Health & Human Services Committee

Thursday, January 30, 2020
9:00 AM – 11:00 AM
Morris Hall (17 HOB)

Meeting Packet

Jose Oliva
Speaker

Ray Rodrigues
Chair

Committee Meeting Notice

HOUSE OF REPRESENTATIVES

Health & Human Services Committee

Start Date and Time: Thursday, January 30, 2020 09:00 am

End Date and Time: Thursday, January 30, 2020 11:00 am

Location: Morris Hall (17 HOB)

Duration: 2.00 hrs

Consideration of the following bill(s):

HB 81 Medicaid School-based Services by Andrade
HB 113 Florida Drug and Cosmetic Act by Roach
HB 221 Osteopathic Physicians Certification and Licensure by Roach
CS/HB 351 Podiatric Medicine by Health Quality Subcommittee, Ponder
HB 409 Health Care Licensing Requirements by Pigman
HB 471 Council on Physician Assistants by Plasencia
HB 485 Athletic Trainers by Antone
HB 575 Applied Behavior Analysis Services by Plasencia
HB 709 Guardianship by Burton
HB 773 Medically Essential Electric Utility Service by Maggard
CS/HB 1103 Electronic Prescribing by Health Quality Subcommittee, Mariano

Pursuant to rule 7.11, the deadline for amendments to bills on the agenda by non-appointed members shall be 6:00 p.m., Wednesday, January 29, 2020.

By request of the Chair, all committee members are asked to have amendments to bills on the agenda submitted to staff by 6:00 p.m., Wednesday, January 29, 2020.

NOTICE FINALIZED on 01/28/2020 4:02PM by Osborne.Erin

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 81 Medicaid School-based Services
SPONSOR(S): Andrade
TIED BILLS: **IDEN./SIM. BILLS:** SB 190

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Market Reform Subcommittee	12 Y, 0 N	Grabowski	Calamas
2) Health Care Appropriations Subcommittee	10 Y, 0 N	Nobles	Clark
3) Health & Human Services Committee		Grabowski	Calamas

SUMMARY ANALYSIS

Medicaid is the health care safety net for low-income Floridians. Medicaid is a partnership of federal and state governments established to provide coverage for health services for eligible persons. The program is administered by the Agency for Health Care Administration (AHCA) and financed by federal and state funds.

The Florida Medicaid Certified School Match Program (program) provides school districts and private and charter schools the opportunity to enroll in Medicaid in order to have Medicaid share in the cost of providing certain school health services to students that are Medicaid recipients. Under the program, schools and school districts use state and local funds to pay for covered health services provided to students that are Medicaid recipients for which AHCA then reimburses them with matching federal Medicaid funds.

Medicaid recipients who receive services through the program must be under the age of 21 and qualify for Part B or H of the Individuals with Disabilities Education Act (IDEA) or for exceptional student services, or must have an individualized education plan (IEP) or individualized family service plan (IFSP). Health services provided must be both educationally relevant and medically necessary and tailored to meet the recipient's individual needs.

Until 2014, the federal Centers for Medicare and Medicaid Services (CMS) prohibited reimbursement for the services covered by the program provided to Medicaid recipients who did not have an IEP or IFSP. In December 2014, the CMS issued guidance which permits reimbursement of covered services provided to Medicaid recipients who do not have an IEP or IFSP.

The bill aligns Florida law with the 2014 CMS guidance by eliminating the requirement that Medicaid recipients receiving services through the Florida Medicaid Certified School Match Program qualify for Part B or H of the IDEA, or for exceptional student services, or have an IEP or IFSP.

The bill has an indeterminate fiscal impact on state government, but existing spending authority will be sufficient to absorb any impact. The bill will have no fiscal impact on local governments.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Florida Medicaid

Medicaid is the health care safety net for low-income Floridians. Medicaid is a partnership of the federal and state governments established to provide coverage for health services for eligible persons. The program is administered by the Agency for Health Care Administration (AHCA) and financed by federal and state funds. AHCA delegates certain functions to other state agencies, including the Department of Children and Families (DCF), the Department of Health, the Agency for Persons with Disabilities, and the Department of Elderly Affairs (DOEA).

The structure of each state's Medicaid program varies and what states must pay for is largely determined by the federal government, as a condition of receiving federal funds.[1] Federal law sets the amount, scope, and duration of services offered in the program, among other requirements. These federal requirements create an entitlement that comes with constitutional due process protections. The entitlement means that two parts of the Medicaid cost equation – people and utilization – are largely predetermined for the states. The federal government sets the minimum mandatory populations to be included in every state Medicaid program. The federal government also sets the minimum mandatory benefits to be covered in every state Medicaid program. These benefits include physician services, hospital services, home health services, and family planning.[2] States can add benefits, with federal approval. Florida has added many optional benefits, including prescription drugs, ambulatory surgical center services, and dialysis.[3]

Florida Medicaid does not cover all low-income Floridians. The maximum income limits for programs are illustrated below as a percentage of the federal poverty level (FPL).

Current Medicaid and CHIP Eligibility Levels in Florida[4] (With Income Disregards and Modified Adjusted Gross Income)						
Children's Medicaid			**CHIP (KidCare)** Age 0-18	**Pregnant Women**	**Parents Caretaker Relatives**	**Childless Adults** (non-disabled)
Age 0-1	Age 1-5	Age 6-18				
206% FPL	140% FPL	133% FPL	210% FPL	191% FPL	28% FPL	0% FPL

Applicants for Medicaid must be United States citizens or qualified noncitizens, must be Florida residents, and must provide social security numbers for data matching. While self-attestation is permitted for a number of data elements on the application, most components are matched through the Federal Data Services Hub.[5] Applicants must also agree to cooperate with Child Support Enforcement during the application process.[6]

[1] Title 42 U.S.C. §§ 1396-1396w-5; Title 42 C.F.R. Part 430-456 (§§ 430.0-456.725) (2016).
[2] S. 409.905, F.S.
[3] S. 409.906, F.S.
[4] U.S. Centers for Medicare and Medicaid Services, Medicaid.gov, *Florida,* http://www.medicaid.gov/medicaid/program-information/medicaid-and-chip-eligibility-levels/index.html (last visited November 4, 2019). For calendar year 2019, the federal poverty level (FPL) is $25,750 for a family of 4 residing in Florida.
[5] Florida Dep't of Children and Families, *Family-Related Medicaid Programs Fact Sheet,* p. 3, http://www.dcf.state.fl.us/programs/access/docs/Family-RelatedMedicaidFactSheet.pdf (last visited November 4, 2019).
[6] Id.

The Florida Medicaid program covers approximately 3.8 million low-income individuals.[7] Medicaid is the second largest single program in the state, behind public education, representing approximately one-third of the total FY 2019-2020 state budget.[8]

Florida Medicaid Certified School Match Program

The Florida Medicaid Certified School Match Program (program) provides school districts and private and charter schools the opportunity to enroll in Medicaid in order to have Medicaid share in the cost of providing school health services to students that are Medicaid recipients.[9] Under the program, schools and school districts use state and local funds to pay for covered health services provided to students that are Medicaid recipients for which AHCA then reimburses them with matching federal Medicaid funds.[10] Schools and school districts participating in the program can either employ or contract directly with Medicaid enrolled health care providers. The following types of health services covered by the program[11]:

- Physical therapy;
- Occupational therapy;
- Speech therapy services;
- Behavioral health services;
- Mental health services; and
- Transportation services.

In addition to the health services listed above, the program also reimburses the federal share for administrative work associated with delivering care to recipients, such as making a referral to a medical service.[12]

Medicaid recipients who receive services through the program must be under the age of 21 and qualify for Part B or H of the Individuals with Disabilities Education Act (IDEA), or for exceptional student services, or have an individualized education plan (IEP) or individualized family service plan (IFSP).[13] Health services provided must be both educationally relevant and medically necessary and tailored to meet the recipient's individual needs.[14]

In December 2014, the Centers for Medicare and Medicaid Services (CMS) issued guidance which allows for reimbursement of covered services provided to Medicaid recipients who do not have an IEP or IFSP.[15] The federal guidance clarified that school health services delivered to the general student population, not just students enrolled in IEPs, are eligible for Medicaid reimbursement.[16]

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[7] Agency for Health Care Administration, *Florida Statewide Medicaid Monthly Enrollment Report*, September 2019, available at https://ahca.myflorida.com/medicaid/Finance/data_analytics/enrollment_report/index.shtml (last accessed November 11, 2019).
[8] Ch. 2019-115, L.O.F. See also *Fiscal Analysis in Brief: 2019 Legislative Session*, available at http://flsenate.gov/UserContent/Committees/Publications/FiscalAnalysisInBrief/2019_Fiscal_Analysis_In_Brief.pdf (last accessed November 4, 2019).
[9] Ss. 409.9071 and 409.9072, F.S
[10] Agency for Health Care Administration, *House Bill 81 Analysis* (October 21, 2019) (on file with the Health Market Reform Subcommittee).
[11] S. 1011.70, F.S.
[12] Supra FN 10.
[13] Supra FN 9
[14] Supra FN 10
[15] U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, *State Medicaid Director Letter #14-006: Medicaid Payment for Services Provided without Charge*, December 15, 2014. Available at https://www.medicaid.gov/federal-policy-guidance/downloads/smd-medicaid-payment-for-services-provided-without-charge-free-care.pdf (last accessed November 4, 2019).
[16] Supra FN 10.

