., such as requiring the products to be sold or delivered only when under the direct control or line of sight of the retailer and requiring a lock-out device if the products are sold or delivered from a vending machine.

Responsible Retail Tobacco Products Dealers

Section 569.008, F.S., provides a process for a retail tobacco product dealer to mitigate penalties imposed against a dealer because of an employee's illegal sale of a tobacco product to a person under 18 years of age.[22] The process encourages retail tobacco product dealers to comply with responsible practices. The Division may mitigate penalties, if:

[17] Section 877.112(5), F.S.
[18] Sections 877.112(6) and (7), F.S.
[19] Section 877.112(8), F.S.
[20] Section 877.112(9), F.S.
[21] Section 877.112(11), F.S.
[22] The Florida Responsible Vendor Act in ss. 561.701 - 561.706, F.S., provides a comparable process for mitigation of penalties against vendors of alcoholic beverages.

- The dealer is qualified as a responsible dealer having established and implemented specified practices designed to ensure that the dealer's employees comply with ch. 569, F.S., such as employee training.
- The dealer had no knowledge of that employee's violation at the time of the violation and did not direct, approve, or participate in the violation.
- The sale was made through a vending machine equipped with an operational lock-out device.[23]

III. Effect of Proposed Changes:

"Tobacco 21 Act"

Section 1 of the bill provides that this act may be cited as the "Tobacco 21 Act."

Mail Order, Internet, and Other Remote Sales of Tobacco Products

Section 2 amends s. 210.095, F.S., to increase the minimum age to purchase tobacco products from 18 to 21 years of age. The bill revises the penalties in s. 210.095, F.S., by:

- Decriminalizing a violation for a person who omits the required disclaimer from the shipping documents.
- Reducing the penalty from a "third degree misdemeanor" to a noncriminal violation with a penalty for a first offense of at least 20 hours of community service, and a penalty for a second or subsequent violation within one year of the first violation of least 40 hours of community service.
- Providing a penalty of a second degree misdemeanor (instead of the current "third degree misdemeanor") for a person who, in connection with a delivery sale, delivers tobacco products on behalf of a delivery service to an individual who is not an adult.

Mandatory Driver License Penalties

Section 3 amends s. 322.056, F.S., to repeal the mandatory revocation or suspension of, or the delay of eligibility for, a driver's license for persons under 18 years of age found guilty of certain tobacco or nicotine product and nicotine dispensing device offenses.

Definitions

Section 5 creates Subsection (6) of s. 569.002, F.S., to define the term "electronic smoking device" as:

> any device that can be used to deliver aerosolized or vaporized nicotine to the person inhaling from the device, including but not limited to, an e-cigarette, e-cigar, e-pipe, vape pen, or e-hookah. The term includes any component, part, or accessory of such a device, sold separately or with the device, and includes any substance intended to be aerosolized or vaporized during the use of the device. The term does not include drugs, devices, or combination products authorized for

[23] See s. 569.008(3), F.S.

> sale by the United States Food and Drug Administration, as those terms are defined in the Federal Food, Drug, and Cosmetic Act.

The bill re-designates existing Subsection (6) of s. 569.002, F.S., as subsection (7) and revises the definition of "tobacco products" to be:

> any product that is made from or derived from tobacco or that contains nicotine and is intended for human consumption or is likely to be consumed, whether smoked, heated, chewed, absorbed, dissolved, inhaled, or ingested by any other means, including, but not limited to, a cigarette, a cigar, pipe tobacco, chewing tobacco, snuff, or snus.

Under the bill, the term "tobacco products" includes electronic smoking devices and any component or accessory used in the consumption of a tobacco product, such as filters, rolling papers, pipes, and liquids used in electronic smoking devices, whether or not they contain nicotine. However, the term does not include drugs, devices, or combination products authorized for sale by the United States Food and Drug Administration, as those terms are defined in the Federal Food, Drug, and Cosmetic Act.

Section 14 repeals s. 877.122, F.S., which defines nicotine dispensing devises and nicotine products.

Retail sellers of electronic smoking devices are required by the bill to be licensed as retail tobacco products dealers because of the bill's amended definition of tobacco products.

Decriminalization and Penalties

Section 9 amends s. 569.101, F.S., to decriminalize penalties for any person who sells, delivers, barters, furnishes, or gives tobacco products to a person under the age of 21. Under the bill, a violation of the prohibition on such acts is a noncriminal violation punishable by a fine of no more than $500 for the first offense, and a fine of no more than $1,000 for a second or subsequent offense within one year of the first violation.

Section 10 amends s. 569.11, F.S., relating to prohibitions on the possession of tobacco products by persons under the minimum age of purchase, to delete the current prohibition on the possession of tobacco products by a person who is under the minimum age for lawful possession of tobacco products and the related penalties for violations of the prohibition.

In lieu of criminal penalties, a person misrepresenting his or her age for the purpose of inducing a dealer or an agent or employee of the dealer to sell any tobacco product, or attempts to purchase any tobacco product from a person or vending machine, is subject to a noncriminal penalty of 20 hours of community service for a first offense, and at least 40 hours of community service for a second or subsequent offense within one year of the first violation.

The bill requires a person accused of a violation of s. 561.11, F.S., to appear before the county court for a hearing. The bill removes the option in current law permitting the accused to pay the applicable fine without having to appear in county court.

The bill decreases the applicable penalties in s. 569.14(5), F.S., for a retail tobacco dealer who fails to post a clear and conspicuous sign stating that the sale of tobacco to a person under the legal age is prohibited under Florida law. A violation of this prohibition remains a second degree misdemeanor, punishable by a fine of no more than $500, as provided in s. 775.083, F.S., and the bill deletes the criminal penalty of a maximum 60-day period of incarceration provided in s. 775.082, F.S.

Sales Restrictions

Section 6 amends s. 569.007(1), F.S., and **Section 14** repeals s. 877.112, F.S., to eliminate the general restrictions on the sale or delivery of tobacco products, nicotine dispensing devises, and nicotine products. The bill requires that tobacco products and electronic smoking devices be sold from behind a counter where the products are required to be retrieved and hand delivered by an employee to the consumer. The bill repeals the current authorization for sales of nicotine products and nicotine dispensing devices from a vending machine.

Responsible Retail Tobacco Products Dealers

Section 8 amends s. 569.008, F.S., to remove the authority for the Division to mitigate penalties based on a dealer's adherence to the responsible practices provided in this section. However, the bill retains the current conditions to qualify as a responsible retail tobacco products dealer.

Conforming Provisions

Sections 4, 7, 11, 12, and 13 amend ss. 386.212, 569.075, 569.12, 569.14, and 569.19, F.S., to increase the minimum age for the purchase or sale of tobacco and nicotine products in these provisions from 18 years of age to 21 years of age.

Effective Date

Section 15 provides for an effective date of October 1, 2019.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Persons who violate the current criminal prohibitions in ss. 569.101 and 569.11, F.S., will no longer incur costs under the bill related to the payment of criminal fines or costs related to incarceration.

Retail dealers of electronic smoking devices, such as electronic cigarettes, are required by the bill to obtain a retail tobacco product dealer permit, which has an annual license fee of $50.[24]

C. Government Sector Impact:

The Department of Business and Professional Regulation may incur indeterminate expenses related to personnel or modification of operational priorities needed to accommodate the additional licensure of dealers of electronic smoking devices.

Under current law, clerks of county courts may retain 20 percent of civil penalties received by a county court from penalties imposed for violations of the prohibitions in ss. 569.101 and 569.11, F.S., to cover administrative costs.[25] The bill repeals those penalties, which will eliminate this funding source.

The bill requires a person accused of a violation of s. 561.11, F.S., to appear before the county court for a hearing and removes the option in current law permitting an accused person to pay the applicable fine without having to appear in county court. This may have an indeterminate impact on county courts due to the additional time and personnel required to schedule and hold these hearings.

VI. Technical Deficiencies:

Section 5 re-designates existing subsection (6) of s. 569.002, F.S., as subsection (7). This subsection currently provides exclusions from the meaning of "any person under the age of 18." The bill does not provide comparable exclusions for persons under 21 years of age. Since two of

[24] See s. 569.003(1)(c), F.S.
[25] See ss. 569.11(6) and 877.112(9), F.S.

these current exclusions relate to minors' treatment as adults under other provisions of law, excluding those provisions for an age under 21 is inconsequential. The elimination of these exceptions to the minimum age, coupled with the increase of the minimum age to 21 years of age, requires active duty or reserve military personnel, otherwise exempt under current law, to be 21 to purchase or possess tobacco products, including electronic smoking devices. It is unclear whether this effect is intended.

VII. Related Issues:

The bill does not revise the definition of "tobacco products" in ch. 210, F.S., which governs the excise tax and surcharge imposed and collected on cigarettes and other tobacco products. Consequently, the bill does not affect:

- The collection of excise taxes and surcharge taxes on tobacco products; and
- The licensure, reporting, and recordkeeping of manufacturers and distributors of the additional nicotine delivery products.

Seven states, and the U.S. Territory of Guam, have raised the minimum age for a person to lawfully possess or purchase tobacco products to 21 years of age: California, New Jersey, Oregon, Hawaii, Maine, Massachusetts, and Virginia (effective July 1, 2019). At least 445 localities, including New York City, Chicago, San Francisco, San Antonio, Boston, Cincinnati, Cleveland, Columbus, and Kansas City (in Kansas and Missouri), plus Washington, D.C., have also raised the minimum to 21 years of age.[26]

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 210.095, 322.056, 386.212, 569.002, 569.007, 569.0075, 569.008, 569.101, 569.11, 569.12, 569.14, and 569.19.

This bill repeals the following section of the Florida Statutes: 877.112.

This bill creates one non-statutory section of the Laws of Florida.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.

[26] See Campaign for Tobacco-Free Kids, States and Localities that have Raised the Minimum Legal Sale Age for Tobacco Products to 21, *available at* https://www.tobaccofreekids.org/assets/content/what_we_do/state_local_issues/sales_21/states_localities_MLSA_21.pdf (last visited Mar. 15, 2019).

By Senator Simmons

9-00673-19 20191618__

A bill to be entitled

An act relating to tobacco products; providing a short title; amending s. 210.095, F.S.; revising shipping documentation requirements for specified sales of tobacco products; providing criminal and noncriminal penalties; amending s. 322.056, F.S.; deleting provisions requiring driver license penalties for certain persons who commit tobacco-related offenses; amending s. 386.212, F.S.; revising the age under which it is unlawful to smoke in, on, or near school property; amending s. 569.002, F.S.; defining the term "electronic smoking device"; redefining the term "tobacco products"; deleting exemptions relating to tobacco products for persons under a certain age who meet specified requirements related to disability of nonage, military service, emancipation by a court and release from parental care and responsibility, and acting within the scope of lawful employment with certain entities; amending s. 569.007, F.S.; conforming provisions relating to the sale of tobacco products to federal law; providing an exception to laws relating to the sale of tobacco products for establishments that prohibit persons under 21 years of age from being on the licensed premises; amending s. 569.0075, F.S.; revising the age under which the gift of tobacco products to a person by certain entities is prohibited; amending s. 569.008, F.S.; revising legislative intent to reflect that the Legislature intends to prevent the sale of tobacco products to

persons under 21 years of age; eliminating the division's authority to mitigate penalties imposed against a dealer for certain violations; amending s. 569.101, F.S.; revising the age limitation that applies to the sale, delivery, bartering, furnishing, or giving of tobacco products; revising penalties for violations; conforming the age specified in provisions related to a complete defense for persons charged with certain violations; amending s. 569.11, F.S.; deleting provisions prohibiting persons under 18 years of age from possessing tobacco products; conforming the age specified for misrepresentation of age to unlawfully acquire tobacco products; revising the penalties for certain persons who misrepresent their age; deleting a provision requiring a person participating in community service to be considered an employee of the state for certain purposes; conforming a provision to changes made by the act; amending ss. 569.12, 569.14, and 569.19, F.S.; conforming provisions to changes made by the act; repealing s. 877.112, F.S., relating to restrictions on the sale and delivery of nicotine products and nicotine dispensing devices; providing an effective date.

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

Section 1. <u>This act may be cited as the "Tobacco 21 Act."</u>

Section 2. Subsection (5) and paragraphs (e) and (g) of subsection (8) of section 210.095, Florida Statutes, are amended

to read:

210.095 Mail order, Internet, and remote sales of tobacco products; age verification.—

(5) Each person who mails, ships, or otherwise delivers tobacco products in connection with an order for a delivery sale must:

(a) Include as part of the shipping documents, in a clear and conspicuous manner, the following statement: "Tobacco Products: Florida law prohibits shipping to individuals under 21 ~~18~~ years of age and requires the payment of all applicable taxes."

(b) Use a method of mailing, shipping, or delivery which obligates the delivery service to require:

1. The individual submitting the order for the delivery sale or another adult who resides at the individual's address to sign his or her name to accept delivery of the shipping container. Proof of the legal minimum purchase age of the individual accepting delivery is required only if the individual appears to be under 27 years of age.

2. Proof that the individual is either the addressee or the adult designated by the addressee, in the form of a valid, government-issued identification card bearing a photograph of the individual who signs to accept delivery of the shipping container.

(c) Provide to the delivery service, if such service is used, evidence of full compliance with subsection (7).

Any person who violates paragraph (a) commits a noncriminal violation and must serve at least 20 hours of community service.

Any person who violates paragraph (a) a second or subsequent time within 1 year of the first violation commits a noncriminal violation and must serve at least 40 hours of community service ~~If the person accepting a purchase order for a delivery sale delivers the tobacco products without using a delivery service, the person must comply with all of the requirements of this section which apply to a delivery service. Any failure to comply with a requirement of this section constitutes a violation thereof~~.

(8)

(e) A person who, in connection with a delivery sale, delivers tobacco products on behalf of a delivery service to an individual who is not an adult commits a misdemeanor of the second ~~third~~ degree, punishable as provided in s. 775.082 or s. 775.083.

~~(g) An individual who is not an adult and who knowingly violates any provision of this section commits a misdemeanor of the third degree, punishable as provided in s. 775.082 or s. 775.083.~~

Section 3. Section 322.056, Florida Statutes, is amended to read:

322.056 Mandatory revocation or suspension of, or delay of eligibility for, driver license for persons under age 18 found guilty of certain alcohol or~~,~~ drug~~, or tobacco~~ offenses; prohibition.—

(1) Notwithstanding ~~the provisions of~~ s. 322.055, if a person under 18 years of age is found guilty of or delinquent for a violation of s. 562.11(2), s. 562.111, or chapter 893, and:

(a) The person is eligible by reason of age for a driver license or driving privilege, the court shall direct the department to revoke or to withhold issuance of his or her driver license or driving privilege for a period of:

1. Not less than 6 months and not more than 1 year for the first violation.

2. Two years, for a subsequent violation.

(b) The person's driver license or driving privilege is under suspension or revocation for any reason, the court shall direct the department to extend the period of suspension or revocation by an additional period of:

1. Not less than 6 months and not more than 1 year for the first violation.

2. Two years, for a subsequent violation.

(c) The person is ineligible by reason of age for a driver license or driving privilege, the court shall direct the department to withhold issuance of his or her driver license or driving privilege for a period of:

1. Not less than 6 months and not more than 1 year after the date on which he or she would otherwise have become eligible, for the first violation.

2. Two years after the date on which he or she would otherwise have become eligible, for a subsequent violation.

However, the court may~~, in its sound discretion,~~ direct the department to issue a license for driving privileges restricted to business or employment purposes only, as defined in s. 322.271, if the person is otherwise qualified for such a license.

~~(2) If a person under 18 years of age is found by the court to have committed a noncriminal violation under s. 569.11 or s. 877.112(6) or (7) and that person has failed to comply with the procedures established in that section by failing to fulfill community service requirements, failing to pay the applicable fine, or failing to attend a locally available school-approved anti-tobacco program, and:~~

~~(a) The person is eligible by reason of age for a driver license or driving privilege, the court shall direct the department to revoke or to withhold issuance of his or her driver license or driving privilege as follows:~~

~~1. For the first violation, for 30 days.~~

~~2. For the second violation within 12 weeks of the first violation, for 45 days.~~

~~(b) The person's driver license or driving privilege is under suspension or revocation for any reason, the court shall direct the department to extend the period of suspension or revocation by an additional period as follows:~~

~~1. For the first violation, for 30 days.~~

~~2. For the second violation within 12 weeks of the first violation, for 45 days.~~

~~(c) The person is ineligible by reason of age for a driver license or driving privilege, the court shall direct the department to withhold issuance of his or her driver license or driving privilege as follows:~~

~~1. For the first violation, for 30 days.~~

~~2. For the second violation within 12 weeks of the first violation, for 45 days.~~

~~Any second violation of s. 569.11 or s. 877.112(6) or (7) not within the 12-week period after the first violation will be treated as a first violation and in the same manner as provided in this subsection.~~

~~(3) If a person under 18 years of age is found by the court to have committed a third violation of s. 569.11 or s. 877.112(6) or (7) within 12 weeks of the first violation, the court must direct the Department of Highway Safety and Motor Vehicles to suspend or withhold issuance of his or her driver license or driving privilege for 60 consecutive days. Any third violation of s. 569.11 or s. 877.112(6) or (7) not within the 12-week period after the first violation will be treated as a first violation and in the same manner as provided in subsection (2).~~

(2)~~(4)~~ A penalty imposed under this section shall be in addition to any other penalty imposed by law.

~~(5) The suspension or revocation of a person's driver license imposed pursuant to subsection (2) or subsection (3), shall not result in or be cause for an increase of the convicted person's, or his or her parent's or legal guardian's, automobile insurance rate or premium or result in points assessed against the person's driving record.~~

Section 4. Subsection (1) of section 386.212, Florida Statutes, is amended to read:

386.212 Smoking prohibited near school property; penalty.—

(1) It is unlawful for any person under 21 ~~18~~ years of age to smoke tobacco in, on, or within 1,000 feet of the real property comprising a public or private elementary, middle, or secondary school between the hours of 6 a.m. and midnight. This

section does not apply to any person occupying a moving vehicle or within a private residence.

Section 5. Present subsections (3), (4), and (5) of section 569.002, Florida Statutes, are redesignated as subsections (4), (5), and (6), respectively, present subsections (6) and (7) of that section are amended, and a new subsection (3) is added to that section, to read:

569.002 Definitions.—As used in this chapter, the term:

(3) "Electronic smoking device" means any device that can be used to deliver aerosolized or vaporized nicotine to the person inhaling from the device, including, but not limited to, an e-cigarette, e-cigar, e-pipe, vape pen, or e-hookah. The term includes any component, part, or accessory of such a device, sold separately or with the device, and includes any substance intended to be aerosolized or vaporized during the use of the device. The term does not include drugs, devices, or combination products authorized for sale by the United States Food and Drug Administration, as those terms are defined in the Federal Food, Drug, and Cosmetic Act.