Effect of the Bill

The bill removes the requirement that Medicaid recipients receiving services through the Florida Medicaid Certified School Match Program qualify for Part B or H of the IDEA, or for exceptional student services, or have an IEP or IFSP. The change to Florida law reflects federal regulations allowing the provision of Medicaid school health services to the general population of Medicaid-eligible students.

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

B. SECTION DIRECTORY:

Section 1: Amends s. 409.9071, F.S., relating to Medicaid provider agreements for school districts certifying state match.
Section 2: Amends s. 409.9072, F.S., relating to Medicaid provider agreements for charter schools and private schools.
Section 3: Amends s. 409.908, F.S., relating to reimbursement of Medicaid providers.
Section 4: Provides an effective date.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   The amount of matching federal Medicaid funds for services provided by the program may increase as the amount of students eligible to receive services increases.

2. Expenditures:

   The bill has an indeterminate fiscal impact on state government and existing spending authority will be sufficient to absorb any impact.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   This bill may increase the reimbursement that school districts and charter schools receive for Medicaid services provided for eligible students who no longer need an IEP or IFSP.

2. Expenditures:

   The bill is not anticipated to impact state spending; however school districts may have to reallocate existing state and local funds in order to receive matching federal Medicaid funds.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

AHCA has sufficient rulemaking authority to implement the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to Medicaid school-based services; amending s. 409.9071, F.S.; revising applicable provisions for the reimbursement of school-based services by the Agency for Health Care Administration to certain school districts; deleting a requirement specifying the use of certified state and local education funds for school-based services; conforming a provision to changes made by the act; deleting an obsolete provision; amending s. 409.9072, F.S.; revising a requirement for the agency's reimbursement of school-based services to certain private and charter schools; conforming a provision to changes made by the act; amending s. 409.908, F.S.; specifying the federal agency that may waive certain school-based provider qualifications; providing an effective date.

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

Section 1. Subsection (1), paragraph (b) of subsection (2), and subsection (6) of section 409.9071, Florida Statutes, are amended to read:

409.9071 Medicaid provider agreements for school districts certifying state match.—

(1) The agency shall reimburse school-based services as

provided in ss. 409.908(21) and 1011.70 ~~former s. 236.0812~~ pursuant to the rehabilitative services option provided under 42 U.S.C. s. 1396d(a)(13). For purposes of this section, billing agent consulting services are ~~shall be~~ considered billing agent services, as that term is used in s. 409.913(10), and, as such, payments to such persons may ~~shall~~ not be based on amounts for which they bill nor based on the amount a provider receives from the Medicaid program. This provision may ~~shall~~ not restrict privatization of Medicaid school-based services. Subject to any limitations provided for in the General Appropriations Act, the agency, in compliance with appropriate federal authorization, shall develop policies and procedures and shall allow for certification of state and local education funds that ~~which~~ have been provided for school-based services as specified in s. 1011.70 and authorized by a physician's order where required by federal Medicaid law. ~~Any state or local funds certified pursuant to this section shall be for children with specified disabilities who are eligible for both Medicaid and part B or part H of the Individuals with Disabilities Education Act (IDEA), or the exceptional student education program, or who have an individualized educational plan.~~

(2) School districts that wish to enroll as Medicaid providers and that certify state match in order to receive federal Medicaid reimbursements for services, pursuant to subsection (1), shall agree to:

(b) Develop and maintain the financial and other student ~~individual education plan~~ records needed to document the appropriate use of state and federal Medicaid funds.

~~(6) Retroactive reimbursements for services as specified in former s. 236.0812 as of July 1, 1996, including reimbursement for the 1995-1996 and 1996-1997 school years, are subject to federal approval.~~

Section 2. Subsection (1) and paragraph (b) of subsection (2) of section 409.9072, Florida Statutes, are amended to read:

409.9072 Medicaid provider agreements for charter schools and private schools.—

(1) Subject to a specific appropriation by the Legislature, the agency shall reimburse private schools as defined in s. 1002.01 and schools designated as charter schools under s. 1002.33 which are Medicaid providers for school-based services pursuant to the rehabilitative services option provided under 42 U.S.C. s. 1396d(a)(13) to children younger than 21 years of age ~~with specified disabilities~~ who are eligible for ~~both~~ Medicaid ~~and part B or part H of the Individuals with Disabilities Education Act (IDEA) or the exceptional student education program, or who have an individualized educational plan~~.

(2) Schools that wish to enroll as Medicaid providers and receive Medicaid reimbursement under this section must apply to the agency for a provider agreement and must agree to:

(b) Develop and maintain the financial and student ~~individual education plan~~ records needed to document the appropriate use of state and federal Medicaid funds.

Section 3. Subsection (21) of section 409.908, Florida Statutes, is amended to read:

409.908 Reimbursement of Medicaid providers.—Subject to specific appropriations, the agency shall reimburse Medicaid providers, in accordance with state and federal law, according to methodologies set forth in the rules of the agency and in policy manuals and handbooks incorporated by reference therein. These methodologies may include fee schedules, reimbursement methods based on cost reporting, negotiated fees, competitive bidding pursuant to s. 287.057, and other mechanisms the agency considers efficient and effective for purchasing services or goods on behalf of recipients. If a provider is reimbursed based on cost reporting and submits a cost report late and that cost report would have been used to set a lower reimbursement rate for a rate semester, then the provider's rate for that semester shall be retroactively calculated using the new cost report, and full payment at the recalculated rate shall be effected retroactively. Medicare-granted extensions for filing cost reports, if applicable, shall also apply to Medicaid cost reports. Payment for Medicaid compensable services made on behalf of Medicaid eligible persons is subject to the availability of moneys and any limitations or directions

provided for in the General Appropriations Act or chapter 216. Further, nothing in this section shall be construed to prevent or limit the agency from adjusting fees, reimbursement rates, lengths of stay, number of visits, or number of services, or making any other adjustments necessary to comply with the availability of moneys and any limitations or directions provided for in the General Appropriations Act, provided the adjustment is consistent with legislative intent.

(21) The agency shall reimburse school districts that ~~which~~ certify the state match pursuant to ss. 409.9071 and 1011.70 for the federal portion of the school district's allowable costs to deliver the services, based on the reimbursement schedule. The school district shall determine the costs for delivering services as authorized in ss. 409.9071 and 1011.70 for which the state match will be certified. Reimbursement of school-based providers is contingent on such providers being enrolled as Medicaid providers and meeting the qualifications contained in 42 C.F.R. s. 440.110, unless otherwise waived by the United States Department of Health and Human Services ~~federal Health Care Financing Administration~~. Speech therapy providers who are certified through the Department of Education pursuant to rule 6A-4.0176, Florida Administrative Code, are eligible for reimbursement for services that are provided on school premises. Any employee of the school district who has been fingerprinted and has received a criminal

background check in accordance with Department of Education rules and guidelines is ~~shall be~~ exempt from any agency requirements relating to criminal background checks.

Section 4. This act shall take effect July 1, 2020.

Amendment No. 1

COMMITTEE/SUBCOMMITTEE ACTION

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

Committee/Subcommittee hearing bill: Health & Human Services Committee

Representative Andrade offered the following:

Amendment (with directory and title amendments)

Between lines 78 and 79, insert:

(5) For reimbursements to private schools and charter schools under this section, the agency shall apply the reimbursement schedule developed under s. 409.9071(5). Health care practitioners engaged by a school to provide services under this section must ~~be enrolled as Medicaid providers and~~ meet the qualifications specified under 24 C.F.R. s. 440.110, as applicable. Each school's continued participation in providing Medicaid services under this section is contingent upon the school providing to the agency an annual accounting of how the Medicaid reimbursements are used.

D I R E C T O R Y A M E N D M E N T

Remove lines 58-59 and insert:

Section 2. Subsection (1), paragraph (b) of subsection (2), and subsection (5) of section 409.9072, Florida Statutes, are amended to read:

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

Remove lines 13-14 and insert:

charter schools; removing a requirement that health care practitioners providing services under this section enroll as Medicaid providers; conforming a provision to changes made by the act; amending s. 409.908, F.S.; specifying

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 113 Florida Drug and Cosmetic Act
SPONSOR(S): Roach
TIED BILLS: **IDEN./SIM. BILLS:** SB 172

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	8 Y, 5 N	Morris	McElroy
2) Local, Federal & Veterans Affairs Subcommittee	9 Y, 6 N	Rivera	Miller
3) Health & Human Services Committee		Morris	Calamas

SUMMARY ANALYSIS

The federal Food Drug and Cosmetic Act (FDCA) and the Fair Packaging and Labeling Act (FPLA) regulate drugs and cosmetics in the U.S., including sunscreen, which is an over-the-counter (OTC) drug not requiring a prescription.

The Florida Drug and Cosmetic Act (FLDCA) regulates drugs and cosmetics within Florida, including sunscreen. The Department of Business and Professional Regulation (DBPR) is responsible for administering the provisions of the FLDCA within the Division of Drugs, Devices and Cosmetics (DDC). The DDC issues permits to OTC drug and cosmetics manufacturers, and enforces compliance with state and federal law.

The Florida Constitution grants counties and municipalities broad home rule authority. Specifically, municipalities have governmental, corporate, and proprietary powers necessary to perform their functions and provide services, and exercise any power for municipal purposes, except as otherwise provided by law. State legislation may preempt an area of law, precluding a local government from exercising authority in that particular area. Legislation preempting an area of law may be express, clearly stating the Legislature's intent to preempt the area, or implied, in that the legal regulatory scheme is so pervasive that local laws potentially would conflict with the state scheme if not found to be preempted.

Florida law does not currently preempt the regulation of OTC drugs or cosmetics to the state. Thus, local governments may pass ordinances regulating OTC drugs and cosmetics as long as such ordinances do not conflict with state or federal law.

HB 113 amends s. 499.002, F.S., to expressly preempt the regulation of OTC proprietary drugs and cosmetics to the state.

The bill has no fiscal impact on state and local governments.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Over-the-Counter Drugs and Cosmetics – Federal Regulation

The U.S. Food and Drug Administration (FDA) regulates food, drugs, cosmetics, products[1], medical devices, biologic products, and tobacco products under the Food Drug and Cosmetic Act (FDCA) and the Fair Packaging and Labeling Act (FPLA).[2] The FDCA prohibits the creation, introduction, delivery for introduction, or receipt of adulterated and misbranded drugs or cosmetics into interstate commerce.[3]

The FPLA requires that packages and their labels provide consumers with accurate information about the quantity of contents to prevent consumer deception. Specifically, FPLA regulations require cosmetic product labels to disclose:[4]

- Identification of the product;
- Net quantity of contents in terms of weight, measure, or numerical count;
- Material facts about product and its use, such as directions for safe use;
- Name and place of business of the product's manufacturer, packer, or distributor;
- Warning and caution statements for products that are required to bear such statements by the FDCA and FDA regulations; and
- A list of ingredients in descending order of predominance.

Over-the Counter Drug Regulation

The FDA Center for Drug Evaluation and Research (CDER) regulates the safety and efficacy of drugs in the U.S.[5] The FDA Center for Food Safety and Applied Nutrition (CFSAN) houses the Office of Cosmetics and Colors which regulates cosmetics marketed within the U.S.[6]

Over-the-counter (OTC) drug products are drugs available without a prescription that are safe and effective for use by the general public without the need for treatment by a health professional.[7] The CDER regulates prescription and OTC drugs which include medicines and products such as fluoride toothpaste and sunscreen.[8] For OTC drugs, the CDER must ensure that a drug's benefits outweigh its risks, the drug may be used safely in an unsupervised setting, and is properly labeled.[9]

[1] Although the scope of the FDA's regulatory authority is very broad, it does not include the regulation of meat, poultry and some egg products. U.S. Food and Drug Administration (FDA), *What Does FDA Regulate?,* https://www.fda.gov/about-fda/fda-basics/what-does-fda-regulate (last visited Jan. 24, 2020).
[2] *See* FDA, *What Does FDA Regulate?,* https://www.fda.gov/about-fda/fda-basics/what-does-fda-regulate (last visited Jan. 24, 2020).
[3] 21 U.S.C. § 331.
[4] 15 U.S.C. § 1451-1460 (2009).
[5] FDA, *Drugs*, https://www.fda.gov/drugs (last visited Jan. 24, 2020).
[6] FDA, *Regulatory Procedures Manual*, *Chapter 1 – Regulatory Organization*, available at https://www.fda.gov/media/71908/download (last visited Jan. 24, 2020).
[7] FDA, *Drug Applications for Over-the-Counter (OTC) Drugs,* available at: https://www.fda.gov/drugs/types-applications/drug-applications-over-counter-otc-drugs (last visited Jan. 24, 2020)
[8] FDA, *Center for Drug Evaluation and Research (CDER)*, https://www.fda.gov/about-fda/office-medical-products-and-tobacco/center-drug-evaluation-and-research-cder (last visited Jan. 24, 2020).
[9] FDA, *Office of Drug Evaluation IV: What We Do,* https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/office-drug-evaluation-iv-what-we-do (last visited Jan. 24, 2020).

Because there are more than 300,000 marketed OTC drugs, the CDER reviews the active ingredients[10] and labels for over 80 classes[11] of OTC drugs rather than for each individual drug. For each class, an OTC drug monograph[12] is developed and published in the Federal Register.[13]

Sunscreen Regulation

The FDCA treats sunscreens, and their active ingredients, as regulated OTC drugs.[14] Currently, the FDA has approved 16 acceptable active ingredients, including octinoxate and oxybenzone, in products that are labeled as sunscreen.[15] Active ingredients in sunscreens protect the skin from the sun's ultraviolet rays, while inactive ingredients are all other ingredients.[16]

The FDA recently proposed a new rule addressing the list of acceptable sunscreen active ingredients to make sure that over-the-counter sunscreens are safe and effective for human use.[17] The proposed rule re-assesses the safety and effectiveness of the active ingredients and dosage forms, updates sunscreen testing and recordkeeping requirements, and addresses new uses of sunscreens, including the sale of combination sunscreen-insect repellant products. The rule is not yet effective[18] and the FDA does not expect the affected industry to fully comply with the new standards for at least a year after it becomes effective.[19]

Significantly, the proposed rule will modify the safety and efficacy status of the 16 acceptable active ingredients currently allowed in sunscreens, as follows:[20]

- Zinc oxide and titanium dioxide will be categorized as safe and effective;
- Para-aminobenzoic acid and trolamine salicylate will be categorized as unsafe and ineffective; and
- The remaining 12 ingredients will be identified as not having enough information to determine whether they are safe and effective and the FDA will request additional data from the industry to help make a determination on safety and efficacy.

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[10] An active ingredient is any component that provides pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or animals. FDA, *Drugs@FDA Glossary of Terms,* https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms (last visited Jan. 24, 2020).

[11] Examples of these classes of drugs include those related to acne, allergy, cold and cough, laxative, insect repellant, nasal decongestant, and sunscreen. *See* FDA, *Status of OTC Rulemakings*, https://www.fda.gov/drugs/over-counter-otc-drugs/status-otc-rulemakings (last visited Jan. 24, 2020*See also* FDA, *Division of Nonprescription Drugs*, https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/division-nonprescription-drugs (last visited Jan. 24, 2020).

[12] An OTC monograph establishes conditions under which certain OTC drugs may be marketed without approved new drug applications because they are "generally recognized as safe and effective" (GRASE) and not misbranded. *See* 21 C.F.R. § 330.1.

[13] FDA, *Drug Applications for Over-the-Counter (OTC) Drugs,* available at: https://www.fda.gov/drugs/types-applications/drug-applications-over-counter-otc-drugs (last visited Jan. 24, 2020)

[14] *See* 21 U.S.C. §§ 321(g) and 360fff; See also 61N-1.006 and 61N-1.009, F.A.C.

[15] The remaining acceptable active ingredients are: Aminobenzoic acid, Avobenzone, Cinoxate, Dioxybenzone, Homosalate, Meradimate, Octocrylene, Octisalate, Padimate O, Ensulizole, Sulisobenzone, Titanium dioxide, Trolamine salicylate, and Zinc oxide. FDA, *Sunscreen: How to Help protect Your Skin from the Sun,* https://www.fda.gov/drugs/understanding-over-counter-medicines/sunscreen-how-help-protect-your-skin-sun (last visited Jan. 24, 2020).

[16] *Id.*

[17] Federal Register, *Sunscreen Drug Products for Over-the-Counter Human Use,* https://www.federalregister.gov/documents/2019/02/26/2019-03019/sunscreen-drug-products-for-over-the-counter-human-use (last visited Jan. 24, 2020).

[18] Federal Register, *Sunscreen Drug Products for Over-the-Counter Human Use,* https://www.federalregister.gov/documents/2019/04/18/2019-07710/sunscreen-drug-products-for-over-the-counter-human-use-extension-of-comment-period (last visited Jan. 24, 2020). Despite the November 26, 2019 date, the rule is still in the final rule stage and has not been published in the Federal Register. Generally an agency rule is effective no less than thirty days (sixty days for certain significant or major rules) after the date of publication in the Federal Register. If the agency wants to make the rule effective sooner, it must cite "good cause" as to why this is in the public interest. Federal Register, *A Guide to the Rulemaking Process*, available at https://www.federalregister.gov/uploads/2011/01/the_rulemaking_process.pdf (last visited Jan. 24, 2020).

[19] *See* U.S. Regulations, Sunscreen Drug Products –OPEN, https://www.regulations.gov/docket?D=FDA-1978-N-0018 (last visited Jan. 24, 2020); *See also* 84 FR 6204.

[20] FDA, *FDA advances new proposed regulation to make sure sunscreens are safe and effective,* https://www.fda.gov/news-events/press-announcements/fda-advances-new-proposed-regulation-make-sure-sunscreens-are-safe-and-effective (last visited Jan. 24, 2020).