(7) ~~(6)~~ "Tobacco products" means any product that is made from or derived from tobacco or that contains nicotine and is intended for human consumption or is likely to be consumed, whether smoked, heated, chewed, absorbed, dissolved, inhaled, or ingested by any other means, including, but not limited to, a cigarette, a cigar, pipe tobacco, chewing tobacco, snuff, or snus. The term includes electronic smoking devices and any component or accessory used in the consumption of a tobacco product, such as filters, rolling papers, pipes, and liquids used in electronic smoking devices, whether or not they contain

nicotine. The term does not include drugs, devices, or combination products authorized for sale by the United States Food and Drug Administration, as those terms are defined in the Federal Food, Drug, and Cosmetic Act ~~includes loose tobacco leaves, and products made from tobacco leaves, in whole or in part, and cigarette wrappers, which can be used for smoking, sniffing, or chewing.~~

~~(7) "Any person under the age of 18" does not include any person under the age of 18 who:~~

~~(a) Has had his or her disability of nonage removed under chapter 743;~~

~~(b) Is in the military reserve or on active duty in the Armed Forces of the United States;~~

~~(c) Is otherwise emancipated by a court of competent jurisdiction and released from parental care and responsibility; or~~

~~(d) Is acting in his or her scope of lawful employment with an entity licensed under the provisions of chapter 210 or this chapter~~.

Section 6. Subsections (1) and (2) of section 569.007, Florida Statutes, are amended to read:

569.007 Sale or delivery of tobacco products; restrictions.—

(1) In order to prevent persons under 21 ~~18~~ years of age from purchasing or receiving tobacco products, the sale or delivery of tobacco products is prohibited, except when the tobacco products are sold from behind a counter and are required to be retrieved and hand delivered by an employee to the consumer. Sales from a vending machine are prohibited. This

section does not apply to an establishment that prohibits persons under 21 years of age on the licensed premises~~:~~

~~(a) When under the direct control or line of sight of the dealer or the dealer's agent or employee; or~~

~~(b) Sales from a vending machine are prohibited under the provisions of paragraph (1)(a) and are only permissible from a machine that is equipped with an operational lockout device which is under the control of the dealer or the dealer's agent or employee who directly regulates the sale of items through the machine by triggering the lockout device to allow the dispensing of one tobacco product. The lockout device must include a mechanism to prevent the machine from functioning if the power source for the lockout device fails or if the lockout device is disabled, and a mechanism to ensure that only one tobacco product is dispensed at a time.~~

~~(2) The provisions of subsection (1) shall not apply to an establishment that prohibits persons under 18 years of age on the licensed premises~~.

Section 7. Section 569.0075, Florida Statutes, is amended to read:

569.0075 Gift of sample tobacco products prohibited.—The gift of sample tobacco products to any person under the age of 21 ~~18~~ by an entity licensed or permitted under ~~the provisions of~~ chapter 210 or this chapter, or by an employee of such entity, is prohibited and is punishable as provided in s. 569.101.

Section 8. Subsections (1), (2), and (3) of section 569.008, Florida Statutes, are amended to read:

569.008 Responsible retail tobacco products dealers; qualifications; mitigation of disciplinary penalties; diligent

management and supervision; presumption.—

(1) The Legislature intends to prevent the sale of tobacco products to persons under 21 ~~18~~ years of age and to encourage retail tobacco products dealers to comply with responsible practices in accordance with this section.

(2) To qualify as a responsible retail tobacco products dealer, the dealer must establish and implement procedures designed to ensure that the dealer's employees comply with ~~the provisions of~~ this chapter. The dealer must provide a training program for the dealer's employees which addresses the use and sale of tobacco products and which includes at least the following topics:

(a) Laws covering the sale of tobacco products.

(b) Methods of recognizing and handling customers under 21 ~~18~~ years of age.

(c) Procedures for proper examination of identification cards in order to verify that customers are not under 21 ~~18~~ years of age.

(d) The use of the age audit identification function on electronic point-of-sale equipment, where available.

~~(3) In determining penalties under s. 569.006, the division may mitigate penalties imposed against a dealer because of an employee's illegal sale of a tobacco product to a person under 18 years of age if the following conditions are met:~~

~~(a) The dealer is qualified as a responsible dealer under this section.~~

~~(b) The dealer provided the training program required under subsection (2) to that employee before the illegal sale occurred.~~

~~(c) The dealer had no knowledge of that employee's violation at the time of the violation and did not direct, approve, or participate in the violation.~~

~~(d) If the sale was made through a vending machine, the machine was equipped with an operational lock-out device.~~

Section 9. Section 569.101, Florida Statutes, is amended to read:

569.101 Selling, delivering, bartering, furnishing, or giving tobacco products to persons under 21 ~~18~~ years of age; criminal penalties; defense.—

(1) It is unlawful to sell, deliver, barter, furnish, or give, directly or indirectly, to any person who is under 21 ~~18~~ years of age, any tobacco product.

(2) Any person who violates subsection (1) commits a noncriminal violation punishable by a fine of not more than $500 ~~misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083~~. However, any person who violates subsection (1) for a second or subsequent time within 1 year of the first violation~~,~~ commits a noncriminal violation punishable by a fine of not more than $1,000 ~~misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083~~.

(3) A person charged with a violation of subsection (1) has a complete defense if, at the time the tobacco product was sold, delivered, bartered, furnished, or given:

(a) The buyer or recipient falsely evidenced that she or he was 21 ~~18~~ years of age or older;

(b) The appearance of the buyer or recipient was such that a prudent person would believe the buyer or recipient to be 21 ~~18~~ years of age or older; and

(c) Such person carefully checked a driver license or an identification card issued by this state or another state of the United States, a passport, or a United States armed services identification card presented by the buyer or recipient and acted in good faith and in reliance upon the representation and appearance of the buyer or recipient in the belief that the buyer or recipient was 21 ~~18~~ years of age or older.

Section 10. Section 569.11, Florida Statutes, is amended to read:

569.11 ~~Possession,~~ Misrepresenting age ~~or military service~~ to purchase~~,~~ and purchasing ~~purchase~~ of tobacco products by persons under 21 ~~18~~ years of age prohibited; penalties; jurisdiction~~; disposition of fines~~.—

~~(1) It is unlawful for any person under 18 years of age to knowingly possess any tobacco product. Any person under 18 years of age who violates the provisions of this subsection commits a noncriminal violation as provided in s. 775.08(3), punishable by:~~

~~(a) For a first violation, 16 hours of community service or, instead of community service, a $25 fine. In addition, the person must attend a school-approved anti-tobacco program, if locally available;~~

~~(b) For a second violation within 12 weeks of the first violation, a $25 fine; or~~

~~(c) For a third or subsequent violation within 12 weeks of the first violation, the court must direct the Department of Highway Safety and Motor Vehicles to withhold issuance of or suspend or revoke the person's driver license or driving privilege, as provided in s. 322.056.~~

~~Any second or subsequent violation not within the 12-week time period after the first violation is punishable as provided for a first violation.~~

(1)~~(2)~~ It is unlawful for any person under 21 ~~18~~ years of age to misrepresent his or her age ~~or military service~~ for the purpose of inducing a dealer or an agent or employee of the dealer to sell, give, barter, furnish, or deliver any tobacco product, or to purchase, or attempt to purchase, any tobacco product from a person or a vending machine. ~~Any person under 18 years of age who violates a provision of this subsection commits a noncriminal violation as provided in s. 775.08(3), punishable by:~~

~~(a) For a first violation, 16 hours of community service or, instead of community service, a $25 fine and, in addition, the person must attend a school-approved anti-tobacco program, if available;~~

~~(b) For a second violation within 12 weeks of the first violation, a $25 fine; or~~

~~(c) For a third or subsequent violation within 12 weeks of the first violation, the court must direct the Department of Highway Safety and Motor Vehicles to withhold issuance of or suspend or revoke the person's driver license or driving privilege, as provided in s. 322.056.~~

~~Any second or subsequent violation not within the 12-week time period after the first violation is punishable as provided for a first violation.~~

~~(3) Any person under 18 years of age cited for committing a~~

~~noncriminal violation under this section must sign and accept a civil citation indicating a promise to appear before the county court or comply with the requirement for paying the fine and must attend a school-approved anti-tobacco program, if locally available. If a fine is assessed for a violation of this section, the fine must be paid within 30 days after the date of the citation or, if a court appearance is mandatory, within 30 days after the date of the hearing.~~

(2)~~(4)~~ A person charged with a noncriminal violation under this section must appear before the county court ~~or comply with the requirement for paying the fine~~. The court, after a hearing, shall make a determination as to whether the noncriminal violation was committed. If the court finds the violation was committed, it shall impose an appropriate penalty as specified in subsection (3).

(3) Any person who violates subsection (1) commits a noncriminal violation and must serve at least 20 hours of community service. Any person who violates subsection (1) a second or subsequent time within 1 year of the first violation commits a noncriminal violation and must serve at least 40 hours of community service ~~(1) or subsection (2). A person who participates in community service shall be considered an employee of the state for the purpose of chapter 440, for the duration of such service.~~

~~(5)(a) If a person under 18 years of age is found by the court to have committed a noncriminal violation under this section and that person has failed to complete community service, pay the fine as required by paragraph (1)(a) or paragraph (2)(a), or attend a school-approved anti-tobacco~~

~~program, if locally available, the court must direct the Department of Highway Safety and Motor Vehicles to withhold issuance of or suspend the driver license or driving privilege of that person for a period of 30 consecutive days.~~

~~(b) If a person under 18 years of age is found by the court to have committed a noncriminal violation under this section and that person has failed to pay the applicable fine as required by paragraph (1)(b) or paragraph (2)(b), the court must direct the Department of Highway Safety and Motor Vehicles to withhold issuance of or suspend the driver license or driving privilege of that person for a period of 45 consecutive days.~~

~~(6) Eighty percent of all civil penalties received by a county court pursuant to this section shall be remitted by the clerk of the court to the Department of Revenue for transfer to the Department of Education to provide for teacher training and for research and evaluation to reduce and prevent the use of tobacco products by children. The remaining 20 percent of civil penalties received by a county court pursuant to this section shall remain with the clerk of the county court to cover administrative costs~~.

Section 11. Paragraph (b) of subsection (2) and subsection (3) of section 569.12, Florida Statutes, are amended to read:

569.12 Jurisdiction; tobacco product enforcement officers or agents; enforcement.—

(2)

(b) A tobacco product enforcement officer is authorized to issue a citation to a person under the age of <u>21</u> ~~18~~ when, based upon personal investigation, the officer has reasonable cause to believe that the person has committed a civil infraction in

violation of s. 386.212 or s. 569.11.

(3) A correctional probation officer as defined in s. 943.10(3) is authorized to issue a citation to a person under the age of 21 ~~18~~ when, based upon personal investigation, the officer has reasonable cause to believe that the person has committed a civil infraction in violation of s. 569.11.

Section 12. Section 569.14, Florida Statutes, is amended to read:

569.14 Posting of a sign stating that the sale of tobacco products to persons under 21 ~~18~~ years of age is unlawful; enforcement; penalty.—

(1) A dealer that sells tobacco products shall post a clear and conspicuous sign in each place of business where such products are sold which substantially states the following:

THE SALE OF TOBACCO PRODUCTS TO PERSONS UNDER THE AGE OF 21 ~~18~~ IS AGAINST FLORIDA LAW. PROOF OF AGE IS REQUIRED FOR PURCHASE.

~~(2) A dealer that sells tobacco products and nicotine products or nicotine dispensing devices, as defined in s. 877.112, may use a sign that substantially states the following:~~

~~THE SALE OF TOBACCO PRODUCTS, NICOTINE PRODUCTS, OR NICOTINE DISPENSING DEVICES TO PERSONS UNDER THE AGE OF 18 IS AGAINST FLORIDA LAW. PROOF OF AGE IS REQUIRED FOR PURCHASE.~~

~~A dealer that uses a sign as described in this subsection meets~~

~~the signage requirements of subsection (1) and s. 877.112.~~

(2)~~(3)~~ The division shall make available to dealers of tobacco products signs that meet the requirements of subsection (1) ~~or subsection (2)~~.

(3)~~(4)~~ Any dealer that sells tobacco products shall provide at the checkout counter in a location clearly visible to the dealer or the dealer's agent or employee instructional material in a calendar format or similar format to assist in determining whether a person is of legal age to be sold ~~purchase~~ tobacco products. This point of sale material must contain substantially the following language:

IF YOU WERE NOT BORN BEFORE THIS DATE
(insert date and applicable year)
YOU CANNOT BE SOLD ~~BUY~~ TOBACCO PRODUCTS.

Upon approval by the division, in lieu of a calendar a dealer may use card readers, scanners, or other electronic or automated systems that can verify whether a person is of legal age to purchase tobacco products. Failure to comply with the provisions contained in this subsection shall result in imposition of administrative penalties as provided in s. 569.006.

(4)~~(5)~~ The division, through its agents and inspectors, shall enforce this section.

(5)~~(6)~~ Any person who fails to comply with subsection (1) is guilty of a misdemeanor of the second degree, punishable as provided in ~~s. 775.082 or~~ s. 775.083.

Section 13. Subsection (4) of section 569.19, Florida Statutes, is amended to read:

569.19 Annual report.—The division shall report annually with written findings to the Legislature and the Governor by December 31, on the progress of implementing the enforcement provisions of this chapter. This must include, but is not limited to:

(4) The number of persons under age 21 ~~18~~ cited for violations of s. 569.11 and sanctions imposed as a result of citation.

Section 14. Section 877.112, Florida Statutes, is repealed.

Section 15. This act shall take effect October 1, 2019.

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:
Judiciary, *Chair*
Appropriations
Appropriations Subcommittee on Education
Community Affairs
Education
Rules

SENATOR DAVID SIMMONS
President Pro Tempore
9th District

MEMORANDUM

To: Senator Gayle Harrell
From: Senator David Simmons
Subject: SB 1618: Tobacco Products
Date: March 21, 2019

I am writing to respectfully request that Senator Debbie Mayfield be allowed to present SB 1618 relating to Tobacco Products, in the Monday, March 25th meeting of the Senate Committee on Health Policy.

I will be delayed in travelling to Tallahassee due to a commitment in Orlando on Monday morning.

Thank you for your consideration.

REPLY TO:
❒ 220 Crown Oak Centre Drive, Longwood, FL 32750 (407) 262-7578
❒ 404 Senate Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5009

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

BILL GALVANO
President of the Senate

DAVID SIMMONS
President Pro Tempore

THE FLORIDA SENATE

APPEARANCE RECORD

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

3/25/19
Meeting Date

1618
Bill Number (if applicable)

Topic Tobacco

Amendment Barcode (if applicable)

Name Mark Landreth

Job Title Gov't Relations Director

Address 2851 Remington Green Circle #A
Street

Phone 850.544.3376

Tallahassee FL 32308
City *State* *Zip*

Email mark.landreth@heart.org

Speaking: ☑ For ☐ Against ☐ Information

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

Representing American Heart Association

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

3/25
Meeting Date

1618
Bill Number (if applicable)

Topic TO BE ADDED

Amendment Barcode (if applicable)

Name Rivers Buford III

Job Title Govt Relations

Address 2851 Remington Green
Street

Phone

Tallahassee FL 32308
City *State* *Zip*

Email Rivers.BufordIII@

Speaking: ☐ For ☐ Against ☐ Information

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

Representing American Heart Assn

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☐ No

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S-001 (10/14/14)

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APPEARANCE RECORD

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3/25/19
Meeting Date

SB 1618
Bill Number (if applicable)

Topic Tobacco Products

Amendment Barcode (if applicable)

Name Alexandra Abboud

Job Title Governmental Affairs Liaison

Address 118 E. Jefferson st
Street

Tallahassee FL 32301
City *State* *Zip*

Phone (850)224-1089

Email Aabboud@floridadental.org

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

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

Representing Florida Dental Association

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

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

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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3/25/19
Meeting Date

1618
Bill Number (if applicable)

Topic Tobacco Products

Amendment Barcode (if applicable)

Name Fely Curva, Ph. D.

Job Title Senior Partner, Curva & Assoc. LLC

Address 1212 Piedmont Dr.
Street

Phone (850)508-2256

Tallahassee FL 32312
City *State* *Zip*

Email fely.curva@gmail.com

Speaking: ☑ For ☐ Against ☐ Information

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

Representing SHAPE Florida; Budd Bell Clearinghouse on Human Services

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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3/25/2019
Meeting Date

SB 1618
Bill Number (if applicable)

Topic Tobacco Products

Amendment Barcode (if applicable)

Name Khanh-Lien (Con Lyon) Banko

Job Title Resolutions Chair

Address 1747 Orlando Central Parkway
Street

Phone (407) 855-7604

Orlando, FL 32809
City *State* *Zip*

Email resolutions@floridapta.org

Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida PTA

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☐ Yes ☑ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

3/25/19
Meeting Date

1618
Bill Number (if applicable)

Topic Tobacco Products - 21

Amendment Barcode (if applicable)

Name Marnie George

Job Title Sr. Advisor, Buchanan Ingersoll & Rooney

Address 101 North Monroe Street
Street

Phone 850 510-8866

Tallahassee FL 32303
City *State* *Zip*

Email marnie.george@bipc.com

Speaking: ☐ For ☐ Against ☐ Information

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

Representing FL Chapter, American College of Cardiology

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

3-25-19
Meeting Date

SB 1618
Bill Number (if applicable)

Topic TOBACCO PRODUCTS

Amendment Barcode (if applicable)

Name CHIP CASE

Job Title LOBBYIST FOR AMERICAN CANCER SOCIETY

Address 317 E. PARK AVE.
Street

Phone 850-544-2222

TALLAHASSEE FL 32301
City *State* *Zip*

Email chip@capadvocates.com

Speaking: ☐ For ☐ Against ☐ Information

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

Representing AMERICAN CANCER SOCIETY

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

3/25/19
Meeting Date

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

SB 1018
Bill Number (if applicable)

Topic Tobacco 21

Amendment Barcode (if applicable)

Name Jennifer ~~Lauren~~ Cunningham

Job Title Southeast Regional Manager - State Govt. Affairs ~~JUUL Labs~~

Address 560 20th St.
Street

Phone 404-290-4231

San Francisco CA 94107
City *State* *Zip*

Email jennifer.cunningham@juul.com

Speaking: ☑ For ☐ Against ☐ Information

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

Representing JUUL Labs

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE

Reset Form

APPEARANCE RECORD

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

3/25/2019
Meeting Date

SB 16-19
Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name Michael J. Boling Jr.