In contrast to its sunscreen drug regulations, the FDA's cosmetic regulations exclude more ingredients as being unsafe. Generally, a manufacturer may use any ingredient in the formulation of a cosmetic. Color additives are prohibited. However, the FDA prohibits or restricts the use of 10 other types of ingredients in cosmetic products including chloroform, bithioniol, methylene chloride, and mercury-containing compounds, and sunscreens in cosmetics. If a restricted ingredient is used in a cosmetic, the manufacturer may be required to place a warning statement on the cosmetic container.[21]

OTC Drugs and Cosmetics – State Regulation

Part I of ch. 499, F.S., the Florida Drug and Cosmetic Act (FLDCA), implemented by the DBPR, regulates drugs, cosmetics, and certain devices in Florida. Part of the purpose of the FLDCA is to promote uniformity between federal and state regulation.[22] As such, administration of the FLDCA must conform to the Federal Food, Drug, and Cosmetic Act[23] and the applicable portions of the Federal Trade Commission Act,[24] which prohibit the false advertising of drugs, devices, and cosmetics.[25]

DBPR's Division of Drugs, Devices and Cosmetics (DDC) issues permits to over-the-counter drug manufacturers and cosmetic manufacturers and inspects permittees and enforces FLDCA. [26]

In addition to the above, the FLDCA also provides:[27]

- Criminal prohibitions against distribution of contraband and misbranded prescription drugs;
- Regulations for the advertising and labeling of drugs, devices, and cosmetics; and
- Enforcement authority for DBPR, including seizure and condemnation of drugs, devices, and cosmetics.

State and Local Sunscreen Regulation

DBPR regulates sunscreen as an OTC drug because FDA regulation considers sunscreen a drug.[28] Florida defines an OTC drug as a drug in its unbroken, original package, sold to the public by, or under the authority of, the manufacturer or primary distributor, purchased without a prescription and not misbranded.[29] Florida law does not authorize the DBPR to determine if OTC drug ingredients are safe or unsafe for the environment or use by humans.

Some municipalities have passed or considered ordinances banning the sale and use of certain sunscreens as a result of the findings of recent studies[30] suggesting certain sunscreen chemicals could be linked to damage of coral reefs. In February 2019, the City Commission of Key West passed an ordinance making it unlawful to sell, offer for sale, or distribute for sale in the City of Key West any SPF[31] sunscreen protection personal care product that contains oxybenzone or octinoxate, or both,

[21] FDA, *Prohibited and Restricted Ingredients*. http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm127406.htm (last visited Jan. 24, 2020).
[22] *See* s. 499.002(1), F.S.
[23] 21 U.S.C. ss. 301 *et seq*.
[24] *See* 15 U.S.C. §§ 41-58, as amended.
[25] S. 499.002(1)(b), F.S.
[26] *Id.*
[27] *See* ss. 499.0051, 499.0054, and 499.062, F.S.
[28] *See* FDA*, Clover Custom Blending LLC MARCS-CMS 527994 Warning Letter,* February 28, 2018*,* available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/clover-custom-blending-llc-527994-02282018 (last visited Jan. 24, 2020); *see also* U.S. Food and Drug Administration, *Sunscreen: How to Help protect Your Skin from the Sun,* https://www.fda.gov/drugs/understanding-over-counter-medicines/sunscreen-how-help-protect-your-skin-sun (last visited Jan. 24, 2020).
[29] S. 499.003(43), F.S.,
[30] *See* Danovaro, *et. al.*, *Sunscreens cause coral bleaching by promoting viral infections*, Environmental Health Perspectives, Vol. 116, April 2008, at 441, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2291018/pdf/ehp0116-000441.pdf (last visited Jan. 24, 2020).
[31] Sun protection factor (SPF) is the value indicating the amount of UV radiation exposure it takes to cause a sunburn when using a sunscreen compared to when not using a sunscreen. The higher the SPF value (up to 50) the greater sunburn protection provided.

without a "medically-licensed" prescription.[32] A month later, the City of Miami Beach considered but did not pass similar legislation amid lawmakers' concerns that more research is needed.[33]

In passing the ordinance, the Key West City Commission cited significant harmful impacts from the two chemicals on the marine environment and residing ecosystems around the waters of Key West, including coral reefs that protect the shoreline of Key West and the Florida Keys. The first violation of the ordinance results in a written warning, unless there is a serious threat to public safety or an irreparable violation. Subsequent violations are punishable pursuant through the city's civil citation procedure, which could result in a maximum civil penalty of $500.[34] The city's sunscreen prohibition becomes effective January 1, 2021.[35]

Hawaii[36] and the U.S. Virgin Islands[37] are the only state and territory to pass legislation addressing sunscreen ingredients. The laws go further than the FDA rule and either ban the sale, distribution, or use of sunscreens containing two ingredients, oxybenzone and octinoxate, that the FDA determined needed more data. The Hawaii ban begins on January 1, 2021, and the U.S. Virgin Islands prohibition begins after March 30, 2020. Both laws contain findings referencing the chemicals' impacts on marine life and coral.

Research on Effects of Over-the-Counter Sunscreen Chemicals

Ultraviolet (UV) Radiation

Ultraviolet (UV) radiation is a form of energy most commonly produced by sunlight. There are three types of UV radiation produced by sunlight: UVA, UVB, and UVC. UVC and some UVB radiation is absorbed by the Earth's ozone layer. However, UVA and some UVB radiation comes into contact with humans and can cause damage to the body. Short term[38] overexposure to UV radiation can cause a sunburn while prolonged exposure can cause skin cancer and premature aging.[39]

Exposure to UVB radiation helps the skin produce vitamin D. Vitamin D plays an important role in the bone and muscle health. sSome UV radiation therapies have been used to treat unresponsive and severe conditions such as psoriasis, rickets, and lupus.[40]

The Center for Disease Control (CDC) recommends the use of sunscreen or protective clothing as the best protection against UV damage from the sun. Sunscreens absorb, reflect, or scatter sunlight to help protect the skin from damaging UV effects. Sunscreens are assigned a sun protection factor (SPF) which measure their rate of effectiveness. The minimum SPF recommended by the CDC is SPF15, but

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FDA, *Sun protection factor (SPF)*, https://www.fda.gov/drugs/understanding-over-counter-medicines/sunscreen-how-help-protect-your-skin-sun#spf (last visited Jan. 24, 2020).

[32] Chapter 26, Article VII., Sec. 26-311, Code of Ordinances, City of Key West Florida (Ord. No.19-03, § 1, 2-5-2019, available at https://library.municode.com/fl/key_west/codes/code_of_ordinances?nodeId=SPAGEOR_CH26EN_ARTVIISU (last visited Jan. 24, 2020).

[33] *See* Gurney, Kyra, "Miami Beach considers banning the sale of sunscreens believed to harm coral reefs," Miami Herald, March 13, 2019, available at https://www.miamiherald.com/news/local/community/miami-dade/miami-beach/article227431294.html (last visited Jan. 24, 2020).

[34] Ch. 2, Art. VI, Div. 3, Code of Ordinances, City of Key West Florida.

[35] *See* City of Key West City Commission*, Action Details Amending Chapter 26 – Sunscreen,* available at http://keywest.legistar.com/LegislationDetail.aspx?ID=3763135&GUID=EFF5D76E-F043-4AFF-A898-42EB20A25953&Options=Advanced&Search= (last visited Jan. 24, 2020).

[36] *See* HAW. REV. STAT. § 342D-21 (L 2018, c 104, §2, enacted July 2018), available at https://www.capitol.hawaii.gov/hrscurrent/Vol06_Ch0321-0344/HRS0342D/HRS_0342D-0021.htm (last visited Jan. 24, 2020).

[37] *See* U.S. Virgin Islands Bill No. 33-0043/Act No. 8185 (2019), available at http://legvi.org:82/ShowPDF.aspx?num=8185&type=Act (last visited Jan. 24, 2020).

[38] The Center for Disease Control (CDC) estimates the sun's UV rays can damage the skin in as little as 15 minutes. *See* CDC, *Sun Safety*, https://www.cdc.gov/cancer/skin/basic_info/sun-safety.htm (last visited Jan. 24, 2020).

[39] FDA, *Prohibited and Restricted Ingredients*, available at https://www.fda.gov/radiation-emitting-products/tanning/ultraviolet-uv-radiation (last visited Jan. 24, 2020).

[40] *Id*.

the higher the number the more protection is provided. The CDC also recommends re-applying sunscreen if in the sun more than two hours or after swimming, sweating, or toweling off.[41]

Dermatological Efficacy of Sunscreen

According to the American Academy of Dermatology (AAD),[42] one in five Americans will develop skin cancer in their lifetime with nearly 20 Americans dying from melanoma[43] every day. The AAD's official position is that vitamin D should be obtained from a healthy diet and not unprotected exposure to the sun or indoor tanning beds. The AAD noted studies have shown that UV radiation from the sun and tanning devices can cause oncogenic mutations in skin cells,[44] and there is no scientifically safe level of UV exposure from either the sun or indoor tanning devices. To protect against skin cancer, the AAD recommends a photo-protective regimen including regular and proper use of broad-spectrum sunscreens.[45]

Environmental Effects of Sunscreen

As directed by the Legislature, the Office of Program Policy Analysis and Government Accountability (OPPAGA) compiled recent peer-reviewed research about the effects of oxybenzone and octinoxate on corals and marine life. In the overview of its findings presented to the Legislature in September 2019, OPPAGA recognized that "a small number of scientific studies have shown negative effects[46] of oxybenzone and octinoxate (active ingredients in some sunscreen products) on corals and marine life at concentration levels generally not observed in nature." OPPAGA noted that sunscreens were not the only source of these chemicals, but they were also found in wastewater effluent, plastics dumped in the ocean, and hull paint on ships.[47]

OPPAGA noted that the active ingredients in sunscreen fall into two categories: organic radiation absorbers and inorganic sun-blocking agents. Oxybenzone and octinoxate are organic absorbers used in sunscreens, shampoos, and other personal care products. While on the FDA's approved list, the chemicals are restricted to a maximum amount of 6% for oxybenzone and 7.5% for octinoxate in sunscreens sold in the U.S.[48]

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[41] CDC, *Sun Safety*, https://www.cdc.gov/cancer/skin/basic_info/sun-safety.htm (last visited Jan. 24, 2020).
[42] *See* American Academy of Dermatology (AAD), *Detect Skin Cancer: How to Perform a Skin Self-Exam, available at* https://www.aad.org/skin-cancer-find-check and *Is Sunscreen Safe?*, https://www.aad.org/sun-protection/is-sunscreen-safe (last visited Jan. 24, 2020).
[43] Melanoma is one of the rarer and more dangerous forms of skin cancer. It is much more likely to spread to other parts of the body if not caught and treated early. *See* American Cancer Society (ACS), *What is Melanoma Skin Cancer?,* https://www.cancer.org/cancer/melanoma-skin-cancer/about/what-is-melanoma.html (last visited Jan. 24, 2020).
[44] *See* D M Parkin, D Mesher and P Sasieni, *Cancers Attributable To Solar (Ultraviolet) Radiation Exposure in the UK in 2010,* British Journal of Cancer, Dec. 2011. At 105, available at https://www.nature.com/articles/bjc2011486 (last visited Nov. 22, 2019); International Agency for Research on Cancer, Working Group on artificial ultraviolet (UV) light and skin cancer, *The Association Of Use Of Sunbeds With Cutaneous Malignant Melanoma And Other Skin Cancers: A Systematic Review*, Jan. 2007, https://onlinelibrary.wiley.com/doi/full/10.1002/ijc.22453 (last visited Jan. 24, 2020); *See also* Jennifer S Lin, MD, MCR, Michelle Eder, PhD, Sheila Weinmann, PhD, Sarah P Zuber, MSW, Tracy L Beil, MS, Daphne Plaut, MLS, and Kevin Lutz, MFA, *Behavioral Counseling To Prevent Skin Cancer: A Systematic Review for the U.S. Preventive Services Task Force Recommendation*, Rockville (MD): Agency for Healthcare Research and Quality (US), Feb. 2011, available at https://www.ncbi.nlm.nih.gov/books/NBK53508/. (last visited Jan. 24, 2020).
[45] AAD, P*osition Statement on Vitamin D*, available at https://server.aad.org/forms/policies/uploads/ps/ps-vitamin%20d.pdf? (last visited Nov. 22, 2019); *See also See* Jolieke C. van der Pols, Gail M. Williams, Mirmala Pandeya, Valerie Logan, and Adèle C. Green, *Prolonged Prevention of Squamous Cell Carcinoma of the Skin by Regular Sunscreen Use*, Cancer Epidemiol Biomarkers Prevention, Dec. 2006, at 2546, available at https://cebp.aacrjournals.org/content/15/12/2546 (last visited Nov. 22, 2019) and Caroline G. Watts, MPH, PhD, Martin Drummond, MBiost, Chris Goumas, MPH, et al, *Sunscreen Use and Melanoma Risk Among Young Australian Adults,* JAMA Dermatol. July 2018, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6143037/ (last visited Jan. 24, 2020).
[46] Identified negative effects that may be occurring include the bleaching of coral fragments and coral cells from hard coral and damage to coral DNA and reduced reproductive success.
[47] Office of Program Policy Analysis and Government Accountability (OPPAGA)*, Summary of Peer-Reviewed Research on the Effects of Selected Sunscreen Chemicals on Corals and Marine Life, 2008 to Present* (Sept. 2019) (on file with House Health and Human Services Committee).
[48] *Id.* at pages 1-2.

OPPAGA reviewed 18 peer-reviewed studies from 2008 to the present and detailed the effects of the chemicals oxybenzone and octinoxate in the following chart:

Exhibit 2
Detailed Effects of Oxybenzone and Octinoxate Exposure on Corals and Marine Life, by Concentration in Water

Effect	Organism(s)	Study
Chemical Concentrations of Parts Per Million		
Coral bleaching	Coral	Danovaro, 2008
Damage to coral planulae, coral bleaching, damage to coral DNA	Coral	Downs, 2015
Reduced reproductive success (flatworms and diatoms) and behavioral changes (anemones and coral)	Flatworms, diatoms, sea anemones, and coral	McCoshum, 2016
Reduced reproductive success	Marine phytoplankton Japanese medaka fish Green alga Aquatic midges	Tovar-Sánchez, 2013 Kim, 2014 Mao, 2018 Campos, 2019
Behavioral changes	Siamese fighting fish	Chen, 2016
Immobilization	Aquatic crustaceans	Jang, 2016
Larvae damage	Sea urchins	Corinaldesi, 2017
Mortality	Aquatic crustaceans	Gakowska, 2018
Chemical Concentrations of Parts Per Billion		
Bioaccumulation	Coral Fish including common carp, brown trout, Ebro barbel, and European Eel Zebrafish	He, 2019 Gago-Ferrero, 2015 Zhou, 2019
Reduced reproductive success	Fathead minnows[1]	Christen, 2011
DNA damage	Zebrafish[2]	Zucchi, 2011 Bluthgen, 2012 Zhang, 2017

[1] Fathead minnows are used in EPA testing to determine toxicity levels.

[2] Zebrafish are considered an excellent vertebrate organism for testing toxic effects of chemicals.

Source: OPPAGA analysis.

OPPAGA identified three main categories of deficiencies in current research. First, the lowest concentration of the tested chemicals that would have a negative impact on the marine environment cannot be determined because there is not enough data. Additionally, in Florida the concentration of the tested chemicals is not currently being recorded by any state agency and concentrations vary widely across different locations.

Next, the method of exposure addressed in the studies presents a research gap. Scientists interviewed by OPPAGA noted that the studies addressed short term acute exposure of the tested chemicals on marine life but did examine long term chronic exposure. Scientists also were concerned that the studies were conducted in laboratories absent real world factors affecting coral reefs and marine life such as the amount of organic material in the seawater.

Finally, the effects of multiple combined chemicals has not been sufficiently addressed by current research. Scientists noted that the studies do not examine the effects of combinations of ingredients as they might be found in nature nor do they examine how these chemicals could break down and interact with other compounds in the seawater.[49]

[49] *See* OPPAGA, *Summary of Peer-Reviewed Research on the Effects of Selected Sunscreen Chemicals on Corals and Marine Life, 2008 to Present* (Sept. 2019) 4-5 (on file with House Health and Human Services Committee).

Local Government Authority

The Florida Constitution grants counties[50] and municipalities[51] broad home rule authority. Non-charter county governments may exercise those powers of self-government provided by general or special law.[52] Counties operating under a county charter have all powers of self-government not inconsistent with general law or special law approved by vote of the electors.[53]

Municipalities have those governmental, corporate, and proprietary powers necessary to conduct municipal government, perform their functions and provide services, and exercise any power for municipal purposes,[54] except as otherwise provided by law.[55]

Preemption

Counties and municipalities have broad authority to legislate on any matter that is not inconsistent with federal or state law. A local government enactment may be inconsistent with state law if (1) the Legislature "has preempted a particular subject area" or (2) the local enactment conflicts with a state statute. Where state preemption applies to a particular topic, it precludes a local government[56] from exercising authority in that particular area.[57]

Florida law recognizes two types of preemption: express and implied. Express preemption requires a specific legislative statement; it cannot be implied or inferred.[58] Express preemption of a field by the Legislature must be accomplished by clear language stating that intent.[59] In cases where the Legislature expressly or specifically preempts an area, the intent of the Legislature is readily ascertained.[60] In cases determining the validity of ordinances enacted in the face of state preemption, the effect has been to find such ordinances null and void.[61]

Implied preemption actually is a decision by the courts to recognize state preemption in the absence of an explicit legislative directive.[62] Preemption of a local government enactment is implied only where "the legislative scheme is so pervasive as to evidence an intent to preempt the particular area," and strong public policy reasons exist for finding preemption.[63] Implied preemption is found where the local legislation would present a danger of conflicting with the state's pervasive regulatory scheme.[64]