Job Title Small Business Owner / DOO of Rock Bottom Bottles

Address 8114 Villa Coronado Court
Street

Sarasota, FL 34243
City *State* *Zip*

Phone _____

Email _____

Speaking: ☐ For ☐ Against ☒ Information

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

Representing _____

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☐ No

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

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

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

Reset Form

03/25/2019 (Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting) SB 618

Meeting Date *Bill Number (if applicable)*

Topic _____ *Amendment Barcode (if applicable)*

Name Adrien Ryan Taylor

Job Title _____

Address 8114 Villa Grande ct. Phone (941)807-3412

Street

Sarasota FL 34243 Email adrienSCT@hotmail.com

City *State* *Zip*

Speaking: ☐ For ☐ Against ☒ Information

Waive Speaking: ☐ In Support ☐ Against

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

Representing _____

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

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

Reset Form

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

3/25
Meeting Date

SB1618
Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name Cheryl Lockhart

Job Title Mom, grandmother

Address 4122 Woodacre RW
Street

Tampa, FL 33624
City *State* *Zip*

Phone 304-989-9116

Email CLockhart5567@gmail.com

Speaking: ☐ For ☐ Against ☒ Information

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

Representing _____

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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S-001 (10/14/14)

THE FLORIDA SENATE

Reset Form

APPEARANCE RECORD

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

3-25-19
Meeting Date

SB 1618
Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name JD McCormick

Job Title Owner - Entrepreneur

Address 6265 Old Water Oak Rd #102-B
Street

Phone 407-508-0340

Tallahassee FL 32312
City *State* *Zip*

Email jdmlpv1@gmail.com

Speaking: ☐ For ☐ Against ☑ Information

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

Representing _____

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☐ Yes ☑ No

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S-001 (10/14/14)

THE FLORIDA SENATE

Reset Form

APPEARANCE RECORD

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

3-25-19
Meeting Date

SB 1618
Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name Shannon Whitesell

Job Title _____

Address 3836 Parkside Dr
Street

Valrico FL 33594
City *State* *Zip*

Phone 813-454-1233

Email SmWhitesell@hotmail.com

Speaking: ☐ For ☐ Against ☒ Information

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

Representing _____

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☐ No

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S-001 (10/14/14)

THE FLORIDA SENATE

Reset Form

APPEARANCE RECORD

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

3/25/19
Meeting Date

SB 1618
Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name Jonathan Risteen

Job Title Business Owner

Address 141 Flamingo Rd
Street

Edgewater FL 32141
City *State* *Zip*

Phone 407 489 5944

Email info@gentlemensdraw.com

Speaking: ☐ For ☐ Against ☒ Information

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

Representing _____

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☐ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

Reset Form

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

3/25/19
Meeting Date

SB 1618
Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name Robert Lovett

Job Title Florida Smoke Free Association - President

Address 4001 Conway Place Circle
Street

Phone 352-281-4913

Orlando FL 32812
City *State* *Zip*

Email _____

Speaking: ☐ For ☐ Against ☑ Information

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

Representing _____

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☐ Yes ☑ No

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S-001 (10/14/14)

THE FLORIDA SENATE

Reset Form

APPEARANCE RECORD

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

3-25-19
Meeting Date

SB1618
Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name Cindi Kinch

Job Title Mom

Address 370 GBay Oak Dr
Street

Tarpon Springs Fl 34689
City *State* *Zip*

Phone 727-504-7773

Email CindiKinch@Gmail.com

Speaking: ☐ For ☐ Against ☒ Information

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

Representing _____

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

Reset Form

3/25/19
Meeting Date

SB 1618
Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name Delorse Orlando

Job Title self-employed.

Address 2812 Edenwood St.
Street

Clwtr, FL 33759
City *State* *Zip*

Phone 727-692-6452

Email delorse1@msn.com

Speaking: ☐ For ☐ Against ☑ Information

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

Representing _____

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☐ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

Reset Form

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

3-25-16
Meeting Date

SB 1618
Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name Anthony Nicholas

Job Title Self-employed

Address 3066 englewood dr
Street

Phone 727-421-3847

largo FL 33771
City *State* *Zip*

Email Anthony@CoinBetter.com

Speaking: ☐ For ☐ Against ☒ Information

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

Representing _____

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☐ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

Mar 25, 2019
Meeting Date

1618
Bill Number (if applicable)

Topic Tobacco / driver's license suspensions

Amendment Barcode (if applicable)

Name Dan Hendrickson

Job Title president

Address 319 E Park Ave
Street

Phone 850 570-1967

Tallahassee — Fl — 32301
City — *State* — *Zip*

Email danbhendrickson@comcast.net

Speaking: ☐ For ☐ Against ☐ Information

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

Representing TALLAHASSEE VETERANS LEGAL COLLABORATIVE

Appearing at request of Chair: ☐ Yes ☑ No

Lobbyist registered with Legislature: ☐ Yes ☑ No

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

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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

3/25/19
Meeting Date

1618
Bill Number (if applicable)

Topic Tobacco 21

Amendment Barcode (if applicable)

Name Georgia McKeown

Job Title Consultant - American Cancer Society

Address 501 E PARK AVE
Street
Tallahassee FL 3230
City *State* *Zip*

Phone 904 303 1611

Email georgiae@amcs.org

Speaking: ☐ For ☐ Against ☐ Information

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

Representing ACS

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☑ Yes ☐ No

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S-001 (10/14/14)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	SB 846
INTRODUCER:	Senator Pizzo
SUBJECT:	HIV Prevention
DATE:	March 22, 2019
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Brown	HP	**Pre-meeting**
2.			ACJ	
3.			AP	

I. Summary:

SB 846 revises provisions of law regarding the behavior of persons who are human immunodeficiency virus (HIV) positive and other persons concerning disease status. The bill:

- Reduces the offense of engaging in sex while knowingly HIV positive without the informed consent of the sexual partner from a third degree felony to a first degree misdemeanor;
- Requires the state to prove additional elements to convict for the crime of transmitting a sexually transmitted disease (STD), including:
  - Intent;
  - Conduct imposing a substantial risk of transmission of a specified STD; and
  - Actual transmission of a specified STD.
- Provides that a good faith effort to comply with a treatment regimen or behavioral recommendations is an affirmative defense to the charge of intending to transmit an STD and provides that a lack of compliance with a treatment regime or behavioral recommendations, alone, is insufficient to establish intent;
- Keeps the non-disclosure of HIV status in connection with prostitution a third degree felony, making the offence more severe than a first-time non-disclosure offense not connected with prostitution;
- Removes the donation of blood, plasma, organs, skin, or other human tissue from the list of specified offenses involving the transmission of bodily fluids that require mandatory Hepatitis and HIV testing at a victim's request in certain situation;
- Permits the donation of blood, plasma, organs, skin, or other human tissue by a person with HIV if a licensed physician deems the donation "medically appropriate";
- Reduces the offense of donation of blood, plasma, organs, skin, or other human tissue by a person with an STD, when not deemed medically appropriate, from a third degree felony to a first degree misdemeanor;
- Downgrades from a third degree felony to a first degree misdemeanor the offenses of:

  - Maliciously spreading of any false information concerning a person's STD status; and,
  - Maliciously spreading information regarding a person's STD status for monetary gain;
- Deletes the civil penalty for violating the Department of Health (DOH) rules regarding STDs; and,
- Makes conforming changes to the Criminal Punishment Code severity ranking.

The bill is effective July 1, 2019.

II. Present Situation:

The Human Immunodeficiency Virus (HIV)

HIV is a virus that can lead to acquired immunodeficiency syndrome (AIDS) if not treated. Unlike some other viruses, the human body cannot get rid of HIV completely, even with treatment. Once you get HIV, you have it for life.[1]

HIV is spread through specific activities that result in contact with an infected person's blood, other bodily fluids, mucous membranes, or damaged tissue.[2] In the United States, HIV is mainly transmitted through unprotected anal or vaginal sex and the sharing of needles and syringes, rinse water, or other equipment used to prepare drugs for injection.[3] Less common methods of HIV transmission are through:

- The passage of HIV from mother to child during pregnancy;
- Childbirth;
- Breastfeeding; and
- Being pierced with an HIV-contaminated needle or other sharp object.[4]

Rare methods of HIV transmission include the following activities with an untreated HIV positive person:

- Oral sex;
- Transfusion of blood and blood products;
- Organ or tissue transplants contaminated with HIV;
- Eating food that has been pre-chewed by a person with HIV;
- Human bites that break the skin by an HIV positive person;
- Contact with open wounds or mucus membranes of an HIV positive person; and
- Deep, open-mouth kissing if both persons have mouth sores or bleeding gums.[5]

HIV does not survive long outside the human body, such as on surfaces, and it cannot reproduce outside a human host. HIV is not spread by:

- Mosquitoes, ticks, or other insects;
- Saliva, tears, or sweat that is not mixed with the blood of an HIV positive person;

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[1] Center for Disease Control and Prevention, *About HIV/AIDS,* (page updated March 1, 2019) *available at* https://www.cdc.gov/hiv/basics/whatishiv.html (last visited Mar. 21, 2019).
[2] Centers for Disease Control and Prevention, *HIV Transmission,* (page updated October 31, 2018) *available at* https://www.cdc.gov/hiv/basics/transmission.html (last visited Mar. 21, 2019).
[3] *Id.*
[4] *Id.*
[5] *Id.*

- Hugging, shaking hands, sharing toilets, sharing dishes, or closed-mouth kissing with someone who is HIV positive; or
- Other sexual activities that does not involve the exchange of body fluids.

Once transmitted, HIV attacks the infected person's immune system, specifically, the lymphocytes known as CD4 cells or T Cells, which participate in an immune response.[6] Untreated, HIV reduces a body's ability to fight off infections and disease and can lead to AIDS, the most severe form of HIV infection.[7] There is no effective cure for HIV, but antiretroviral therapy (ART) can slow or prevent the disease's progression and dramatically prolong the lifespan of an infected person.[8] When treated, an infected person can expect to live nearly as long as a person without HIV.[9] Antiretroviral therapy can also reduce the amount of HIV in a person's blood, known as the viral load.[10] Persons who attain an undetectable viral load have effectively no risk of transmitting HIV through sexual conduct.[11]

In the United States, about 51 percent of an estimated 1.1 million people with HIV[12] had achieved an undetectable viral load by the end of 2015.[13] In Florida, 62 percent of the 116,944 people living with HIV[14] had achieved an undetectable viral load.[15]

National Criminal HIV Exposure Laws

Nearly two-thirds of all states criminalize certain conduct related to HIV exposure.[16] Such laws attempt to deter HIV transmission by:

- Criminalizing behaviors that result in HIV exposure;
- Criminalizing behaviors that result in STD or other communicable or infectious disease exposure, which may include HIV exposure;
- Increasing sentence lengths for certain crimes committed by a person infected with HIV; and

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[6] Centers for Disease Control and Prevention, *About HIV/AIDS*, (March 1, 2019) *available at* https://www.cdc.gov/hiv/basics/whatishiv.html (last visited Mar. 21, 2019).
[7] *Id.*
[8] *Id.*
[9] Centers for Disease Control and Prevention, *HIV Care Saves Lives infographic*, *available at* https://www.cdc.gov/vitalsigns/hiv-aids-medical-care/infographic.html (last visited Mar. 21, 2019).
[10] S*upra* note 6.
[11] *Id.*
[12] The annual number of new HIV diagnoses in the United States remained stable between 2012 and 2017, with 2017 resulting in approximately 38,739 new HIV diagnoses. Centers for Disease Control and Prevention, *HIV in the United States and Dependent Areas* (January 2019), *available at* https://www.cdc.gov/hiv/pdf/statistics/overview/cdc-hiv-us-ataglance.pdf (last visited Mar. 21, 2019).
[13] Centers for Disease Control and Prevention, *HIV in the United States and Dependent Areas*, (January 2019) *available at* https://www.cdc.gov/hiv/pdf/statistics/overview/cdc-hiv-us-ataglance.pdf (last visited Mar. 21, 2019).
[14] Florida reported an estimated 4,949 new HIV diagnoses in 2017. Florida Department of Health, *HIV Data Center*, (Nov 28, 2018) *available at* http://www.floridahealth.gov/diseases-and-conditions/aids/surveillance/index.html (last visited Mar. 21, 2019).
[15] Florida Department of Health, *HIV Data Center*, *available at* http://www.floridahealth.gov/diseases-and-conditions/aids/surveillance/index.html (last visited Mar. 21, 2019).
[16] J. Stan Lehman, et al., *Prevalence and Public Health Implications of State Laws that Criminalize Potential HIV Exposure in the United States*, AIDS and Behavior (March 15, 2014), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4019819/ (last visited Mar. 21, 2019).

- Increasing sentence lengths for certain crimes committed by a person infected with an STD, which may include HIV.[17]

Additionally, all 50 states have general criminal laws, such as assault, battery, reckless endangerment, and attempted murder, under which the state can prosecute a person with HIV for engaging in certain behaviors.[18]

Opponents of criminal HIV exposure laws argue that such laws can lead to unintended consequences by:
- Encouraging the deferral of HIV testing;
- Reinforcing hostility towards HIV-positive persons;
- Exacerbating HIV-related stigma; and
- Deterring HIV-positive status disclosure.[19]

Opponents also point out that most criminal HIV exposure laws do not account for scientifically supported risk levels associated with the type of activity the offender engages in or any risk reduction measures. As a result, these laws may criminalize behaviors that the federal Center for Disease Control and Prevention (CDC) regards as posing little or no risk for HIV transmission.[20] In light of scientific advancements in HIV treatment and prevention, the United States Department of Justice (DOJ) recommends that states reform HIV criminal exposure laws to eliminate HIV-specific penalties, except when a person knows he or she is HIV positive and:
- Commits a sex crime with the risk of transmission (e.g., rape or other sexual assault);
- Evidence clearly demonstrates that the person intended to transmit HIV; and
- The person's behavior posed a significant risk of transmission.[21]

Florida Law

STDs and Non-Disclosure

Under Florida law, a person commits a third degree felony[22] if the person knows he or she has HIV, has been informed of the risk of transmission through sexual intercourse, and has sexual intercourse with another person, unless that person consented with knowledge of the diagnosis.[23] A person commits a first degree felony[24] for a second or subsequent non-disclosure offense.[25]

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[17] Centers for Disease Control and Prevention, *HIV and STD Criminal Laws*, (November 30, 2018) *available at* https://www.cdc.gov/hiv/policies/law/states/exposure.html (last visited Mar. 21, 2019).
[18] *Id.*
[19] C. Galletly, Z. Lazzarini, C. Sanders, and S.D. Pinkerton, *Criminal HIV Exposure Laws: Moving Forward*, AIDS and Behavior (June 2014), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4084714/ (last visited Mar. 21, 2019).
[20] U.S. Department of Justice (DOJ), *Best Practice Guide to Reform HIV-Specific Criminal Laws to Align with Scientifically-Supported Factors*, *available at* https://www.hivlawandpolicy.org/sites/default/files/DOj-HIV-Criminal-Law-Best-Practices-Guide.pdf (last visited Mar. 21, 2019).
[21] *Id.*
[22] A third degree felony is punishable by up to 5 years imprisonment and a $5,000 fine. *See* ss. 775.082(3)(e) and 775.083(1)(c), F.S.
[23] Sections 384.24(2) and 384.34(5), F.S.
[24] A first degree felony is punishable by up to 30 years imprisonment and a $10,000 fine. *See* ss. 775.082(3)(b)1. and 775.083(1)(b), F.S.
[25] *Id.*

Conviction for a non-disclosure offense does not require the intent to transmit or the actual transmission of HIV.

Florida law does not currently define "sexual intercourse." However, the Florida Supreme Court has defined sexual intercourse to include penile-vaginal penetration and acts of oral and anal intercourse.[26]

Penalties for Sex Workers

A person who engages in sexual activity for hire, except as between spouses, commits the offense of prostitution.[27] The severity of the offense depends in part on the existence of any prior conviction for prostitution. Prostitution is a second degree misdemeanor for a first offense;[28] a first degree misdemeanor for a second offense;[29] and a third degree felony for a third or subsequent offense.[30] A person convicted of prostitution must undergo STD screening, including HIV screening.[31]

A person who commits or offers to commit prostitution, or who procures another for prostitution by engaging in sexual activity in a manner likely to transmit HIV, commits a third degree felony if, prior to the offense, he or she tested positive for HIV and was informed of the positive result and the risk of transmission through sexual activity.[32] An offender may be convicted of, and sentenced separately for, this offense and for prostitution.[33] A conviction for this offense does not require the intent to transmit or the actual transmission of HIV.

Criminal Transmission of HIV

A person convicted of committing or attempting to commit a specified offense involving the transmission of bodily fluids from one person to another must undergo HIV testing.[34] Specified offenses include:[35]

- Sexual battery;[36]
- Incest;[37]
- Lewd or lascivious offenses on a person under 16;[38]
- Assault[39] or aggravated assault;[40]

[26] *Debaun v. State*, 213 So. 3d 747 (Fla. 2017), Supreme Ct. Case # SC13-2336, *available at* http://onlinedocketssc.flcourts.org/ (last visited Mar. 21, 2019).
[27] Section 796.07(1)(a), F.S.
[28] A second degree misdemeanor is punishable by up to 60 days in jail and a $500 fine. *See* ss. 775.082(4)(b) and 775.083(1)(e), F.S.
[29] A first degree misdemeanor is punishable by up to 1 year in jail and a $1,000 fine. *See* ss. 775.082(4)(a) and 775.083(1)(d), F.S.
[30] Section 796.07(4)(a)1.- 3., F.S.
[31] Section. 775.0877(1), F.S.
[32] Section. 796.08(5)(a)-(b), F.S.
[33] Section 775.0877(5), F.S.
[34] Section 775.0877(1), F.S.
[35] *Id.*
[36] Section 794.011, F.S.
[37] Section 826.04, F.S.
[38] Section 800.04, F.S.
[39] Sections 784.011, 784.07(2)(a), and 784.08(2)(d), F.S.
[40] Sections 784.021, 784.07(2)(c), and 784.08(2)(b), F.S.

- Battery[41] or aggravated battery;[42]
- Child abuse[43] or aggravated child abuse;[44]
- Abuse of an elderly person or disabled adult[45] or aggravated abuse of an elderly person or disabled adult;[46]
- Sexual performance of a minor;[47]
- Prostitution;[48]
- Human trafficking;[49] and
- Donation of blood, plasma, organs, skin, or other human tissue under certain conditions.[50]

A person who tests positive for HIV following a conviction for a specified offense, who is informed of the result, and who later commits another specified offense, commits criminal transmission of HIV.[51] An offender may be convicted of, and sentenced separately for, criminal transmission of HIV and for the underlying offense.[52] A conviction for criminal transmission of HIV does not require the intent to transmit or the actual transmission of HIV.[53]

Court-Ordered Hepatitis and HIV Testing

At the request of a victim,[54] a court must order an offender charged with the commission of a specified offense to undergo Hepatitis and HIV testing if the offense:

- Involves the transmission of bodily fluids from one person to another;[55] or
- Is a sexual offense and the victim was a minor, a disabled adult, or an elderly person.[56]

The specified offenses include all the offenses that form the basis for a conviction of criminal transmission of HIV, except human trafficking.[57]

Organ, Blood, Plasma, Skin and Tissue Donation

Due to increased life expectancy, the number of HIV-positive persons in need of organ transplants has increased.[58] However, the number of people on the organ transplant waiting list

[41] Sections 784.03, 784.07(2)(b), 784.08(2)(c), F.S.
[42] Sections 784.045, 784.07(2)(d), and 784.08(2)(a), F.S.
[43] Section 827.03(2)(c), F.S.
[44] Section 827.03(2)(a), F.S.
[45] Section 825.102(1), F.S.
[46] Section 825.102(2), F.S.
[47] Section 827.071, F.S.
[48] Sections 796.07 and 796.08, F.S.
[49] Sections 787.06(3)(b), (d), (f), and (g), F.S.
[50] Section 381.0041(11)(b), F.S.
[51] Section 775.0877(3), F.S.
[52] *Id.*
[53] Section. 775.0877(5), F.S.
[54] A request may also come from a victim's legal guardian or the parents of a minor victim pursuant to s. 960.003, F.S.. *See* s. 775.0877(2), F.S.
[55] Section. 960.003(2)(a), F.S.
[56] Section 960.003(2)(b), F.S.
[57] *Id.*
[58] Christine Durand, M.D., *The Transformation of Transplantation*, HIV Specialist (July 2018), *available at* https://aahivm.org/wp-content/uploads/2018/07/FINALHIVspecialist_July2018FINAL-1.pdf (last visited Mar. 21, 2019).

far outweighs the number of available organs.[59] This shortage disproportionately affects persons with HIV, who have a higher mortality rate than persons without HIV on the organ transplant waiting list.[60]

For decades, federal law prohibited persons with HIV from donating organs for transplantation, even to HIV-positive recipients.[61] However, in 2013, the HIV Organ Policy Equity (HOPE) Act legalized HIV-positive organ donations for transplantation into HIV-positive candidates under approved research protocols designed to evaluate the feasibility, effectiveness, and safety of such organ transplants.[62]

Although authorized by federal law, it is a third degree felony in Florida for an HIV-positive person to donate blood, plasma, organs, skin, or other human tissue when he or she knew of the HIV infection and was informed that transmission could occur through such donation.[63] Florida prohibits HIV-positive persons from donating human tissue to other HIV-positive recipients or as part of a clinical research study.[64]

Release of Information

A person who maliciously disseminates any false information or report about the existence of any STD, including HIV, commits a third degree felony.[65] A person who obtains information identifying a person with an STD, including HIV, who knew or should have known the nature of the information and who maliciously, or for monetary gain, spreads such information to anyone other than a physician or a nurse employed by the DOH or to a law enforcement agency, commits a third degree felony.[66]

The DOH promulgates rules regulating STD testing, confidentiality of information, disease reporting, quarantine orders, and notification requirements.[67] A person who violates DOH rules related to STDs[68] is subject to a $500 fine for each violation.[69] The DOH can impose the fine in addition to other penalties provided by ch. 384, F.S.[70]

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[59] *Id.*
[60] *Id.*
[61] UNOS, *At Two Years, HOPE Act Still Offering Hope*, (December 1, 2017) *available at* https://unos.org/at-two-years-hope-act-still-offering-hope/ (last visited Mar. 21, 2019).
[62] *Id.*
[63] Section. 381.0041(11)(b), F.S.
[64] *Id.*
[65] Section 384.34(3), F.S.
[66] Section 384.34(6), F.S.
[67] Rule 64D-3, F.A.C.
[68] For example, Rule 64D-3.029, F.A.C., requires practitioners, hospitals, and laboratories to report to DOH diseases or conditions identified by DOH as being of public health significance, including HIV, within specified timeframes.
[69] Section 384.34(4), F.S.
[70] *Id.* Other penalties include criminal misdemeanor penalties for violations of s. 384.29, F.S., relating to the confidentiality of information and records held by DOH, and for violations of s. 384.26, F.S., relating to the confidentiality of information gathered by DOH during an investigation into the source and spread of an STD.

III. Effect of Proposed Changes:

Sexually Transmitted Disease Definitions

SB 846 defines three terms previously undefined by in ch. 384, F.S., Sexually Transmitted Diseases. The definition for "sexual conduct," is similar to that set forth by the Florida Supreme Court in DeBaun.[71] The bill defies the term as conduct between persons, regardless of gender, which is capable of transmitting a sexually transmissible disease, including, but not limited to, contact between a:

- Penis and a vulva or an anus; or
- Mouth and a penis, a vulva, or an anus.

The bill defines "substantial risk of transmission" as a reasonable probability of disease transmission as proven by competent medical or epidemiological evidence. The bill also defines the term "behavioral recommendations" to include, but not be limited to, the use of a prophylactic device to limit the risk of transmission of the disease. Under the bill, evidence of the person's failure to comply with such a treatment regimen or such behavioral recommendations is not, in and of itself, sufficient to establish that he or she acted with intent.

STDs and Non-Disclosure

The bill amends ss. 384.24 and 384.34, F.S., to replace the undefined phrase, "sexual intercourse" with the defined phrase "sexual conduct" and to reduce the offense of engaging in sex while knowingly HIV positive without the informed consent of the other party from a third degree felony to a first degree misdemeanor. This change makes non-disclosure of HIV the same offense level as non-disclosure of other enumerated STDs. However, the bill makes a second or subsequent non-disclosure offense under s. 384.24, F.S., for any enumerated STD a third degree felony.

The bill requires the state to prove additional elements for a conviction under s. 384.24, F.S., including that the offender:

- Acted with intent to transmit HIV or another specified STD;
- Engaged in conduct that imposed a substantial risk of transmission of HIV or another specified STD when the other person was unaware of the HIV or specified STD diagnosis; and,
- Actually transmitted HIV or another specified STD.

Finally, the bill specifies that a person does not act with the intent to transmit HIV or a specified STD if he or she:

- In good faith complies with a prescribed treatment regimen or with the behavioral recommendations of a health care provider or public health officials to limit the risk of transmission; or
- Offers to comply with such behavioral recommendations but the sexual partner rejects the offer.

[71] See note 27.

The bill defines "behavioral recommendations" to include the use of a prophylactic device, such as a condom, and specifies that evidence of person's failure to comply with a treatment regimen or behavioral recommendations does not, in and of itself, constitute sufficient evidence of intent to transmit HIV or another specified STD.

Penalties for Sex Workers

Under the bill, the non-disclosure of HIV in connection with prostitution remains a third degree felony. As a result, the bill makes the non-disclosure of HIV in connection with prostitution a more severe offense than a first-time non-disclosure of HIV offense not connected with prostitution, now reduced to a first degree misdemeanor. Further, a conviction under this section still does not require the intent to transmit or the actual transmission of HIV, though these elements are required for conviction of a non-disclosure offense not involving prostitution.

Criminal Transmission of HIV

The bill removes the donation of blood, plasma, organs, skin, or other human tissue from the list of specified offenses in s. 775.0877, F.S. As a result, a person convicted of donation of human tissue by an HIV positive person does not have to submit to HIV testing as part of his or her sentence, and a second or subsequent offense would not constitute criminal transmission of HIV.

However, a second or subsequent conviction for any of the remaining enumerated crimes constitutes criminal transmission of HIV, a third degree felony. A conviction for this offense still does not require the intent to transmit or the actual transmission of HIV.

Court-Ordered Hepatitis and HIV Testing

The bill deletes all references to s. 775.0877(1)(n), F.S., from the list of offenses that qualify for mandatory Hepatitis and HIV testing at a victim's request if:

- The offense involves the transmission of bodily fluids from one person to another; or
- The offense is a sexual offense and the victim was a minor, a disabled adult, or an elderly person.

In effect, the commission of an offense involving the donation of human tissue by a person with HIV would not subject the offender to court-ordered Hepatitis or HIV testing at the request of a victim under this section. However, the donated tissue would still be tested for STDs and other communicable diseases.[72]

Organ, Blood, Plasma, Skin and Tissue Donation

The bill amends s. 381.0041, F.S., to permit the donation of blood, plasma, organs, skin, or other human tissue by a person with HIV if a licensed physician deems the donation "medically appropriate," but does not define what is "medically appropriate." This may authorize persons with HIV to donate human tissue to other persons with HIV, or even non-HIV patients, and to participate in clinical research trials authorized by the HOPE Act.

[72] Section 381.0041(1), F.S.

The bill also reduces the offense level for the donation of blood, plasma, organs, skin, or other human tissue by a person with HIV when not deemed medically appropriate by a licensed physician from a third degree felony to a first degree misdemeanor. The severity of the offense for unauthorized tissue donation by an HIV positive person aligns with most other HIV exposure offenses.

Release of Information

The bill amends s. 384.34, F.S., to downgrade from a third degree felony to a first degree misdemeanor the offenses of:

- Maliciously spreading any false information or report concerning the existence of any STD, including HIV; and
- Maliciously or for monetary gain spreading information identifying an individual with an STD, including HIV, when the offender knew or should have known the nature of the information.

The bill deletes the $500 civil penalty for violating DOH rules regarding STDs.

Criminal Severity Ranking Chart

The bill amends s. 921.0022, F.S., to conform the Criminal Punishment Code offense severity ranking chart[73] to changes made by the bill. Specifically, the HIV related offenses reduced by the bill from felonies to first degree misdemeanors are removed from the chart.[74]

The bill is effective July 1, 2019.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

[73] The Criminal Punishment Code offense severity ranking chart sets forth 10 offense levels, ranked from least severe (level 1) to most severe (level 10). Each felony offense is assigned to an offense level according to the severity of the offense, and each offense level corresponds to a point value used to determine whether a felony offender must serve time in a state prison.
[74] As a misdemeanor offender will not serve time in a state prison, misdemeanor offenses are not ranked and do not appear in the chart. *See* ss. 775.082, 775.083, and 921.0022, F.S.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

The Department of Corrections may experience a minimal financial impact for technology modifications due to the changes on the CPC severity ranking chart. The cost would likely be absorbed by existing resources.[75]

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 381.0041, 384.23, 384.24, 384.34, 775.0877, 921.0022, and 960.003.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.

[75] Department of Corrections *(Senate Bill 846 Fiscal Analysis)* (Mar. 15, 2019) (on file with the Senate Committee on Health Policy).

By Senator Pizzo

38-01286-19 2019846__

A bill to be entitled

An act relating to HIV prevention; providing a short title; amending s. 381.0041, F.S.; providing an exception to allow the donation of human tissue by a person who has human immunodeficiency virus infection under certain circumstances; reclassifying a criminal offense relating to such donations; amending s. 384.23, F.S.; providing definitions; amending s. 384.24, F.S.; expanding the scope of unlawful acts by a person infected with a sexually transmissible disease; expanding the list of sexually transmissible diseases to include human immunodeficiency virus infection; providing that certain actions are not sufficient evidence to establish intent on the part of the person who transmits the disease; providing a definition; amending s. 384.34, F.S.; reclassifying specified criminal offenses; removing a fine for specified rule violations; amending ss. 775.0877 and 921.0022, F.S.; conforming provisions to changes made by the act; amending s. 960.003, F.S.; conforming cross-references; providing an effective date.

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

Section 1. <u>This act may be cited as the "HIV Prevention Justice Act."</u>

Section 2. Paragraph (b) of subsection (11) of section 381.0041, Florida Statutes, is amended to read:

381.0041 Donation and transfer of human tissue; testing

requirements.—

(11)

(b) Except when the donation is deemed medically appropriate by a licensed physician, any person who has human immunodeficiency virus infection, who knows he or she is infected with human immunodeficiency virus, and who has been informed that he or she may communicate this disease by donating blood, plasma, organs, skin, or other human tissue who donates blood, plasma, organs, skin, or other human tissue commits ~~is guilty of~~ a misdemeanor ~~felony~~ of the first ~~third~~ degree, punishable as provided in s. 775.082 or~~,~~ s. 775.083~~, or s. 775.084~~.

Section 3. Subsection (3) of section 384.23, Florida Statutes, is renumbered as subsection (4) and a new subsection (3) and subsection (5) are added to that section, to read:

384.23 Definitions.—

(3) "Sexual conduct" means conduct between persons, regardless of gender, which is capable of transmitting a sexually transmissible disease, including, but not limited to, contact between a:

(a) Penis and a vulva or an anus; or

(b) Mouth and a penis, a vulva, or an anus.

(5) "Substantial risk of transmission" means a reasonable probability of disease transmission as proven by competent medical or epidemiological evidence.

Section 4. Section 384.24, Florida Statutes, is amended to read:

384.24 Unlawful acts.—

(1) It is unlawful for any person who has chancroid,

gonorrhea, granuloma inguinale, lymphogranuloma venereum, genital herpes simplex, chlamydia, nongonococcal urethritis (NGU), pelvic inflammatory disease (PID)/acute salpingitis, ~~or~~ syphilis, or human immunodeficiency virus infection, when such person knows he or she is infected with one or more of these diseases and when such person has been informed that he or she may communicate this disease to another person through sexual conduct ~~intercourse~~, to act with the intent to transmit the disease, to engage in ~~have~~ sexual conduct that poses a substantial risk of transmission to another person when the ~~intercourse with any~~ other person is unaware that the person is a carrier of the disease, and to transmit the disease to the~~,~~ ~~unless such~~ other person ~~has been informed of the presence of the sexually transmissible disease and has consented to the sexual intercourse~~.

(2) A person does not act with the intent set forth in subsection (1) if he or she in good faith complies with a treatment regimen prescribed by his or her health care provider or with the behavioral recommendations of his or her health care provider or public health officials to limit the risk of transmission, or if he or she offers to comply with such behavioral recommendations, but such offer is rejected by the other person with whom he or she is engaging in sexual conduct. For purposes of this section, the term "behavioral recommendations" includes, but is not limited to, the use of a prophylactic device to limit the risk of transmission of the disease. Evidence of the person's failure to comply with such a treatment regimen or such behavioral recommendations is not, in and of itself, sufficient to establish that he or she acted with

the intent set forth in subsection (1) ~~It is unlawful for any person who has human immunodeficiency virus infection, when such person knows he or she is infected with this disease and when such person has been informed that he or she may communicate this disease to another person through sexual intercourse, to have sexual intercourse with any other person, unless such other person has been informed of the presence of the sexually transmissible disease and has consented to the sexual intercourse~~.

Section 5. Section 384.34, Florida Statutes, is amended to read:

384.34 Penalties.—

(1) Any person who violates s. 384.24 ~~the provisions of s. 384.24(1)~~ commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(2) Any person who violates ~~the provisions of~~ s. 384.26 or s. 384.29 commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(3) Any person who maliciously disseminates any false information or report concerning the existence of any sexually transmissible disease commits a misdemeanor ~~felony~~ of the first ~~third~~ degree, punishable as provided in s. 775.082 or s. 775.083 ~~ss. 775.082, 775.083, and 775.084~~.

(4) ~~Any person who violates the provisions of the department's rules pertaining to sexually transmissible diseases may be punished by a fine not to exceed $500 for each violation. Any penalties enforced under this subsection shall be in addition to other penalties provided by this chapter. The department may enforce this section and adopt rules necessary to~~

~~administer this section.~~

~~(5) Any person who violates s. 384.24(2) commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. Any person who commits multiple violations of s. 384.24(2) commits a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.~~

~~(6)~~ Any person who obtains information that identifies an individual who has a sexually transmissible disease, who knew or should have known the nature of the information and maliciously, or for monetary gain, disseminates this information or otherwise makes this information known to any other person, except by providing it either to a physician or nurse employed by the Department of Health or to a law enforcement agency, commits a misdemeanor ~~felony~~ of the first ~~third~~ degree, punishable as provided in s. 775.082 or~~,~~ s. 775.083~~, or s. 775.084~~.

Section 6. Subsections (1) and (3)of section 775.0877, Florida Statutes, are amended to read:

775.0877 Criminal transmission of HIV; procedures; penalties.—

(1) In any case in which a person has been convicted of or has pled nolo contendere or guilty to, regardless of whether adjudication is withheld, any of the following offenses, or the attempt thereof, which offense or attempted offense involves the transmission of body fluids from one person to another:

(a) Section 794.011, relating to sexual battery;

(b) Section 826.04, relating to incest;

(c) Section 800.04, relating to lewd or lascivious offenses committed upon or in the presence of persons less than 16 years of age;

(d) Sections 784.011, 784.07(2)(a), and 784.08(2)(d), relating to assault;

(e) Sections 784.021, 784.07(2)(c), and 784.08(2)(b), relating to aggravated assault;

(f) Sections 784.03, 784.07(2)(b), and 784.08(2)(c), relating to battery;

(g) Sections 784.045, 784.07(2)(d), and 784.08(2)(a), relating to aggravated battery;

(h) Section 827.03(2)(c), relating to child abuse;

(i) Section 827.03(2)(a), relating to aggravated child abuse;

(j) Section 825.102(1), relating to abuse of an elderly person or disabled adult;

(k) Section 825.102(2), relating to aggravated abuse of an elderly person or disabled adult;

(l) Section 827.071, relating to sexual performance by person less than 18 years of age;

(m) Sections 796.07 and 796.08, relating to prostitution; or

(n) ~~Section 381.0041(11)(b), relating to donation of blood, plasma, organs, skin, or other human tissue; or~~

~~(o)~~ Sections 787.06(3)(b), (d), (f), and (g), relating to human trafficking,

the court shall order the offender to undergo HIV testing, to be performed under the direction of the Department of Health in accordance with s. 381.004, unless the offender has undergone HIV testing voluntarily or pursuant to procedures established in s. 381.004(2)(h)6. or s. 951.27, or any other applicable law or

rule providing for HIV testing of criminal offenders or inmates, subsequent to her or his arrest for an offense enumerated in paragraphs (a)-(m) ~~(a)-(n)~~ for which she or he was convicted or to which she or he pled nolo contendere or guilty. The results of an HIV test performed on an offender pursuant to this subsection are not admissible in any criminal proceeding arising out of the alleged offense.