[50] Counties are subdivisions of the state created by law. *See* art. VIII, s. 1(a), Fla. Const.
[51] Municipalities are created by general or special law or recognized pursuant to art. VIII, s. 2 or s. 6, Fla. Const. *See* s. 165.031(3), F.S. The term "municipality" may be used interchangeably with the terms "city," "town," or "village."
[52] Art. VIII, s. 1(f), Fla. Const.
[53] Art. VIII, s. 1(g), Fla. Const.
[54] A "municipal purpose" is any activity or power which may be exercised by the state or its political subdivisions. *See* s. 166.021(2), F.S.
[55] Art. VIII, s. 2(b), Fla. Const. *See also* s. 166.021(1), F.S.
[56] Including without limitation counties, municipalities, school districts, special districts, or any other subdivision of the state.
[57] Wolf, *The Effectiveness of Home Rule: A Preemption and Conflict Analysis*, 83 Fla. B.J. 92 (June 2009), available at https://www.floridabar.org/the-florida-bar-journal/the-effectiveness-of-home-rule-a-preemption-and-conflict-analysis/ (last visited Oct. 25, 2019).
[58] *See City of Hollywood v. Mulligan*, 934 So. 2d 1238, 1243 (Fla. 2006); *Phantom of Clearwater, Inc. v. Pinellas County*, 894 So. 2d 1011, 1018 (Fla. 2d DCA 2005), approved in *Phantom of Brevard, Inc. v. Brevard County*, 3 So. 3d 309 (Fla. 2008).
[59] *Mulligan*, *supra* at 934 So. 2d at 1243.
[60] *Sarasota Alliance for Fair Elections, Inc. v. Browning*, 28 So. 3d 880, 886 (Fla. 2010).
[61] *See, e.g., Nat'l Rifle Ass'n of Am., Inc. v. City of S. Miami,* 812 So.2d 504 (Fla. 3d DCA 2002).
[62] *Phantom of Clearwater, Inc.*, 894 So.2d at 1019.
[63] *Id*., quoting *Tallahassee Memorial Regional Medical Center, Inc. v. Tallahassee Medical Center, Inc.,* 681 So.2d 826, 831 (Fla. 1st DCA 1996), citing *Tribune Co. v. Cannella*, 458 So.2d 1075 (Fla. 1984).
[64] *Sarasota Alliance for Fair Elections, Inc.,* 28 So.3d at 886.

Effect of Proposed Changes

The bill amends s. 499.002, F.S., to expressly preempt the regulation of OTC proprietary drugs and cosmetics to the state. This nullifies the current City of Key West ordinance banning the sale of any SPF sunscreen product containing oxybenzone or octinonate and prevents local governments from enacting similar ordinances in the future.

B. SECTION DIRECTORY:

Section 1 Amends s. 499.002, F.S., to preempt the regulation of over-the-counter drugs and cosmetics to the state.

Section 2 Provides an effective date of July 1, 2020.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   Not Applicable. This bill does not appear to require counties or municipalities to spend funds or take action requiring the expenditures of funds; reduce the authority that counties or municipalities have to raise revenues in the aggregate; or reduce the percentage of state tax shared with counties or municipalities.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

The bill neither requires nor authorizes executive branch rulemaking.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to the Florida Drug and Cosmetic Act; amending s. 499.002, F.S.; preempting the regulation of over-the-counter proprietary drugs or cosmetics to the state; providing an effective date.

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

Section 1. Subsection (7) is added to section 499.002, Florida Statutes, to read:

499.002 Purpose, administration, and enforcement of and exemption from this part.—

(7) Notwithstanding any other law or local ordinance or regulation to the contrary, the regulation of over-the-counter proprietary drugs and cosmetics is expressly preempted to the state.

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

HB 221

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 221 Osteopathic Physicians Certification and Licensure
SPONSOR(S): Roach
TIED BILLS: **IDEN./SIM. BILLS:** CS/SB 218

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	14 Y, 0 N	Siples	McElroy
2) Health Care Appropriations Subcommittee	11 Y, 0 N	Mielke	Clark
3) Health & Human Services Committee		Siples	Calamas

SUMMARY ANALYSIS

Currently, an applicant for licensure as an osteopathic physician must, in addition to other requirements, complete a resident internship approved by the American Osteopathic Association (AOA) or any other internship program upon showing of good cause by the applicant.

In 2014, the AOA, Accreditation Council for Graduate Medical Education (ACGME), and American Association of Colleges of Osteopathic Medicine entered into a Memorandum of Understanding to transition to a single accreditation system for graduate medical education (GME). Under this agreement, graduates of all allopathic and osteopathic medical schools complete residencies or fellowships in ACGME-accredited programs. On July 1, 2015, the AOA and the ACGME began transitioning to a single GME accreditation system, and the AOA will cease accrediting GME programs on June 30, 2020.

HB 221 allows an applicant to qualify for licensure as an osteopathic physician by completing an ACGME-accredited residency or internship and retains current law allowing for completion of an AOA-accredited residency or internship. The bill also repeals the Board of Osteopathic Medicine's authority to approve any other internship programs if they are not AOA- or ACGME-accredited.

The bill has an insignificant, positive fiscal impact and an insignificant, negative fiscal impact on the Department of Health, which current resources are adequate to absorb. The bill has no fiscal impact on local governments.

The bill is effective upon becoming law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Florida licenses two types of physicians to practice medicine in this state: allopathic physicians licensed under ch. 458, F.S., (MDs) and osteopathic physicians licensed under ch. 459, F.S., (DOs). DOs may practice in all areas of medicine and can offer all the same services as an MD.[1] More than 100,000 DOs practice in the United States and may specialize in every recognized area of medicine.[2] However, more than half of all DOs practice in primary care areas, such as pediatrics, general practice, obstetrics/gynecology, and internal medicine.[3] As of June 30, 2019, there are 9,328 DOs licensed in this state.[4]

Licensure of Osteopathic Physicians

Any person desiring to be licensed as a DO in Florida must:[5]

- Submit an application with a fee;
- Be at least 21 years of age;
- Be of good moral character;
- Have completed at least three years of pre-professional postsecondary education;
- Have not previously committed any act that would constitute a violation of ch. 459, F.S.;
- Not be under investigation anywhere for an act that would constitute a violation of ch. 459, F.S.;
- Have not been denied a license to practice osteopathic medicine, or had his or her osteopathic medicine license revoked, suspended, or otherwise acted against by any jurisdiction;
- Have met the criteria for:
    - A limited license under s. 459.0075, F.S.;
    - An osteopathic faculty certificate under s. 459.0077, F.S.; or
    - A resident physician, intern, or fellow under s. 459.021, F.S.;
- Demonstrate that he or she is a graduate of a medical college recognized and approved by the American Osteopathic Association (AOA);
- Demonstrate that he or she has successfully completed a resident internship of at least 12 months in a hospital approved the AOA or any other internship program approved by the Board of Osteopathic Medicine (Board) upon a showing of good cause; and
- Demonstrate that he or she has achieved a passing score on all parts of the examination conducted by the National Board of Osteopathic Medical Examiners or other examination approved by the Board within the five years before application.

[1] Florida Osteopathic Medical Association, *Osteopathic Medicine*, available at https://www.foma.org/osteopathic-medicine.html (last visited January 25, 2020).
[2] American Osteopathic Association, *The DO Difference*, available at https://doctorsthatdo.org/difference (last visited January 25, 2020).
[3] Id.
[4] E-mail correspondence with the Department of Health, dated October 15, 2019 (on file with the Health Quality Subcommittee).
[5] Section 459.0055, F.S. An individual who holds a valid DO license from another state may obtain a Florida license if less than five years have passed since passage of an acceptable licensure examination. If the DO has not practiced within two years of application, the Board has discretion to deny the applicant, require compliance with certain conditions prior to issuing a license, or issue a license with reasonable restrictions.

Osteopathic Residencies

Following graduation from an AOA-approved medical school, DOs must complete an approved 12-month internship.[6] Interns rotate through hospital departments, including internal medicine, family practice, and surgery. They may then choose to complete a residency program in a specialty area, which requires two to six years of additional training.[7]

Florida law requires DOs to complete an AOA-approved residency for licensure.[8] However, the Board will accept a residency accredited by the Accreditation Council for Graduate Medical Education (ACGME)[9] for licensure if the applicant demonstrates good cause, such as:[10]

- Personal limitation created by a documented physical or medical disability;
- Unique documented opportunity otherwise unavailable that meets a practice area of critical need;
- Documented legal restriction which requires the physical presence in a particular state or local area;
- Documented unusual or exceptional family circumstances which limit training opportunities;
- Previous program met all AOA requirements, but due to documented circumstances beyond the control of the applicant, was discontinued;
- Documented inability to relocate to another geographic area with undue hardship; or
- Documented inability to obtain an AOA internship.

Single Graduate Medical Education Accreditation System

In 2014, the ACGME, AOA, and American Association of Colleges of Osteopathic Medicine entered into a Memorandum of Understanding to transition to a single accreditation system for graduate medical education (GME).[11] Under this agreement, graduates of all allopathic and osteopathic medical schools complete residencies or fellowships in ACGME-accredited programs.[12] On July 1, 2015, the AOA and the ACGME began transitioning to a single GME accreditation system.[13]

The single accreditation system will:[14]

- Establish and maintain consistent evaluation and accountability for the competency of resident physicians across all accredited GME programs;
- Eliminate duplication in GME accreditation;
- Achieve efficiencies and cost savings for institutions that sponsor both AOA-accredited and ACGME-accredited programs; and
- Ensure all residency and fellowship applicants are eligible to enter all accredited programs in the nation and can transfer from one accredited program to another without repeating training or causing a sponsoring institution to lose Medicare funding.