(3) An offender who has undergone HIV testing pursuant to subsection (1), and to whom positive test results have been disclosed pursuant to subsection (2), who commits a second or subsequent offense enumerated in paragraphs (1)(a)-(m) ~~(1)(a)-(n)~~, commits criminal transmission of HIV, a felony of the third degree, punishable as provided in s. 775.082 or~~,~~ s. 775.083~~, or s. 775.084~~. A person may be convicted and sentenced separately for a violation of this subsection and for the underlying crime enumerated in paragraphs (1)(a)-(m) ~~(1)(a)-(n)~~.

Section 7. Paragraph (e) of subsection (3) of section 921.0022, Florida Statutes, is amended to read:

921.0022 Criminal Punishment Code; offense severity ranking chart.—

(3) OFFENSE SEVERITY RANKING CHART

(e) LEVEL 5

Florida Statute	Felony Degree	Description
316.027(2)(a)	3rd	Accidents involving personal injuries other than serious bodily injury, failure to stop;

		leaving scene.
316.1935(4)(a)	2nd	Aggravated fleeing or eluding.
316.80(2)	2nd	Unlawful conveyance of fuel; obtaining fuel fraudulently.
322.34(6)	3rd	Careless operation of motor vehicle with suspended license, resulting in death or serious bodily injury.
327.30(5)	3rd	Vessel accidents involving personal injury; leaving scene.
379.365(2)(c)1.	3rd	Violation of rules relating to: willful molestation of stone crab traps, lines, or buoys; illegal bartering, trading, or sale, conspiring or aiding in such barter, trade, or sale, or supplying, agreeing to supply, aiding in supplying, or giving away stone crab trap tags or certificates; making, altering, forging, counterfeiting, or reproducing stone crab trap tags; possession of forged, counterfeit, or imitation stone

		crab trap tags; and engaging in the commercial harvest of stone crabs while license is suspended or revoked.
379.367(4)	3rd	Willful molestation of a commercial harvester's spiny lobster trap, line, or buoy.
379.407(5)(b)3.	3rd	Possession of 100 or more undersized spiny lobsters.
~~381.0041(11)(b)~~	~~3rd~~	~~Donate blood, plasma, or organs knowing HIV positive.~~
440.10(1)(g)	2nd	Failure to obtain workers' compensation coverage.
440.105(5)	2nd	Unlawful solicitation for the purpose of making workers' compensation claims.
440.381(2)	2nd	Submission of false, misleading, or incomplete information with the purpose of avoiding or reducing workers' compensation premiums.
624.401(4)(b)2.	2nd	Transacting insurance without a

		certificate or authority; premium collected $20,000 or more but less than $100,000.
626.902(1)(c)	2nd	Representing an unauthorized insurer; repeat offender.
790.01(2)	3rd	Carrying a concealed firearm.
790.162	2nd	Threat to throw or discharge destructive device.
790.163(1)	2nd	False report of bomb, explosive, weapon of mass destruction, or use of firearms in violent manner.
790.221(1)	2nd	Possession of short-barreled shotgun or machine gun.
790.23	2nd	Felons in possession of firearms, ammunition, or electronic weapons or devices.
796.05(1)	2nd	Live on earnings of a prostitute; 1st offense.
800.04(6)(c)	3rd	Lewd or lascivious conduct; offender less than 18 years of

		age.
800.04(7)(b)	2nd	Lewd or lascivious exhibition; offender 18 years of age or older.
806.111(1)	3rd	Possess, manufacture, or dispense fire bomb with intent to damage any structure or property.
812.0145(2)(b)	2nd	Theft from person 65 years of age or older; $10,000 or more but less than $50,000.
812.015(8)	3rd	Retail theft; property stolen is valued at $300 or more and one or more specified acts.
812.019(1)	2nd	Stolen property; dealing in or trafficking in.
812.131(2)(b)	3rd	Robbery by sudden snatching.
812.16(2)	3rd	Owning, operating, or conducting a chop shop.
817.034(4)(a)2.	2nd	Communications fraud, value $20,000 to $50,000.

817.234(11)(b)	2nd	Insurance fraud; property value $20,000 or more but less than $100,000.
817.2341(1), (2)(a) & (3)(a)	3rd	Filing false financial statements, making false entries of material fact or false statements regarding property values relating to the solvency of an insuring entity.
817.568(2)(b)	2nd	Fraudulent use of personal identification information; value of benefit, services received, payment avoided, or amount of injury or fraud, $5,000 or more or use of personal identification information of 10 or more persons.
817.611(2)(a)	2nd	Traffic in or possess 5 to 14 counterfeit credit cards or related documents.
817.625(2)(b)	2nd	Second or subsequent fraudulent use of scanning device, skimming device, or reencoder.

825.1025(4)	3rd	Lewd or lascivious exhibition in the presence of an elderly person or disabled adult.
827.071(4)	2nd	Possess with intent to promote any photographic material, motion picture, etc., which includes sexual conduct by a child.
827.071(5)	3rd	Possess, control, or intentionally view any photographic material, motion picture, etc., which includes sexual conduct by a child.
828.12(2)	3rd	Tortures any animal with intent to inflict intense pain, serious physical injury, or death.
839.13(2)(b)	2nd	Falsifying records of an individual in the care and custody of a state agency involving great bodily harm or death.
843.01	3rd	Resist officer with violence to

		person; resist arrest with violence.
847.0135(5)(b)	2nd	Lewd or lascivious exhibition using computer; offender 18 years or older.
847.0137 (2) & (3)	3rd	Transmission of pornography by electronic device or equipment.
847.0138 (2) & (3)	3rd	Transmission of material harmful to minors to a minor by electronic device or equipment.
874.05(1)(b)	2nd	Encouraging or recruiting another to join a criminal gang; second or subsequent offense.
874.05(2)(a)	2nd	Encouraging or recruiting person under 13 years of age to join a criminal gang.
893.13(1)(a)1.	2nd	Sell, manufacture, or deliver cocaine (or other s. 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)5. drugs).

893.13(1)(c)2.	2nd	Sell, manufacture, or deliver cannabis (or other s. 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., (2)(c)6., (2)(c)7., (2)(c)8., (2)(c)9., (2)(c)10., (3), or (4) drugs) within 1,000 feet of a child care facility, school, or state, county, or municipal park or publicly owned recreational facility or community center.
893.13(1)(d)1.	1st	Sell, manufacture, or deliver cocaine (or other s. 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)5. drugs) within 1,000 feet of university.
893.13(1)(e)2.	2nd	Sell, manufacture, or deliver cannabis or other drug prohibited under s. 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., (2)(c)6., (2)(c)7., (2)(c)8., (2)(c)9., (2)(c)10., (3), or (4) within 1,000 feet of property used for religious services or a

		specified business site.
893.13(1)(f)1.	1st	Sell, manufacture, or deliver cocaine (or other s. 893.03(1)(a), (1)(b), (1)(d), or (2)(a), (2)(b), or (2)(c)5. drugs) within 1,000 feet of public housing facility.
893.13(4)(b)	2nd	Use or hire of minor; deliver to minor other controlled substance.
893.1351(1)	3rd	Ownership, lease, or rental for trafficking in or manufacturing of controlled substance.

Section 8. Paragraphs (a) and (b) of subsection (2) and paragraph (a) of subsection (3) of section 960.003, Florida Statutes, are amended to read:

960.003 Hepatitis and HIV testing for persons charged with or alleged by petition for delinquency to have committed certain offenses; disclosure of results to victims.—

(2) TESTING OF PERSON CHARGED WITH OR ALLEGED BY PETITION FOR DELINQUENCY TO HAVE COMMITTED CERTAIN OFFENSES.—

(a) In any case in which a person has been charged by information or indictment with or alleged by petition for delinquency to have committed any offense enumerated in s. 775.0877(1)(a)-(m) ~~s. 775.0877(1)(a)-(n)~~, which involves the

transmission of body fluids from one person to another, upon request of the victim or the victim's legal guardian, or of the parent or legal guardian of the victim if the victim is a minor, the court shall order such person to undergo hepatitis and HIV testing within 48 hours after the information, indictment, or petition for delinquency is filed. In the event the victim or, if the victim is a minor, the victim's parent or legal guardian requests hepatitis and HIV testing after 48 hours have elapsed from the filing of the indictment, information, or petition for delinquency, the testing shall be done within 48 hours after the request.

(b) However, when a victim of any sexual offense enumerated in s. 775.0877(1)(a)-(m) ~~s. 775.0877(1)(a)-(n)~~ is under the age of 18 at the time the offense was committed or when a victim of any sexual offense enumerated in s. 775.0877(1)(a)-(m) ~~s. 775.0877(1)(a)-(n)~~ or s. 825.1025 is a disabled adult or elderly person as defined in s. 825.1025 regardless of whether the offense involves the transmission of bodily fluids from one person to another, then upon the request of the victim or the victim's legal guardian, or of the parent or legal guardian, the court shall order such person to undergo hepatitis and HIV testing within 48 hours after the information, indictment, or petition for delinquency is filed. In the event the victim or, if the victim is a minor, the victim's parent or legal guardian requests hepatitis and HIV testing after 48 hours have elapsed from the filing of the indictment, information, or petition for delinquency, the testing shall be done within 48 hours after the request. The testing shall be performed under the direction of the Department of Health in accordance with s. 381.004. The

results of a hepatitis and HIV test performed on a defendant or juvenile offender pursuant to this subsection shall not be admissible in any criminal or juvenile proceeding arising out of the alleged offense.

(3) DISCLOSURE OF RESULTS.—

(a) The results of the test shall be disclosed no later than 2 weeks after the court receives such results, under the direction of the Department of Health, to the person charged with or alleged by petition for delinquency to have committed or to the person convicted of or adjudicated delinquent for any offense enumerated in s. 775.0877(1)(a)-(m) ~~s. 775.0877(1)(a)-(n)~~, which involves the transmission of body fluids from one person to another, and, upon request, to the victim or the victim's legal guardian, or the parent or legal guardian of the victim if the victim is a minor, and to public health agencies pursuant to s. 775.0877. If the alleged offender is a juvenile, the test results shall also be disclosed to the parent or guardian. When the victim is a victim as described in paragraph (2)(b), the test results must also be disclosed no later than 2 weeks after the court receives such results, to the person charged with or alleged by petition for delinquency to have committed or to the person convicted of or adjudicated delinquent for any offense enumerated in s. 775.0877(1)(a)-(m) ~~s. 775.0877(1)(a)-(n)~~, or s. 825.1025 regardless of whether the offense involves the transmission of bodily fluids from one person to another, and, upon request, to the victim or the victim's legal guardian, or the parent or legal guardian of the victim, and to public health agencies pursuant to s. 775.0877. Otherwise, hepatitis and HIV test results obtained pursuant to

this section are confidential and exempt from the provisions of s. 119.07(1) and s. 24(a), Art. I of the State Constitution and shall not be disclosed to any other person except as expressly authorized by law or court order.

Section 9. This act shall take effect July 1, 2019.

The Florida Senate

Committee Agenda Request

To: Senator Gayle Harrell, Chair
Committee on Health Policy

Subject: Committee Agenda Request

Date: February 15, 2019

I respectfully request that **Senate Bill #846**, relating to HIV Prevention, be placed on the:

☒ committee agenda at your earliest possible convenience.

☐ next committee agenda.

Senator Jason W.B. Pizzo
Florida Senate, District 38

File signed original with committee office

S-020 (03/2004)

The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	SB 884
INTRODUCER:	Senator Baxley
SUBJECT:	Clinical Social Workers, Marriage and Family Therapists, and Mental Health Counselors
DATE:	March 21, 2019 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Brown	HP	**Pre-meeting**
2.			AHS	
3.			AP	

I. Summary:

SB 884 makes numerous changes to multiple sections in ch. 491, F.S., to:

- Define the terms "certified master social worker" and the "practice of generalist social work";
- Limit the Board of Clinical Social Work, Marriage and Family Therapy and Mental Health Counseling (the board) to make a one-time exception for an additional intern registration;
- Require interns to complete an 8-hour, board-approved course on laws and rules;
- Revise the licensure requirements for Clinical Social Workers, Marriage and Family Therapists, and Licensed Mental Health Counselors;
- Correct a technical discrepancy in the number of years of clinical experience required for a marriage and family therapist applicant from 3 years to 2 years;
- Eliminate the requirement for marriage and family therapists to complete 12 specific content areas and 180 practicum hours;
- Reduce the number of practicum, internship, or field experience hours for mental health counseling applicants who graduated from a non-Council for Accreditation of Counseling and Related Educational Programs (CACREP) from 1,000 hours to 700 hours; to match CACREP accredited programs;
- Delete requirement that applicants for licensure under ch. 491, F.S., complete a course on human immunodeficiency virus and acquired immune deficiency syndrome;
- Remove the exemption for certified master social worker from the continuing education requirements for the first certificate renewal period;
- Change from the Department of Health (DOH), to the board, the authority to take certain actions, make rules, and take disciplinary action against Clinical Social Workers, Marriage and Family Therapists, Mental Health Counselors and Certified Master Social Workers;
- Require the use of applicable professional titles by licensees and certificate holders, provisional licensees, and registrants on social media and other specified materials; and,

- Delete obsolete language and make technical and conforming changes.

The bill has an insignificant negative impact on state revenues and expenditures, which can be absorbed within existing resources of the DOH.

The bill takes effect July 1, 2019.

II. Present Situation:

Clinical Social Workers, Marriage and Family Therapists, Mental Health Counselors and Certified Master Social Workers

The Board

Section 491.004, F.S., creates the Board of Clinical Social Work, Marriage and Family Therapy and Mental Health Counseling (the board) within the DOH to ensure that every clinical social worker, marriage and family therapist, and mental health counselor practicing in this state meets minimum requirements for safe practice. The board is responsible for licensing, monitoring, disciplining, and educating clinical social workers, marriage and family therapists, and mental health counselors to assure competency and safety to practice in Florida.

Education and Examination

Section 491.005, F.S., sets out the educational and examination requirements for a clinical social worker, marriage and family therapist, and mental health counselor to obtain a license by examination in Florida. An individual applying for licensure by examination who has satisfied the clinical experience requirements of s. 491.005, F.S., or an individual applying for licensure by endorsement pursuant to s. 491.006, F.S., intending to provide clinical social work, marriage and family therapy, or mental health counseling services in Florida, while satisfying coursework or examination requirements for licensure, must obtain a provisional license in the profession for which he or she is seeking licensure prior to beginning practice.[1]

Interns

An individual who has not satisfied the postgraduate or post-master's level of experience requirements under s. 491.005, F.S., must register as an intern in the profession for which he or she is seeking licensure before commencing the post-master's experience requirement. An individual who intends to satisfy part of the required graduate-level practicum, internship, or field experience, outside the academic arena for any profession, must register as an intern in the profession for which he or she is seeking licensure before commencing the practicum, internship, or field experience.[2]

Section 491.0045(6), F.S., specifies the length of time an intern registration for clinical social work, marriage and family therapy, and mental health counseling is valid. A footnote to this section points out that, through multiple amendatory acts to s. 491.0045(6), F.S., during the same

[1] Section 491.0046, F.S.
[2] Section 491.0045, F.S.

legislative session, two irreconcilable versions of the section were created, and the editors were thus required to publish both versions of the amended provision.

Section 491.0045(6), F.S., states, "[a]n intern registration issued on or before March 31, 2017, expires March 31, 2022, and may not be renewed or reissued. A registration issued after March 31, 2017, expires 60 months after the date of issuance. No subsequent intern registration may be issued unless the candidate has passed the theory and practice examination described in s. 491.005(1)(d), (3)(d), and (4)(d)." The footnote refers to an April 1, 2017, date, rather than the March 31, 2017 in the statute.

Clinical Social Worker

Section 491.005(1), F.S., directs the DOH to issue a license to a clinical social worker applicant whom the board certifies:

- Has submitted an application and paid the appropriate fee;
- Has received a doctoral degree in social work from an accredited graduate school of social which:
  - Was accredited by the Council on Social Work Education;
  - Was accredited by the Canadian Association of Schools of Social Work; or
  - Was from an equivalent to programs approved by the Council on Social Work Education by the Foreign Equivalency Determination Service of the Council on Social Work Education.
- Has complete coursework in six content areas;
- Has complete a supervised field placement;
- Has complete 24 semester hours or 32 quarter hours in theory of human behavior and practice methods in clinically oriented services;
- Has completed at least two years of clinical social work experience, after completion of a graduate degree. An individual who intends to practice in Florida to satisfy clinical experience requirements must register as an intern before commencing practice.
- Has passed a theory and practice examination; and
- Has demonstrated knowledge of the Florida laws and rules governing the practice of clinical social work.

Marriage & Family Therapist

Section 491.005(3)(b), F.S., relating to licensure by examination for marriage and family therapists requires:

- A master's degree with major emphasis in marriage and family therapy or a closely related field;
- Specific coursework in 12 content areas; and
- A practicum, internship, or field experience of 180 hours providing direct client contact hours of marriage and family services under the supervision of a licensed marriage and family therapist with at least five years of experience.

According to the DOH, the specific course work requirement must be an exact match. Lack of an exact match may significantly delay an applicant's licensure.[3]

Section 491.005(3)(c), F.S., is inconsistent as it requires both two years, and three years, of clinical experience for a marriage and family therapy licensure applicant. According to the DOH, the three years of clinical experience was a technical error and is inconsistent with other statutory requirements. Only two years of clinical experience for a marriage and family therapy applicant is required.[4]

Mental Health Counselor

Section 491.005(4), F.S., relating to licensure by examination for mental health counselors names the Professional Examination Service for the National Academy of Certified Clinical Mental Health Counselors as the required examination for a mental health counselor. The correct name of the examination required for licensure as a mental health counselor is the National Clinical Mental Health Counseling Examination. The examination was developed by, and is administered by, the National Board for Certified Counselors.

Section 491.005(4), F.S., contains a 300-hour difference between the hours of practicum, internship, or field experience required for graduates from a CACREP and non-CACREP graduates. A mental health counselor applicant who graduated from a program not accredited by CACREP is required to complete 1,000 hours of practicum, internship, or field experience. An MHC applicant who graduated from a CACREP accredited program is required to meet the CACREP standards to complete 700 hours of practicum or internship.[5]

Section 491.006, F.S., relating to licensure or certification by endorsement requires an applicant for licensure by endorsement in the practice of clinical social work, marriage and family therapy, or mental health counseling to demonstrate to the board that he or she:

- Has knowledge of the laws and rules governing the practice of clinical social work, marriage and family therapy, and mental health counseling;
- Holds an active valid license to practice, and has actively practiced the profession in another state for three of the last five years immediately preceding licensure;
- Meets the education requirements of ch. 491, F.S., in the profession for which the applicant seeks licensure;
- Has passed a substantially equivalent licensure examination in another state, or has passed the licensure examination in this state in the profession for which the applicant seeks licensure;
- Holds a license in good standing; and
- Is not under investigation for, or been found to have committed, an act that would constitute a violation of ch. 491, F.S.

To satisfy the education requirements of s. 491.005, F.S., specific particular course work, rather than a degree from an accredited school or college, or proof of licensure in another state, is

[3] *Supra* note 1.
[4] *Id.*
[5] Council for Accreditation of Counseling & Related Educational Programs, *2016 CACREP Standards,* available at http://www.cacrep.org/wp-content/uploads/2018/05/2016-Standards-with-Glossary-5.3.2018.pdf (last visited Feb. 1, 2019).

required of an applicant for licensure by endorsement under ch. 491, F.S. The endorsement applicant must show proof that he or she completed certain statutorily-specified courses, which may not have been available at the time he or she graduated. Current law places barriers on licensure by endorsement by requiring many applicants to complete additional courses often difficult to obtain when the applicant is not a full-time graduate student.

Certified Master Social Worker

Section 491.0145, F.S., permits the DOH to certify an applicant for a designation as a "certified master social worker" upon the following conditions:

- The applicant submits an application and nonrefundable fee to the DOH at least 60 days before the examination to qualify to take the exam;
- Submits an official transcript that the applicant has received:
  - A doctoral degree in social work, or
  - A master's degree in social work with an emphasis on clinical practice or administration in seven content areas;
- Submit proof of at least 3 years' experience in clinical services or administrative experience; and
- Has passed the national Advanced Generalist level examination developed by the Association of Social Work Boards required by the DOH.[6]

A certified master social worker is not licensed or authorized to provide clinical social work services.

License Renewal

Section 491.007(3), F.S., provides for the renewal of a license, registration, or certificate for clinical social workers, marriage and family therapists, and mental health counselors, and gives the Board of Clinical Social Work, Marriage and Family Therapy and Mental Health Counseling rulemaking authority to prescribe the requirements for renewal of an intern registration. Section 491.0045(6), F.S., now addresses renewal of an intern registration; therefore, rulemaking authority is no longer necessary.

License Discipline

Section 491.009, F.S., sets out what acts by a clinical social worker, marriage and family therapist, or mental health counselor constitute grounds for discipline, or denial of licensure. However, s. 491.009(2), F.S., incorrectly references psychologists, who are not licensed under ch. 491, F.S., and does not include the certified master social worker profession regulated by the DOH.

III. Effect of Proposed Changes:

SB 884 amends s. 491.003, F.S., to define the terms "certified master social worker" and the "practice of generalist social work" for ch, 491, F.S. A "certified master social worker" is a

[6]The Department of Health, Board of Clinical Social work, Marriage & Family Therapy and Mental health Counseling, *Certified Master Social Worker*, available at https://floridasmentalhealthprofessions.gov/licensing/certified-master-social-worker/ (last visited Mar.20, 2019).

person licensed under ch.. 491, F.S., to practice generalist social work. "General social work" is the application of social work theory, knowledge, methods and ethics, and the professional use of self to restore or enhance social, psychosocial, or biopsychosocial functioning of individuals, couples, families, groups, organizations, or communities. The term includes the application of specialized knowledge and advanced practice skills in non-diagnostic assessment, treatment planning, implementation and evaluation, case management, information and referral, supervision, consultation, education, research, advocacy, community organization, and the development, implementation, and administration of policies, programs, and activities.

The bill amends s. 491.0045, F.S., to clarify conflicting language passed in the same legislative session to permit the Board of Clinical Social Work, Marriage and Family Therapy and Mental Health Counseling to make a one-time exception for an additional intern registration. For an intern seeking a second registration after March 31, 2022, that board may grant an additional intern registration in emergency or hardship cases, as defined by rule, if the candidate has passed the theory and practice examination described in ss. 491.055(1)(d), (3)(d), and (4)(d), F.S. The bill requires interns to complete an eight-hour board approved course on laws and rules.

The bill amends s. 491.005(1), F.S., to authorize the board to designate which theory and practice examination applicants must take and pass. It changes the entity from whom the DOH is to purchase the clinical social worker examinations from the American Association of State Social Worker's Boards, to the Association of Social Work boards or its successor; and deletes the specific list of graduate courses necessary to be taken to be eligible for licensure. The bill requires the board, rather than the DOH, to designate the theory and practice examination to be passed by applicants for licensure.

The bill amends s. 491.005(2), F.S., to change the name of the Canadian social work graduate education accrediting body to the Canadian Social Work Education.

The bill amends s 491.005(3), F.S., relating to licensure by examination for marriage and family therapists, to require:

- A master's degree with major emphasis in marriage and family therapy from a program accredited by the Commission of Accreditation for Marriage and Family Therapy Education; or,
- A master's degree with major emphasis in marriage and family therapy from a Florida university program accredited by the Counseling and Related Education Program; or
- Graduate courses approved by the board.

The bill eliminates the requirement for marriage and family therapists to complete 12 specific content areas and 180 practicum hours. This change will simplify the education review process, eliminate the course requirement review, and expedite licensure.

The bill amends s. 491.005(3)(c), F.S., to correct a technical discrepancy in the number of years of clinical experience required for a marriage and family therapist applicant from three years to two years.

The bill amends s. 491.005(3), F.S, to require applicants for licensure for Marriage and Family Therapists to pay actual cost of the exam and updates that the exam is to be purchased from the

Association of Marital and Family Therapy Regulatory Boards. The bill eliminates the specific course requirements to be included in a master's degree in marriage and family therapy and requires instead that the program be accredited by the commission on accreditation for Marriage and Family Therapy Education, or be a Florida university program accredited by the CACREP.

The bill amends s. 491.005(4), F.S., relating to mental health counseling applicants, to update the name of the examination to be taken by a mental health counselor applicant. The bill amends s. 491.005(4)(b)1.c., F.S., to reduce the number of practicum, internship, or field experience hours for those applicants who graduated from a non-CACREP accredited program, from 1,000 hours to 700 hours, bringing them in line with graduates from CACREP accredited programs. The bill deletes the requirement that master's degree courses include a course in human sexuality and substance abuse and adds a course in legal, ethical and professional standards. Amending this provision promotes regulatory efficiency and makes licensure requirements more balanced between the two programs.

The bill also updates the accrediting agencies for institutions of higher education and the mental health counseling graduate-level coursework to address diagnostic processes, differential diagnosis and the use of the current diagnostic tools, such as the most-recent edition of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders. The graduate program must have emphasized the common core curricular experience. The bill mandates that by 2025 an applicant for a license for mental health counseling must have a master's degree from a program accredited by the CACREP which consist of 60 semester hours or 80 quarter hours to apply for licensure.

The bill amends s.491.0057, F.S., to require the DOH to issue a duel license as a marriage and family therapist to anyone who demonstrates to the board that he or she has passed the examination designated provided by the board, rather than the department, for marriage and family therapy.

The bill amends s. 491.006, F.S., relating to licensure, or certification by endorsement, for applicants for licensure in clinical social work, marriage and family therapy, or mental health counseling. The bill removes the requirement for endorsement applicants to meet the same educational requirements required of new applicants, provided the applicant for endorsement meets the requirement to have an active, valid license and has actively practiced the profession in another state for three of the last 5 years. Amending this provision will increase licensure portability for applicants applying by endorsement for licensure as marriage and family therapists in Florida. The bill deletes the directive that the application fee for master social worker is non-refundable.

The bill repeals s. 491.0065, F.S., directing the board to require, as a condition of granting a license under ch.491, F.S., that an applicant complete a course on human immunodeficiency virus and acquired immune deficiency syndrome.

The bill amends s. 491.007, F.S., relating to renewal of a license, registration, or certificate, to delete obsolete rulemaking authority regarding intern registration renewal. The bill also deletes the directive that a certified master social worker is exempt from the continuing education requirements for the first renewal of the certificate.

The bill amends s. 491.009(2), F.S., to delete an inaccurate reference to psychologists who are licensed under ch. 490, F.S. The bill changes from the DOH, to the board, who has the authority to take disciplinary action for certain violations.

The bill amends 491.012, F.S., to add the "certified master social worker" to the list of titles that it is a violation of ch. 491, F.S., to use unless the individual holds a valid, active license as a clinical social worker under ch. 491; and removes obsolete language.

The bill amends s. 491.0145, F.S., to require the DOH to license an applicant for the designation as a "certified master social worker" if the person submits an application to the DOH, and other required information, with the board, rather than the DOH, determining the amount of the non-refundable fee, the adequacy of the documents submitted, the examination to be passed, and making the rules to implement the section.

The bill amends s. 491.0149, F.S., adding to the list of promotional materials, "social media," that all licensees and certificate holders, interns, and provisional licensees, must include their professional titles. The bill also requires a generalist social worker to include the words "certified master social worker" or the letters "CMSW" on all his or her promotional materials.

The bill repeals s. 491.015, F.S. which removes from the DOH the authority to make rules and regulate the certified master social worker.

The bill removes obsolete language in s. 491.004, F.S., and makes additional technical amendments to s. 414.065, F.S., to conform cross-references.

The bill takes effect July 1, 2019.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 491.003, 491.004, 491.0045, 491.005, 491.0057, 491.006, 491.007, 491.009, 491.012, 491.0145, 491.0149, and 414.065.

This bill repeals the following sections of the Florida Statutes: 491.0065 and 491.015.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.

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LEGISLATIVE ACTION

Senate . House

. . . . .

The Committee on Health Policy (Baxley) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Present subsections (2) through (7) of section 491.003, Florida Statutes, are redesignated as subsections (3) through (8), respectively, present subsections (8) through (17) are redesignated as subsections (10) through (19), respectively, and new subsections (2) and (9) are added to that section, to read:

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491.003 Definitions.—As used in this chapter:

(2) "Certified master social worker" means a person certified by the department under this chapter to practice generalist social work.

(9) The term "practice of generalist social work" means the application of social work theory, knowledge, and methods and ethics to and the professional use of self to restore or enhance social, psychosocial, or biopsychosocial functioning of individuals, couples, families, groups, organizations, or communities. The term includes the application of specialized knowledge and advanced practice skills to nondiagnostic assessment, treatment planning, implementation and evaluation, case management, information and referral, supervision, consultation, education, research, advocacy, community organization and the development, implementation, and administration of policies, programs, and activities.

Section 2. Present subsections (4) through (7) of section 491.004, Florida Statutes, are redesignated as subsections (3) through (6), respectively, and present subsection (3) is amended, to read:

491.004 Board of Clinical Social Work, Marriage and Family Therapy, and Mental Health Counseling.—

~~(3) No later than January 1, 1988, the Governor shall appoint nine members of the board as follows:~~

~~(a) Three members for terms of 2 years each.~~

~~(b) Three members for terms of 3 years each.~~

~~(c) Three members for terms of 4 years each.~~

Section 3. Section 491.0145, Florida Statutes, is amended to read:


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491.0145 Certified master social worker.—The department shall ~~may~~ certify an applicant for a designation as a certified master social worker who, upon applying to the department and remitting the appropriate fee, demonstrates to the department that he or she has met all of the following conditions:

(1) The applicant has submitted ~~The applicant completes~~ an application and has paid ~~to be provided by the department and pays~~ a nonrefundable fee not to exceed $250 to be established by rule of the department. ~~The completed application must be received by the department at least 60 days before the date of the examination in order for the applicant to qualify to take the scheduled exam.~~

(2) The applicant submits proof satisfactory to the department that the applicant has received a doctoral degree in social work, or a master's degree in social work with a major emphasis or specialty in ~~clinical practice or administration, including, but not limited to, agency~~ administration and supervision, program planning and evaluation, staff development, research, community organization, community services, social planning, or ~~and~~ human service advocacy. Doctoral degrees must have been received from a graduate school of social work which at the time the applicant was enrolled and graduated was accredited by an accrediting agency approved by the United States Department of Education. Master's degrees must have been received from a graduate school of social work which at the time the applicant was enrolled and graduated was accredited by the Council on Social Work Education or the Canadian Association of Schools for ~~of~~ Social Work Education or by one that meets comparable standards.

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(3) The applicant has had at least 2 ~~3~~ years' experience, as defined by rule, including, but not limited to, clinical services or administrative activities as defined in subsection (2), 2 years of which must be at the post-master's level under the supervision of a person who meets the education and experience requirements for certification as a certified master social worker, as defined by rule, or licensure as a clinical social worker under this chapter. A doctoral internship may be applied toward the supervision requirement.

(4) Any person who holds a master's degree in social work from institutions outside the United States may apply to the department for certification if the academic training in social work has been evaluated as equivalent to a degree from a school accredited by the Council on Social Work Education. Any such person shall submit a copy of the academic training from the Foreign Equivalency Determination Service of the Council on Social Work Education.

(5) The applicant has passed an examination required by the department for this purpose. ~~The nonrefundable fee for such examination may not exceed $250 as set by department rule.~~

(6) ~~Nothing in~~ This chapter does not ~~shall be construed to~~ authorize a certified master social worker to provide clinical social work services.

(7) The department may adopt rules to implement this section.

Section 4. Section 491.0149, Florida Statutes, is amended to read:

491.0149 Display of license; use of professional title on promotional materials.—

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(1)(a) A person licensed under this chapter as a clinical social worker, marriage and family therapist, or mental health counselor, or certified as a master social worker shall conspicuously display the valid license or certificate issued by the department or a true copy thereof at each location at which the licensee practices his or her profession.

(b)1. A licensed clinical social worker shall include the words "licensed clinical social worker" or the letters "LCSW" on all promotional materials, including cards, brochures, stationery, advertisements, social media, and signs, naming the licensee.

2. A licensed marriage and family therapist shall include the words "licensed marriage and family therapist" or the letters "LMFT" on all promotional materials, including cards, brochures, stationery, advertisements, social media, and signs, naming the licensee.

3. A licensed mental health counselor shall include the words "licensed mental health counselor" or the letters "LMHC" on all promotional materials, including cards, brochures, stationery, advertisements, social media, and signs, naming the licensee.

(c) A generalist social worker shall include the words "certified master social worker" or the letters "CMSW" on all promotional materials, including cards, brochures, stationery, advertisements, social media, and signs, naming the licensee.

(2)(a) A person registered under this chapter as a clinical social worker intern, marriage and family therapist intern, or mental health counselor intern shall conspicuously display the valid registration issued by the department or a true copy

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thereof at each location at which the registered intern is completing the experience requirements.

(b) A registered clinical social worker intern shall include the words "registered clinical social worker intern," a registered marriage and family therapist intern shall include the words "registered marriage and family therapist intern," and a registered mental health counselor intern shall include the words "registered mental health counselor intern" on all promotional materials, including cards, brochures, stationery, advertisements, social media, and signs, naming the registered intern.

(3)(a) A person provisionally licensed under this chapter as a provisional clinical social worker licensee, provisional marriage and family therapist licensee, or provisional mental health counselor licensee shall conspicuously display the valid provisional license issued by the department or a true copy thereof at each location at which the provisional licensee is providing services.

(b) A provisional clinical social worker licensee shall include the words "provisional clinical social worker licensee," a provisional marriage and family therapist licensee shall include the words "provisional marriage and family therapist licensee," and a provisional mental health counselor licensee shall include the words "provisional mental health counselor licensee" on all promotional materials, including cards, brochures, stationery, advertisements, social media, and signs, naming the provisional licensee.

Section 5. This act shall take effect July 1, 2019.

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156
157 ========== T I T L E A M E N D M E N T ==========
158 And the title is amended as follows:
159 Delete everything before the enacting clause
160 and insert:
161 A bill to be entitled
162 An act relating to clinical social workers, marriage
163 and family therapists, and mental health counselors;
164 amending s. 491.003, F.S.; defining the terms
165 "certified master social worker" and "practice of
166 generalist social work"; amending s. 491.004, F.S.;
167 deleting an obsolete provision; amending s. 491.0145,
168 F.S.; requiring the Department of Health to certify an
169 applicant for designation as a certified master social
170 worker under certain circumstances; providing that
171 applicants for designation as a certified master
172 social worker submit their application to the
173 department; deleting a provision relating to the
174 nonrefundable fee for examination set by department
175 rule; authorizing the department to adopt rules;
176 amending s. 491.0149, F.S.; requiring the use of
177 applicable professional titles by licensees,
178 certificate holders, provisional licensees, and
179 registrants on social media and other specified
180 materials; providing an effective date.

By Senator Baxley

12-00822-19 2019884__

A bill to be entitled

An act relating to clinical social workers, marriage and family therapists, and mental health counselors; amending s. 491.003, F.S.; defining the terms "certified master social worker" and "practice of generalist social work"; amending s. 491.004, F.S.; deleting an obsolete provision; amending s. 491.0045, F.S.; revising intern registration requirements; providing an exception; amending s. 491.005, F.S.; revising the licensure requirements for clinical social workers, marriage and family therapists, and mental health counselors; amending s. 491.0057, F.S.; requiring that an applicant for dual licensure as a marriage and family therapist pass an examination designated by the board; amending s. 491.006, F.S.; revising requirements for licensure or certification by endorsement for certain professions; repealing s. 491.0065, F.S., relating to requirements for instruction on HIV and AIDS; amending s. 491.007, F.S.; deleting a provision providing certified master social workers an exemption from continuing education requirements; deleting a provision requiring the Board of Clinical Social Work, Marriage and Family Therapy and Mental Health Counseling to establish a procedure for the biennial renewal of intern registrations; amending s. 491.009, F.S.; revising who may enter an order denying licensure or imposing penalties against an applicant for licensure under certain circumstances; amending s. 491.012, F.S.; providing

that using the title "certified master social worker" without a valid, active license is unlawful; deleting an obsolete provision; amending s. 491.0145, F.S.; requiring the Department of Health to license an applicant for designation as a certified master social worker under certain circumstances; providing that applicants for designation as a certified master social worker submit their application to the board; deleting a provision relating to the nonrefundable fee for examination set by department rule; authorizing the board to adopt rules; amending s. 491.0149, F.S.; requiring the use of applicable professional titles by licensees, provisional licensees, and registrants on social media and other specified materials; repealing s. 491.015, F.S., relating to duties of the department as to certified master social workers; amending s. 414.065, F.S.; conforming provisions to changes made by the act; providing an effective date.