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[6] Florida Osteopathic Medical Association, *Osteopathic Education*, available at https://www.foma.org/osteopathic-education.html (last visited January 25, 2020).
[7] Id.
[8] Section 459.055(1)(l), F.S.
[9] The Accreditation Council for Graduate Medical Education sets the standards for U.S. graduate medical education (residency and fellowship) programs and accredits such programs based on compliance with these standards. In 2017-2018, there were 830 ACGME-accredited institutions sponsoring more than 11,000 residency and fellowship programs. *See* Accreditation Council for Graduate Medical Education, *What We Do*, available at https://www.acgme.org/What-We-Do/Overview (last visited January 25, 2020).
[10] Rule 64B15-16, F.A.C.
[11] American Association of Colleges of Osteopathic Medicine, *Single GME Accreditation System*, available at https://www.aacom.org/news-and-events/single-gme-accreditation-system (last visited January 25, 2020).
[12] Accreditation Council for Graduate Medical Education, *Single GME Accreditation System*, available at https://www.acgme.org/What-We-Do/Accreditation/Single-GME-Accreditation-System (last visited January 25, 2020).
[13] Id.
[14] Accreditation Council for Graduate Medical Education, *Frequently Asked Questions: Single Accreditation System*, available at https://www.acgme.org/Portals/0/PDFs/Nasca-Community/FAQs.pdf (last visited January 25, 2020).

The AOA will cease accrediting GME programs on June 30, 2020.[15] The single accreditation system requires all training programs to be ACGME-accredited by that date. If a program is solely AOA-accredited, the program must apply for ACGME accreditation or stop accepting trainees by June 30, 2020.[16] However, AOA may extend a program's accreditation if the program has made a good faith effort to obtain ACGME accreditation, but has not transitioned to ACGME accreditation by June 30, 2020.[17]

Effect of Proposed Legislation

HB 221 allows an applicant to qualify for licensure as an osteopathic physician by completing an ACGME-accredited residency or internship or an AOA-accredited residency or internship. The bill also repeals the Board of Osteopathic Medicine's authority to approve any other internship programs if they are not AOA- or ACGME-accredited programs.

The bill is effective upon becoming law.

B. SECTION DIRECTORY:

Section 1: Amends s. 459.0055, F.S., relating to general licensure requirements.
Section 2: Provides an effective date of upon becoming law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The Board of Osteopathic Medicine will experience a decrease in workload related to reviewing and determining whether an applicant for licensure has demonstrated good cause for completing an ACGME-accredited residency instead of an AOA-approved residency.

   DOH will incur insignificant, nonrecurring costs to repeal rules related to the Board of Osteopathic Medicine's approval of internship programs not accredited by AOA and to revise the licensure application form. Current budget resources are adequate to absorb these costs.[18]

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

[15] American Osteopathic Association, *Single GME Resident FAQs*, available at https://osteopathic.org/residents/resident-resources/residents-single-gme/single-gme-resident-faqs/ (last visited January 25, 2020).
[16] Id.
[17] Id.
[18] Department of Health, *2020 Agency Legislative Bill Analysis for HB 221*, on file with the Health Quality Subcommittee.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The Board of Osteopathic Medicine has sufficient rulemaking authority to implement the bill under s. 459.005, F.S.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to osteopathic physician certification and licensure; amending s. 459.0055, F.S.; requiring the successful completion of an internship or residency for licensure or certification as an osteopathic physician; providing accreditation requirements for such internships and residencies; providing an effective date.

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

Section 1. Paragraph (l) of subsection (1) of section 459.0055, Florida Statutes, is amended to read:

459.0055 General licensure requirements.—

(1) Except as otherwise provided herein, any person desiring to be licensed or certified as an osteopathic physician pursuant to this chapter shall:

(l) Demonstrate that she or he has successfully completed an internship or residency ~~a resident internship~~ of not less than 12 months in a program accredited ~~hospital approved~~ for this purpose by the ~~Board of Trustees of the~~ American Osteopathic Association or the Accreditation Council for Graduate Medical Education ~~any other internship program approved by the board upon a showing of good cause by the applicant~~. This requirement may be waived for an applicant who matriculated in a

college of osteopathic medicine during or before 1948; and

Section 2. This act shall take effect upon becoming a law.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 351 Podiatric Medicine
SPONSOR(S): Health Quality Subcommittee, Ponder and others
TIED BILLS: **IDEN./SIM. BILLS:**

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

SUMMARY ANALYSIS

A podiatric physician diagnoses or provides medical, surgical, palliative, and mechanical treatment of ailments affecting the human foot and leg. Podiatric medicine also includes the amputation of toes and other parts of the foot, but does not include amputation of the entire leg or foot.

A physician assistant (PA) is licensed to perform health care services delegated by a supervising physician, in the specialty areas in which he or she has been trained. PAs are governed by the respective physician practice acts for allopathic physicians (MDs) and osteopathic physicians (DOs). A physician is responsible and liable for the performance and the acts and omissions of a PA he or she supervises. Currently, podiatric physicians may not delegate health care services to PAs.

Medical assistants are non-licensed personal that may assist a physician in all aspects of a medical practice under the direct supervision and responsibility of a physician. Current law does not specifically authorize podiatric physicians to utilize medical assistants in their practices.

CS/HB 351 authorizes podiatric physician to delegate the performance of health care services to PAs in the same manner as MDs and DOs. The bill also authorizes podiatric physicians to employ and supervise medical assistants in the same manner as physicians.

Section 456.0301, F.S., requires health care practitioners with authority to prescribe controlled substances to take a board-approved 2-hour continuing education course on safe and effective prescribing of controlled substances biennially offered by certain statewide professional organizations of physicians. However, if a licensee's practice act requires the licensee to complete a 2-hour course on safe and effective prescribing of controlled substances, the licensee is exempt from the requirements of s. 456.0301, F.S. Podiatric physicians are required to complete 40 hours of continuing professional education biennially, but their practice act does not specifically require continuing education on controlled substances.

The bill requires podiatric physicians to complete a 2-hour continuing education course on safe and effective prescribing of controlled substances as a part of the 30 hours of continuing professional education required for biennial licensure renewal. Podiatric physicians will no longer be subject to the requirements of s. 456.0301, F.S., including the requirement that the course be offered only by certain physician organizations.

Currently, individuals may enter into direct health care agreements with allopathic physicians, osteopathic physicians, chiropractic physicians, nurses, or dentists, or a group or a health care group practice for the provision of health care services. The bill adds podiatric physicians to the list of health care providers who may offer such agreements.

The bill has an insignificant, negative fiscal impact on the Department of Health, which current resources are adequate to absorb. The bill has no fiscal impact on local governments.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Podiatric Medicine

Podiatric medicine is the diagnosis or medical, surgical, palliative, and mechanical treatment of ailments of the human foot or leg.[1] It also includes the amputation of toes or other parts of the foot, but does not include the amputation of the entire foot or leg. A podiatric physician is authorized to prescribe drugs specifically related to his or her scope of practice.[2]

Licensure Requirements

Florida law requires a podiatric physician to meet the following requirements for licensure:[3]

- Be at least 18 years of age;
- Hold a degree from a school or college of podiatric medicine or chiropody recognized and approved by the Council on Podiatry Education of the American Podiatric Medical Association;
- Have successfully completed one of the following clinical experience requirements:
  - One year of residency in a residency program approved by the board;[4] or
  - Ten years of continuous, active licensed practice of podiatric medicine in another state immediately preceding application and completion of at least the same continuing education requirements during those ten years as are required of podiatric physicians licensed in this state;
- Successfully complete a background screening; and
- Obtain passing scores on the national examinations administered by the National Board of Podiatric Medical Examiners.[5]

A license to practice podiatric medicine must be renewed biennially.

Continuing Education

A podiatric physician must complete 40 hours of continuing education as a part of the biennial licensure renewal, which must include:[6]

- One hour on risk management;
- One hour on the laws and rules related to podiatric medicine;
- Two hours on the prevention of medical errors;
- Two hours on HIV/AIDS (due for the first renewal only); and
- One hour on human trafficking (beginning January 1, 2021).[7]

[1] Section 461.003(5), F.S.
[2] Id.
[3] Section 461.006, F.S.
[4] If it has been more than four years since the completion of the residency, an applicant must have two years of active, licensed practice of podiatric medicine in another jurisdiction in the four years immediately preceding application or successfully complete a board-approved postgraduate program or board-approved course within the year preceding application.
[5] Rule 64B18-11.002, F.A.C.
[6] Section 461.007(3), F.S., and r. 64B18-17, F.A.C.
[7] Section 456.0341, F.S.

Controlled Substance Prescribers

Effective July 1, 2018, every person registered with the United States Drug Enforcement Administration and authorized to prescribe controlled substances, must complete a 2-hour continuing education course on prescribing controlled substances.[8] The course must include information on the current standards for prescribing controlled substances, particularly opiates; alternatives to these standards; non-pharmacological therapies; prescribing emergency opioid antagonists; and the risks of opioid addiction following all stages of treatment in the management of acute pain.