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

Section 1. Present subsections (2) through (7) of section 491.003, Florida Statutes, are renumbered as subsections (3) through (8), respectively, present subsections (8) through (17) are renumbered as subsections (10) through (19), respectively, and new subsections (2) and (9) are added to that section, to read:

491.003 Definitions.—As used in this chapter:

(2) "Certified master social worker" means a person

licensed under this chapter to practice generalist social work.

(9) "Practice of generalist social work" means the application of social work theory, knowledge, methods and ethics, and the professional use of self to restore or enhance social, psychosocial, or biopsychosocial functioning of individuals, couples, families, groups, organizations, or communities. The term includes the application of specialized knowledge and advanced practice skills in nondiagnostic assessment, treatment planning, implementation and evaluation, case management, information and referral, supervision, consultation, education, research, advocacy, community organization, and the development, implementation, and administration of policies, programs, and activities.

Section 2. Present subsections (4) through (7) of section 491.004, Florida Statutes, are renumbered as subsections (3) through (6), respectively, and present subsection (3) is amended to read:

491.004 Board of Clinical Social Work, Marriage and Family Therapy, and Mental Health Counseling.—

~~(3) No later than January 1, 1988, the Governor shall appoint nine members of the board as follows:~~

~~(a) Three members for terms of 2 years each.~~

~~(b) Three members for terms of 3 years each.~~

~~(c) Three members for terms of 4 years each.~~

Section 3. Subsections (2) and (6) of section 491.0045, Florida Statutes, are amended to read:

491.0045 Intern registration; requirements.—

(2) The department shall register as a clinical social worker intern, marriage and family therapist intern, or mental

health counselor intern each applicant who the board certifies has:

(a) Completed the application form and remitted a nonrefundable application fee not to exceed $200, as set by board rule;

(b)1. Completed the education requirements as specified in s. 491.005(1)(c), (3)(c), or (4)(c) for the profession for which he or she is applying for licensure, if needed; and

2. Submitted an acceptable supervision plan, as determined by the board, for meeting the practicum, internship, or field work required for licensure that was not satisfied in his or her graduate program.

(c) Identified a qualified supervisor.

(d) Completed an 8-hour Florida laws and rules course approved by the board.

(6) A registration issued on or before March 31, 2017, expires March 31, 2022, and may not be renewed or reissued. Any registration issued after March 31, 2017, expires 60 months after the date it is issued. The board may make a one-time exception from the requirements of this section in emergency or hardship cases, as defined by board rule, if ~~A subsequent intern registration may not be issued unless~~ the candidate has passed the theory and practice examination described in s. 491.005(1)(d), (3)(d), and (4)(d).

Section 4. Subsection (1), paragraph (b) of subsection (2), and subsections (3) and (4) of section 491.005, Florida Statutes, are amended to read:

491.005 Licensure by examination.—

(1) CLINICAL SOCIAL WORK.—Upon verification of

documentation and payment of a fee not to exceed $200, as set by board rule, plus the actual per applicant cost ~~to the department~~ for purchase of the examination from the ~~American~~ Association of ~~State~~ Social Work ~~Worker's~~ Boards or its successor ~~a similar national organization~~, the department shall issue a license as a clinical social worker to an applicant who the board certifies:

(a) Has submitted an application and paid the appropriate fee.

(b)1. Has received a doctoral degree in social work from a graduate school of social work which at the time the applicant graduated was accredited by an accrediting agency recognized by the United States Department of Education or has received a master's degree in social work from a graduate school of social work which at the time the applicant graduated:

a. Was accredited by the Council on Social Work Education;

b. Was accredited by the Canadian Association of Schools of Social Work; or

c. Has been determined to have been a program equivalent to programs approved by the Council on Social Work Education by the Foreign Equivalency Determination Service of the Council on Social Work Education. An applicant who graduated from a program at a university or college outside of the United States or Canada must present documentation of the equivalency determination from the council in order to qualify.

2. The applicant's graduate program must have emphasized direct clinical patient or client health care services, including, but not limited to, coursework in clinical social work, psychiatric social work, medical social work, social casework, psychotherapy, or group therapy. The applicant's

graduate program must have included all of the following coursework:

a. A supervised field placement which was part of the applicant's advanced concentration in direct practice, during which the applicant provided clinical services directly to clients.

b. Completion of 24 semester hours or 32 quarter hours in courses approved by rule of the board ~~theory of human behavior and practice methods as courses in clinically oriented services, including a minimum of one course in psychopathology, and no more than one course in research, taken in a school of social work accredited or approved pursuant to subparagraph 1~~.

~~3. If the course title which appears on the applicant's transcript does not clearly identify the content of the coursework, the applicant shall be required to provide additional documentation, including, but not limited to, a syllabus or catalog description published for the course.~~

(c) Has had at least 2 years of clinical social work experience, which took place subsequent to completion of a graduate degree in social work at an institution meeting the accreditation requirements of this section, under the supervision of a licensed clinical social worker or the equivalent who is a qualified supervisor as determined by the board. An individual who intends to practice in Florida to satisfy clinical experience requirements must register pursuant to s. 491.0045 before commencing practice. If the applicant's graduate program was not a program which emphasized direct clinical patient or client health care services as described in subparagraph (b)2., the supervised experience requirement must

take place after the applicant has completed a minimum of 15 semester hours or 22 quarter hours of the coursework required. A doctoral internship may be applied toward the clinical social work experience requirement. A licensed mental health professional must be on the premises when clinical services are provided by a registered intern in a private practice setting.

(d) Has passed a theory and practice examination designated ~~provided~~ by the board ~~department for this purpose~~.

(e) Has demonstrated, in a manner designated by rule of the board, knowledge of the laws and rules governing the practice of clinical social work, marriage and family therapy, and mental health counseling.

(2) CLINICAL SOCIAL WORK.—

(b) An applicant from a master's or doctoral program in social work which did not emphasize direct patient or client services may complete the clinical curriculum content requirement by returning to a graduate program accredited by the Council on Social Work Education or the Canadian Association for Social Work Education ~~of Schools of Social Work~~, or to a clinical social work graduate program with comparable standards, in order to complete the education requirements for examination. However, a maximum of 6 semester or 9 quarter hours of the clinical curriculum content requirement may be completed by credit awarded for independent study coursework as defined by board rule.

(3) MARRIAGE AND FAMILY THERAPY.—Upon verification of documentation and payment of a fee not to exceed $200, as set by board rule, plus the actual cost ~~to the department~~ for the purchase of the examination from the Association of Marital and

Family Therapy Regulatory Boards ~~Board~~, or its successor ~~similar national~~ organization, the department shall issue a license as a marriage and family therapist to an applicant who the board certifies:

(a) Has submitted an application and paid the appropriate fee.

(b)~~1.~~ Has a minimum of a master's degree with major emphasis in marriage and family therapy from a program accredited by the Commission on Accreditation for Marriage and Family Therapy Education or from a Florida university program accredited by the Council for Accreditation of Counseling and Related Educational Programs, or a closely related field, and graduate courses approved by the Board of Clinical Social Work, Marriage and Family Therapy and Mental Health Counseling ~~has completed all of the following requirements:~~

~~a. Thirty-six semester hours or 48 quarter hours of graduate coursework, which must include a minimum of 3 semester hours or 4 quarter hours of graduate-level course credits in each of the following nine areas: dynamics of marriage and family systems; marriage therapy and counseling theory and techniques; family therapy and counseling theory and techniques; individual human development theories throughout the life cycle; personality theory or general counseling theory and techniques; psychopathology; human sexuality theory and counseling techniques; psychosocial theory; and substance abuse theory and counseling techniques. Courses in research, evaluation, appraisal, assessment, or testing theories and procedures; thesis or dissertation work; or practicums, internships, or fieldwork may not be applied toward this requirement.~~

~~b. A minimum of one graduate-level course of 3 semester hours or 4 quarter hours in legal, ethical, and professional standards issues in the practice of marriage and family therapy or a course determined by the board to be equivalent.~~

~~c. A minimum of one graduate-level course of 3 semester hours or 4 quarter hours in diagnosis, appraisal, assessment, and testing for individual or interpersonal disorder or dysfunction; and a minimum of one 3-semester-hour or 4-quarter-hour graduate-level course in behavioral research which focuses on the interpretation and application of research data as it applies to clinical practice. Credit for thesis or dissertation work, practicums, internships, or fieldwork may not be applied toward this requirement.~~

~~d. A minimum of one supervised clinical practicum, internship, or field experience in a marriage and family counseling setting, during which the student provided 180 direct client contact hours of marriage and family therapy services under the supervision of an individual who met the requirements for supervision under paragraph (c). This requirement may be met by a supervised practice experience which took place outside the academic arena, but which is certified as equivalent to a graduate-level practicum or internship program which required a minimum of 180 direct client contact hours of marriage and family therapy services currently offered within an academic program of a college or university accredited by an accrediting agency approved by the United States Department of Education, or an institution which is publicly recognized as a member in good standing with the Association of Universities and Colleges of Canada or a training institution accredited by the Commission on~~

~~Accreditation for Marriage and Family Therapy Education recognized by the United States Department of Education. Certification shall be required from an official of such college, university, or training institution.~~

~~2. If the course title which appears on the applicant's transcript does not clearly identify the content of the coursework, the applicant shall be required to provide additional documentation, including, but not limited to, a syllabus or catalog description published for the course~~.

The required master's degree must have been received in an institution of higher education which at the time the applicant graduated was: fully accredited by a regional accrediting body recognized by the Council for Higher Education Accreditation ~~Commission on Recognition of Postsecondary Accreditation~~; publicly recognized as a member in good standing with ~~the Association of~~ Universities ~~and Colleges of~~ Canada; or an institution of higher education located outside the United States and Canada, which at the time the applicant was enrolled and at the time the applicant graduated maintained a standard of training substantially equivalent to the standards of training of those institutions in the United States which are accredited by a regional accrediting body recognized by the Commission on Recognition of Postsecondary Accreditation. Such foreign education and training must have been received in an institution or program of higher education officially recognized by the government of the country in which it is located as an institution or program to train students to practice as professional marriage and family therapists or psychotherapists.

The burden of establishing that the requirements of this provision have been met shall be upon the applicant, and the board shall require documentation, such as, but not limited to, an evaluation by a foreign equivalency determination service, as evidence that the applicant's graduate degree program and education were equivalent to an accredited program in this country. An applicant with a master's degree from a program which did not emphasize marriage and family therapy may complete the coursework requirement in a training institution fully accredited by the Commission on Accreditation for Marriage and Family Therapy Education recognized by the United States Department of Education.

(c) Has had at least 2 years of clinical experience during which 50 percent of the applicant's clients were receiving marriage and family therapy services, which must be at the post-master's level under the supervision of a licensed marriage and family therapist with at least 5 years of experience, or the equivalent, who is a qualified supervisor as determined by the board. An individual who intends to practice in Florida to satisfy the clinical experience requirements must register pursuant to s. 491.0045 before commencing practice. If a graduate has a master's degree with a major emphasis in marriage and family therapy or a closely related field that did not include all the coursework required under paragraph (b) ~~sub-subparagraphs (b)1.a.-c.~~, credit for the post-master's level clinical experience shall not commence until the applicant has completed a minimum of 10 of the courses required under paragraph (b) ~~sub-subparagraphs (b)1.a.-c.~~, as determined by the board, and at least 6 semester hours or 9 quarter hours of the

course credits must have been completed in the area of marriage and family systems, theories, or techniques. Within the 2 ~~3~~ years of required experience, the applicant shall provide direct individual, group, or family therapy and counseling, to include the following categories of cases: unmarried dyads, married couples, separating and divorcing couples, and family groups including children. A doctoral internship may be applied toward the clinical experience requirement. A licensed mental health professional must be on the premises when clinical services are provided by a registered intern in a private practice setting.

(d) Has passed a theory and practice examination designated ~~provided~~ by the board ~~department~~ for this purpose.

(e) Has demonstrated, in a manner designated by rule of the board, knowledge of the laws and rules governing the practice of clinical social work, marriage and family therapy, and mental health counseling.

(f) For the purposes of dual licensure, the department shall license as a marriage and family therapist any person who meets the requirements of s. 491.0057. Fees for dual licensure shall not exceed those stated in this subsection.

(4) MENTAL HEALTH COUNSELING.—Upon verification of documentation and payment of a fee not to exceed $200, as set by board rule, plus the actual per applicant cost ~~to the department~~ for purchase of the examination from the National Board for Certified Counselors or its successor ~~Professional Examination Service for the National Academy of Certified Clinical Mental Health Counselors or a similar national organization~~, the department shall issue a license as a mental health counselor to an applicant who the board certifies:

(a) Has submitted an application and paid the appropriate fee.

(b)1. Has a minimum of an earned master's degree from a mental health counseling program accredited by the Council for the Accreditation of Counseling and Related Educational Programs that consists of at least 60 semester hours or 80 quarter hours of clinical and didactic instruction~~, including a course in human sexuality and a course in substance abuse~~. If the master's degree is earned from a program related to the practice of mental health counseling that is not accredited by the Council for the Accreditation of Counseling and Related Educational Programs, then the coursework and practicum, internship, or fieldwork must consist of at least 60 semester hours or 80 quarter hours and meet the following requirements:

a. Thirty-three semester hours or 44 quarter hours of graduate coursework, which must include a minimum of 3 semester hours or 4 quarter hours of graduate-level coursework in each of the following 11 content areas: counseling theories and practice; human growth and development; diagnosis and treatment of psychopathology; human sexuality; group theories and practice; individual evaluation and assessment; career and lifestyle assessment; research and program evaluation; social and cultural foundations; substance abuse; and legal, ethical, and professional standards issues in the practice of mental health counseling ~~in community settings; and substance abuse~~. Courses in research, thesis or dissertation work, practicums, internships, or fieldwork may not be applied toward this requirement.

b. A minimum of 3 semester hours or 4 quarter hours of

graduate-level coursework addressing diagnostic processes, including differential diagnosis and the use of the current diagnostic tools, such as the most-recent edition of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders. The graduate program must have emphasized the common core curricular experience ~~in legal, ethical, and professional standards issues in the practice of mental health counseling, which includes goals, objectives, and practices of professional counseling organizations, codes of ethics, legal considerations, standards of preparation, certifications and licensing, and the role identity and professional obligations of mental health counselors. Courses in research, thesis or dissertation work, practicums, internships, or fieldwork may not be applied toward this requirement~~.

c. The equivalent, as determined by the board, of at least 700 ~~1,000~~ hours of university-sponsored supervised clinical practicum, internship, or field experience that includes at least 280 hours of direct client services, as required in the accrediting standards of the Council for Accreditation of Counseling and Related Educational Programs for mental health counseling programs. This experience may not be used to satisfy the post-master's clinical experience requirement.

2. If the course title which appears on the applicant's transcript does not clearly identify the content of the coursework, the applicant shall be required to provide additional documentation, including, but not limited to, a syllabus or catalog description published for the course.

Education and training in mental health counseling must have

been received in an institution of higher education which at the time the applicant graduated was: fully accredited by a regional accrediting body recognized by the Council for Higher Education or its successor ~~Commission on Recognition of Postsecondary Accreditation~~; publicly recognized as a member in good standing with ~~the Association of~~ Universities ~~and Colleges of~~ Canada; or an institution of higher education located outside the United States and Canada, which at the time the applicant was enrolled and at the time the applicant graduated maintained a standard of training substantially equivalent to the standards of training of those institutions in the United States which are accredited by a regional accrediting body recognized by the Council for Higher Education or its successor ~~Commission on Recognition of Postsecondary Accreditation~~. Such foreign education and training must have been received in an institution or program of higher education officially recognized by the government of the country in which it is located as an institution or program to train students to practice as mental health counselors. The burden of establishing that the requirements of this provision have been met shall be upon the applicant, and the board shall require documentation, such as, but not limited to, an evaluation by a foreign equivalency determination service, as evidence that the applicant's graduate degree program and education were equivalent to an accredited program in this country. Beginning July 1, 2025, an applicant must have a master's degree in a program that is accredited by the Council for Accreditation of Counseling and Related Educational Programs which consists of at least 60 semester hours or 80 quarter hours to apply for licensure under this paragraph.

(c) Has had at least 2 years of clinical experience in mental health counseling, which must be at the post-master's level under the supervision of a licensed mental health counselor or the equivalent who is a qualified supervisor as determined by the board. An individual who intends to practice in Florida to satisfy the clinical experience requirements must register pursuant to s. 491.0045 before commencing practice. If a graduate has a master's degree with a major related to the practice of mental health counseling that did not include all the coursework required under sub-subparagraphs (b)1.a.-b., credit for the post-master's level clinical experience shall not commence until the applicant has completed a minimum of seven of the courses required under sub-subparagraphs (b)1.a.-b., as determined by the board, one of which must be a course in psychopathology or abnormal psychology. A doctoral internship may be applied toward the clinical experience requirement. A licensed mental health professional must be on the premises when clinical services are provided by a registered intern in a private practice setting.

(d) Has passed a theory and practice examination <u>designated</u> ~~provided~~ by the <u>board</u> ~~department~~ for this purpose.

(e) Has demonstrated, in a manner designated by rule of the board, knowledge of the laws and rules governing the practice of clinical social work, marriage and family therapy, and mental health counseling.

Section 5. Subsection (3) of section 491.0057, Florida Statutes, is amended to read:

491.0057 Dual licensure as a marriage and family therapist.—The department shall license as a marriage and family

therapist any person who demonstrates to the board that he or she:

(3) Has passed the examination designated ~~provided~~ by the board ~~department~~ for marriage and family therapy.

Section 6. Paragraph (b) of subsection (1) of section 491.006, Florida Statutes, is amended to read:

491.006 Licensure or certification by endorsement.—

(1) The department shall license or grant a certificate to a person in a profession regulated by this chapter who, upon applying to the department and remitting the appropriate fee, demonstrates to the board that he or she:

(b)1. Holds an active valid license to practice and has actively practiced the profession for which licensure is applied in another state for 3 of the last 5 years immediately preceding licensure.

~~2. Meets the education requirements of this chapter for the profession for which licensure is applied.~~

2.~~3.~~ Has passed a substantially equivalent licensing examination in another state or has passed the licensure examination in this state in the profession for which the applicant seeks licensure.

3.~~4.~~ Holds a license in good standing, is not under investigation for an act that would constitute a violation of this chapter, and has not been found to have committed any act that would constitute a violation of this chapter. ~~The fees paid by any applicant for certification as a master social worker under this section are nonrefundable.~~

Section 7. Section 491.0065, Florida Statutes, is repealed.

Section 8. Subsections (2) and (3) of section 491.007,

Florida Statutes, are amended to read:

491.007 Renewal of license, registration, or certificate.—

(2) Each applicant for renewal shall present satisfactory evidence that, in the period since the license or certificate was issued, the applicant has completed continuing education requirements set by rule of the board or department. Not more than 25 classroom hours of continuing education per year shall be required. ~~A certified master social worker is exempt from the continuing education requirements for the first renewal of the certificate.~~

~~(3) The board or department shall prescribe by rule a method for the biennial renewal of an intern registration at a fee set by rule, not to exceed $100.~~

Section 9. Subsection (2) of section 491.009, Florida Statutes, is amended to read:

491.009 Discipline.—

(2) The ~~department, or, in the case of psychologists, the~~ board~~,~~ may enter an order denying licensure or imposing any of the penalties in s. 456.072(2) against any applicant for licensure or licensee who is found guilty of violating any provision of subsection (1) of this section or who is found guilty of violating any provision of s. 456.072(1).

Section 10. Paragraphs (a) and (n) of subsection (1) of section 491.012, Florida Statutes, are amended to read:

491.012 Violations; penalty; injunction.—

(1) It is unlawful and a violation of this chapter for any person to:

(a) Use the following titles or any combination thereof, unless she or he holds a valid, active license as a clinical

social worker issued pursuant to this chapter:

1. "Licensed clinical social worker."

2. "Clinical social worker."

3. "Licensed social worker."

4. "Psychiatric social worker."

5. "Psychosocial worker."

6. "Certified master social worker."

(n) ~~Effective October 1, 2000,~~ Practice juvenile sexual offender therapy in this state, as the practice is defined in s. 491.0144, for compensation, unless the person holds an active license issued under this chapter and meets the requirements to practice juvenile sexual offender therapy. An unlicensed person may be employed by a program operated by or under contract with the Department of Juvenile Justice or the Department of Children and Families if the program employs a professional who is licensed under chapter 458, chapter 459, s. 490.0145, or s. 491.0144 who manages or supervises the treatment services.

Section 11. Section 491.0145, Florida Statutes, is amended to read:

491.0145 Certified master social worker.—The department shall license ~~may certify~~ an applicant for a designation as a certified master social worker who, upon applying to the department and remitting the appropriate fee, demonstrates to the board that he or she has met all of the following conditions:

(1) The applicant has submitted ~~The applicant completes~~ an application and has paid ~~to be provided by the department and pays~~ a nonrefundable fee not to exceed $250 to be established by rule of the board ~~department~~. ~~The completed application must be~~

~~received by the department at least 60 days before the date of the examination in order for the applicant to qualify to take the scheduled exam.~~

(2) The applicant submits proof satisfactory to the board ~~department~~ that the applicant has received a doctoral degree in social work, or a master's degree in social work with a major emphasis or specialty in ~~clinical practice or administration, including, but not limited to, agency~~ administration and supervision, program planning and evaluation, staff development, research, community organization, community services, social planning, and human service advocacy. Doctoral degrees must have been received from a graduate school of social work which at the time the applicant was enrolled and graduated was accredited by an accrediting agency approved by the United States Department of Education. Master's degrees must have been received from a graduate school of social work which at the time the applicant was enrolled and graduated was accredited by the Council on Social Work Education or the Canadian Association of Schools for ~~of~~ Social Work Education or by one that meets comparable standards.

(3) The applicant has had at least 2 ~~3~~ years' experience, as defined by rule, including, but not limited to, clinical services or administrative activities as defined in subsection (2), 2 years of which must be at the post-master's level under the supervision of a person who meets the education and experience requirements for certification as a certified master social worker, as defined by rule, or licensure as a clinical social worker under this chapter. A doctoral internship may be applied toward the supervision requirement.

(4) Any person who holds a master's degree in social work from institutions outside the United States may apply to the board ~~department~~ for certification if the academic training in social work has been evaluated as equivalent to a degree from a school accredited by the Council on Social Work Education. Any such person shall submit a copy of the academic training from the Foreign Equivalency Determination Service of the Council on Social Work Education.

(5) The applicant has passed an examination required by the board ~~department~~ for this purpose. ~~The nonrefundable fee for such examination may not exceed $250 as set by department rule.~~

(6) ~~Nothing in~~ This chapter does not ~~shall be construed to~~ authorize a certified master social worker to provide clinical social work services.

(7) The board may adopt rules to implement this section.

Section 12. Section 491.0149, Florida Statutes, is amended to read:

491.0149 Display of license; use of professional title on promotional materials.—

(1)(a) A person licensed under this chapter as a clinical social worker, marriage and family therapist, or mental health counselor, or certified as a master social worker shall conspicuously display the valid license issued by the department or a true copy thereof at each location at which the licensee practices his or her profession.

(b)1. A licensed clinical social worker shall include the words "licensed clinical social worker" or the letters "LCSW" on all promotional materials, including cards, brochures, stationery, advertisements, social media, and signs, naming the

licensee.

2. A licensed marriage and family therapist shall include the words "licensed marriage and family therapist" or the letters "LMFT" on all promotional materials, including cards, brochures, stationery, advertisements, social media, and signs, naming the licensee.

3. A licensed mental health counselor shall include the words "licensed mental health counselor" or the letters "LMHC" on all promotional materials, including cards, brochures, stationery, advertisements, social media, and signs, naming the licensee.

(c) A generalist social worker shall include the words "certified master social worker" or the letters "CMSW" on all promotional materials, including cards, brochures, stationery, advertisements, social media, and signs, naming the licensee.

(2)(a) A person registered under this chapter as a clinical social worker intern, marriage and family therapist intern, or mental health counselor intern shall conspicuously display the valid registration issued by the department or a true copy thereof at each location at which the registered intern is completing the experience requirements.

(b) A registered clinical social worker intern shall include the words "registered clinical social worker intern," a registered marriage and family therapist intern shall include the words "registered marriage and family therapist intern," and a registered mental health counselor intern shall include the words "registered mental health counselor intern" on all promotional materials, including cards, brochures, stationery, advertisements, social media, and signs, naming the registered

intern.

(3)(a) A person provisionally licensed under this chapter as a provisional clinical social worker licensee, provisional marriage and family therapist licensee, or provisional mental health counselor licensee shall conspicuously display the valid provisional license issued by the department or a true copy thereof at each location at which the provisional licensee is providing services.

(b) A provisional clinical social worker licensee shall include the words "provisional clinical social worker licensee," a provisional marriage and family therapist licensee shall include the words "provisional marriage and family therapist licensee," and a provisional mental health counselor licensee shall include the words "provisional mental health counselor licensee" on all promotional materials, including cards, brochures, stationery, advertisements, social media, and signs, naming the provisional licensee.

Section 13. Section 491.015, Florida Statutes, is repealed.

Section 14. Paragraph (c) of subsection (4) of section 414.065, Florida Statutes, is amended to read:

414.065 Noncompliance with work requirements.—

(4) EXCEPTIONS TO NONCOMPLIANCE PENALTIES.—Unless otherwise provided, the situations listed in this subsection shall constitute exceptions to the penalties for noncompliance with participation requirements, except that these situations do not constitute exceptions to the applicable time limit for receipt of temporary cash assistance:

(c) *Noncompliance related to treatment or remediation of past effects of domestic violence.*—An individual who is

determined to be unable to comply with the work requirements under this section due to mental or physical impairment related to past incidents of domestic violence may be exempt from work requirements, except that such individual shall comply with a plan that specifies alternative requirements that prepare the individual for self-sufficiency while providing for the safety of the individual and the individual's dependents. A participant who is determined to be out of compliance with the alternative requirement plan shall be subject to the penalties under subsection (1). The plan must include counseling or a course of treatment necessary for the individual to resume participation. The need for treatment and the expected duration of such treatment must be verified by a physician licensed under chapter 458 or chapter 459; a psychologist licensed under s. 490.005(1), s. 490.006, or the provision identified as s. 490.013(2) in s. 1, chapter 81-235, Laws of Florida; a therapist as defined in s. 491.003(3) or (7) ~~s. 491.003(2) or (6)~~; or a treatment professional who is registered under s. 39.905(1)(g), is authorized to maintain confidentiality under s. 90.5036(1)(d), and has a minimum of 2 years' ~~years~~ experience at a certified domestic violence center. An exception granted under this paragraph does not automatically constitute an exception from the time limitations on benefits specified under s. 414.105.

Section 15. This act shall take effect July 1, 2019.

THE FLORIDA SENATE

SENATOR DENNIS BAXLEY
12th District

COMMITTEES:
Ethics and Elections, *Chair*
Appropriations Subcommittee on Education
Education
Finance and Tax
Health Policy
Judiciary

JOINT COMMITTEE:
Joint Legislative Auditing Committee

February 20, 2019

The Honorable Chair Gayle Harrell
310 Senate Office Building
404 South Monroe Street
Tallahassee, FL 32309

Dear Chairwoman Harrell,

I would like to request that SB 884 Clinical Social Workers, Marriage and Family Therapists, and Mental Health Counselors be heard in the next Health Policy Committee meeting.

This bill deals with licensure revisions for Clinical social workers, marriage and family therapists and mental health counselors. It revises intern registration requirements, revises the licensure requirements for clinical social workers, marriage and family therapists and mental health counselors.

I appreciate your favorable consideration.

Onward & Upward,

Senator Dennis Baxley
Senate District 12

DKB/dd

cc: Allen Brown, Staff Director

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Bill Galvano
President of the Senate

David Simmons
President Pro Tempore

CourtSmart Tag Report

Room: KN 412 **Case:** **Type:**
Caption: Senate Health Policy Committee **Judge:**

Started: 3/25/2019 1:34:24 PM
Ends: 3/25/2019 3:25:54 PM **Length: 01:51:31**

1:34:23 PM Meeting called to order
1:34:34 PM Comments from Chair
1:34:44 PM Roll call - Quorum is present
1:35:13 PM Tab 7 - SB 1618 -Tobacco Products by Senator Simmons presented by Senator Mayfield
1:37:54 PM Chair
1:37:56 PM Questions?
1:38:02 PM Senator Rouson
1:38:32 PM Senator Mayfield
1:38:44 PM Senator Hooper
1:39:29 PM Senator Mayfield
1:39:47 PM Appearance Forms?
1:39:52 PM Chip Case, Lobbyist, American Cancer Society, waives in support
1:39:57 PM Marnie George, Sr. Advisor, Buchanan Ingersoll & Rooney, Fl. Chapter, American College of Cardiology, waives in support
1:40:09 PM Khauh-Lein Banko, Resolutions Chair, Florida PTA, waives in support
1:40:17 PM Fely Curva, Senior Partner, Cauva & Associates, LLC, SHAPE Florida, Budd Bell clearinghouse on Human Services, waives in support
1:40:27 PM Alexandra Abboud, Gov. Affairs Liaison, Florida Dental Association, waives in support
1:40:35 PM Rivers Buford, III, Gov. Relations, American Heart Association, waives in support
1:40:47 PM Mark Landreth, Gov. Relations Director, American Heart Association, waives in support
1:41:40 PM Jennifer Cunningham, Southeast Region Manager, State Gov. Affairs, JUUL Labs, speaking in support
1:43:10 PM Michael Boling, Jr., small business owner representing self, speaking for information
1:46:21 PM Adrien Ryan Taylor, representing self, speaking for information
1:49:02 PM Cheryl Lockhart, representing self, speaking against
1:51:25 PM JB McCormick, Entrepreneur, speaking against bill
1:53:24 PM Jonathan Risteen, Business Owner, speaking against
1:55:17 PM Shannon Whitesell, small business owner, speaking against
1:57:18 PM Robert Lovett, Florida Smoke Free Association, President, speaking for information
1:59:10 PM Cindi Kinch, representing self, speaking against
2:00:00 PM Delorse Orlando, self-employed, speaking against
2:02:42 PM Anthony Niebias, self-employed, speaking against the bill
2:05:44 PM Dan Hendrickson, President, Tallahassee Veterans Legal Collaborative, waives in support
2:06:40 PM Georgia McKeown, Consultant, American Cancer Society, waives in support
2:06:49 PM Debate?
2:06:53 PM Senator Berman
2:07:44 PM Further Debate?
2:08:43 PM Senator Bean
2:09:23 PM Senator Diaz
2:11:13 PM Senator Rouson
2:12:03 PM Senator Mayfield to close
2:15:06 PM Roll Call SB 1618 - Favorable
2:15:28 PM Tab 8 - SB 846 by Senator Pizzo - HIV Prevention
2:17:44 PM Questions?
2:18:44 PM Senator Bean
2:19:14 PM Senator Pizzo
2:19:54 PM Appearance Cards?
2:20:54 PM Michael King, speaking for self, waives in support
2:21:02 PM Dr. Elizabeth McCarthy, doctor cardiologist, LGBTA, waives in support
2:21:06 PM Alejandro Acosla, HIV Project Coordinator, Equality Florida, speaking in support
2:22:18 PM Michael E. Rajner, representing self, speaking in support
2:24:09 PM Kamaria Laffrey, Fl. Community organizer, FL HIV Justice Association, speaking in support
2:25:49 PM Angelisa Austin, Fl. HIV Coalition, speaking in support

2:26:36 PM Dr. Hanssel Tookes, Assistant Professor of Medicine, representing self, waives in support
2:26:46 PM Debate?
2:26:54 PM Senator Baxley
2:29:15 PM Senator Pizzo
2:30:27 PM Senator Pizzo
2:30:28 PM Motion to TP
2:30:33 PM Motion is adopted
2:30:38 PM Tab 3 - SB 1650 -Senator Albritton - Child Welfare
2:32:04 PM Strike All Amendment 234018 by Senator Albritton
2:34:09 PM Questions on amendment?
2:35:15 PM Appearance Cards on amendment
2:35:30 PM Victoria Zepp, Chief Policy and Research Center, FCC, speaking for the amendment
2:37:15 PM Michael Wickersham, Legislative Affairs Director, DCF, waives in support
2:37:53 PM Debate? None
2:37:58 PM Senator Albritton waives to close
2:38:11 PM Amendment 234018 is adopted
2:38:37 PM Back on bill as amended
2:38:40 PM Victoria Zepp, FCC, waives in support
2:38:50 PM Michael Wickersham, DCC, waives in support
2:38:51 PM Georgia McKeown, Consultant, Florida Coalition for Children, waives in support
2:38:52 PM Debate?
2:38:57 PM Senator Baxley
2:39:22 PM Senator Albritton, waives close
2:39:28 PM Roll Call SB 1650 - Favorable
2:39:36 PM Tab 6- SB 1436 by Senator Gibson - Closing the Gap Grant Proposals
2:40:53 PM Questions? None
2:41:53 PM Appearance Cards? None
2:41:59 PM Debate? None
2:42:07 PM Senator Gibson waives close
2:42:14 PM Roll Call SB 1436 Favorable
2:42:57 PM Vice Chair Berman in Chair
2:43:00 PM Tab 2 - SB 1526 by Senator Harrell - Telehealth
2:47:37 PM Chair
2:48:37 PM Questions?
2:48:43 PM Senator Berman
2:48:53 PM Senator Harrell
2:49:17 PM Senator Beman
2:49:24 PM Senator Harrell
2:49:42 PM Appearance Cards?
2:49:55 PM Paul Stanford, Florida Insurance Council & Florida Blue, speaking for information
2:50:51 PM Jack Herbert, Govt. Affairs Director, Florida Chiropractic Association, waives in support
2:50:55 PM Alison Dudley, President, The Florida Radiological Society, waives in support
2:51:01 PM
2:51:07 PM Corrie Howard, MD, President, FMA, speaking in support
2:52:15 PM Diego Echeverri, Director of Coalitions, Americans for Prosperity, waives in support
2:53:15 PM Ron Watson, Lobbyist, Florida Renal Coalition, waives in support
2:53:23 PM Stephen Winn, Exec. Director, Fl Osteopathic Medical Association, waives in support
2:53:30 PM Victoria Zepp, waives in support
2:53:40 PM Dorene Barker, AARP, waives in support
2:53:48 PM Chris Nuland, Fla. Chapter American College of Physicians, waives in support
2:53:52 PM Marnie George, FL Chapter American College of Cardiology, waives in support
2:54:01 PM Debate? None
2:54:06 PM Senator Harrell waives close
2:54:11 PM Roll Call SB 1526 - Favorable
2:54:43 PM Chair Harrell back in Chair
2:54:53 PM Tab 1 - SB 1528 by Senator Bean, Prescription Drug Importation Programs for Public Programs
2:58:03 PM Strike All Amendment 958184 by Senator Bean
3:04:58 PM Amendment to Amendment 209730 Senator Rouson
3:06:36 PM Amendment 209730 is w/d
3:07:25 PM Senator Baxley for a motion to vote at a time certain on amendment 3:25 pm
3:07:39 PM Motion is adopted
3:07:44 PM Questions?

3:07:51 PM Senator Hooper
3:08:27 PM Senator Bean
3:08:32 PM Senator Hooper
3:08:40 PM Senator Bean
3:09:00 PM Senator Rouson
3:10:16 PM Senator Bean
3:10:23 PM Senator Rouson
3:11:16 PM Senator Bean
3:11:53 PM Senator Rouson
3:12:07 PM Senator Bean
3:12:13 PM Senator Mayfield
3:13:03 PM Senator Bean
3:13:58 PM Senator Mayfield
3:14:47 PM Senator Bean
3:15:36 PM Senator Berman
3:15:52 PM Senator Bean
3:16:28 PM Senator Berman
3:16:38 PM Senator Bean
3:17:42 PM Senator Berman
3:18:01 PM Senator Bean
3:18:23 PM Senator Cruz
3:19:39 PM Senator Bean
3:20:05 PM Chair
3:20:08 PM Appearance Cards?
3:20:12 PM Don Bell, PSM, Ontario, speaking against
3:21:46 PM Peter Pitts, Center for Medicare in the Public Interest, speaking against
3:23:12 PM Chair
3:23:33 PM Roll call on Strike All - Favorable
3:23:59 PM Back on bill as amended
3:24:04 PM Senator Bean waives close
3:24:10 PM Debate?
3:24:13 PM Senator Rouson
3:24:20 PM Roll call SB 1528 - Favorable
3:25:12 PM Any votes for members to record? None
3:25:43 PM Senator Bean moves to adjourn. Motion adopted. We are adjourned.