The course can only be offered by a statewide professional association of physicians in this state that is accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award Category 1 Credit or the American Osteopathic Category 1-A medical continuing education on the safe and effective prescribing of controlled substances each biennial license renewal.[9] Currently the course is provided by the:[10]

- Florida Medical Association;
- Florida Osteopathic Medical Association;
- InforMed;
- Emergency Medicine Learning and Resource Center; and
- Florida Academy of Family Physicians.

This requirement does not apply to a licensee who is required by his or her applicable practice act to complete a minimum of two hours of continuing education on the safe and effective prescribing of controlled substances.[11] This requirement applies to podiatric physicians because their practice act does not specifically require a two hours of continuing education on the safe and effective prescribing of controlled substances.

Physician Assistants

Physician assistants (PAs) are regulated by the Florida Council on Physician Assistants (Council) in conjunction with either the Board of Medicine for PAs licensed under ch. 458, F.S., or the Board of Osteopathic Medicine for PAs licensed under ch. 459, F.S. The boards are responsible for adopting the principles that a supervising physician must use for developing a PA's scope of practice, developing a formulary of drugs that may be prescribed by a PA, and approving educational programs.[12]

Council on Physician Assistants

The Council consists of five members including three physicians who are members of the Board of Medicine, one physician who is a member of the Board of Osteopathic Medicine, and one licensed PA appointed by the Surgeon General.[13] Two of the physicians must be physicians who supervise physician assistants in their practice. The Council is responsible for:[14]

- Making recommendations to DOH regarding the licensure of PAs;
- Developing rules for the regulation of PAs for consideration for adoption by the boards;
- Making recommendations to the boards regarding all matters relating to PAs;
- Addressing concerns and problems of practicing PAs to ensure patient safety; and

[8] Section 1, ch. 2018-13, Laws of Fla., codified at s. 456.0301, F.S.
[9] Id.
[10] Department of Health, *Take Control of Controlled Substances*, available at http://www.flhealthsource.gov/FloridaTakeControl/ (last visited January 25, 2020). To access a list of providers, select Podiatric Medicine.
[11] *Supra* note 8.
[12] Sections 458.347(4) and (6), F.S., and 459.022(4) and (6), F.S.
[13] Sections 458.347(9), F.S., and 459.022(9), F.S. Members of the Board of Medicine and the Board of Osteopathic Medicine are appointed by the Governor and confirmed by the Senate. *See* ss. 458.307, F.S., and 459.004, F.S., respectively.
[14] Id.

- Denying, restricting, or placing conditions on the license of PA who fails to meet the licensing requirements.

Licensure and Regulation of PAs

An applicant for a PA license must apply to the Department of Health (DOH). DOH must issue a license to a person certified by the Council as having met all of the following requirements:[15]

- Completed an approved PA training program;
- Obtained a passing score on the National Commission on Certification of Physician Assistants examination;
- Acknowledged any prior felony convictions;
- Submitted to a background screening and have no disqualifying offenses;[16]
- Acknowledged any previous revocation or denial of licensure in any state; and
- Provided a copy of course transcripts and a copy of the course description from a PA training program describing the course content in pharmacotherapy if the applicant is seeking prescribing authority.

PAs must renew their licenses biennially. During each biennial renewal cycle a PA must complete 100 hours of continuing medical education or must demonstrate current certification issued by the National Commission on Certification of Physician Assistants.[17] To maintain certification, a PA must earn at least 100 hours of continuing medical education biennially and must take a re-certification examination every 10 years.[18]

PA Scope of Practice

PAs may only practice under the direct or indirect supervision of an allopathic or osteopathic physician with whom they have a clinical relationship.[19] A supervising physician may only delegate tasks and procedures to the PA that are within the supervising physician's scope of practice.[20] The supervising physician is responsible and liable for any acts or omissions of the PA and may not supervise more than four PAs at any time.[21]

The Boards have established by rule that "responsible supervision" of a PA means the ability of the supervising physician to exercise control and provide direction over the services or tasks performed by the PA. Whether the supervision of a PA is adequate, is dependent upon the:[22]

- Complexity of the task;
- Risk to the patient;
- Background, training and skill of the PA;
- Adequacy of the direction in terms of its form;
- Setting in which the tasks are performed;
- Availability of the supervising physician;
- Necessity for immediate attention; and
- Number of other persons that the supervising physician must supervise.

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[15] Sections 458.347(7), F.S., and 459.022(7), F.S.
[16] Section 456.0135, F.S.
[17] Sections 458.347(7)(c), F.S., and 459.022(7)(c), F.S.
[18] National Commission on Certification of Physician Assistants, *Maintaining Certification*, available at https://www.nccpa.net/CertificationProcess (last visited January 25, 2020).
[19] Sections 458.347(2)(f), F.S., and 459.022(2)(f), F.S., define supervision as responsible supervision and control which requires the easy availability or physical presence of the licensed physician for consultation and direction of the PA.
[20] Rules 64B8-30.012, F.A.C., and 64B15-6.010, F.A.C.
[21] Sections 458.347(15), F.S., and 459.022(15), F.S.
[22] Rules 64B8-30.001, F.A.C., and 64B15-6.001, F.A.C.

A supervising physician decides whether to permit a PA to perform a task or procedure under direct or indirect supervision based on reasonable medical judgment regarding the probability of morbidity and mortality to the patient.[23] A supervising physician may delegate the authority for a PA to:

- Prescribe or dispense any medicinal drug used in the supervising physician's practice unless such medication is listed in the formulary established by the Council;[24]
- Order any medication for administration to the supervising physician's patient in a hospital or other facility licensed under chapter 395, F.S., or a nursing homes licensed under part II of chapter 400, F.S.;[25] and
- Any other service that are is not expressly prohibited in ch. 458, F.S., ch. 459, F.S., or the rules adopted thereunder.[26]

Currently, podiatric physicians are not authorized to supervise or delegate tasks and procedures to PAs.

Medical Assistants

A medical assistant is a multi-skilled person that assists in all aspects of a medical practice under the direct supervision and responsibility of a physician.[27] There are no formal educational for becoming a medical assistant in most states, including Florida.[28] Most medical assistants have postsecondary education, such as a certificate; however, others enter the occupation with a high school diploma and learn through on-the-job training.[29]

A medical assistant assists with patient care management, executes administrative and clinical procedures, and performs managerial and supervisory functions. In Florida, a medical assistant may perform the following duties under the direct supervision of a physician: [30]

- Clinical procedures, including:
  - Performing aseptic procedures;
  - Taking vital signs;
  - Preparing patients for physician care;
  - Performing venipunctures and nonintravenous injections; and
  - Observing and reporting patients' signs and symptoms;
- Administering basic first aid;
- Assisting with patient examinations or treatments;
- Operating office medical equipment;
- Collecting routine laboratory specimens as directed by the physician;
- Administering medication as directed by the physician;
- Performing basic laboratory procedures;
- Performing office procedures and general administrative duties required by the physician; and

[23] "Direct supervision" refers to the physical presence of the supervising physician so that the physician is immediately available to the PA when needed. "Indirect supervision" refers to the reasonable physical proximity of the supervising physician to the PA or availability by telecommunication. *Supra* note 22.
[24] Sections 458.347(4)(f), F.S., and 459.022(e), F.S., directs the Council to establish a formulary listing the medical drugs that a PA may not prescribe. The formulary in rules 64B8-30.008, F.A.C., and 64B15-6.0038, F.A.C., prohibits PAs from prescribing; general, spinal or epidural anesthetics; radiographic contrast materials; and psychiatric mental health controlled substances for children younger than 18 years of age. It also restricts the prescribing of Schedule II controlled substances to a 7-day supply. However, the rules authorize physicians to delegate to PAs the authority to order controlled substances in hospitals and other facilities licensed under ch. 395, F.S.
[25] Chapter 395, F.S., provides for the regulation and the licensure of hospitals and trauma centers, part II of ch. 400, F.S., provides for the regulation and licensure of nursing home facilities.
[26] Sections 458.347(4), F.S., and 459.022(e), F.S.
[27] Section 458.3485, F.S.
[28] United States Department of Labor, *Occupational Outlook Handbook: Medical Assistants*, (last rev. Sept. 4, 2019), available at https://www.bls.gov/ooh/healthcare/medical-assistants.htm#tab-4 (last visited January 25, 2020).
[29] Id.
[30] Supra note 27.

- Performing dialysis procedures, including home dialysis.

Medical assistants are not required to be licensed, certified, or registered to practice in Florida.

Direct Health Care Agreements

Under current law, individuals may contract directly with certain health care providers, outside the scope of insurance, for the provision of health care services.[31] Since a direct health care agreement is not considered health insurance, it is exempt from the Florida Insurance Code and the Office of Insurance Regulation does not have authority to regulate such agreements.[32] These direct health care agreements must:[33]

- Be in writing;
- Be signed by the health care provider, or his or her agent, and the patient, the patient's legal representative, or the patient's employer;
- Allow either party to terminate the agreement by giving the other party 30 days' advance written notice;
- Allow immediate termination of the agreement for a violation of physician-patient relationship or a breach of the terms of the agreement;
- Describe the scope of health care services that are covered by the monthly fee;
- Specify the monthly fee and any fees for health care services not covered under the agreement;
- Specify the duration of the agreement and any automatic renewal provisions;
- Offer a refund to the patient of monthly fees paid in advance if the health care provider stops offering health care services for any reason;
- State that the agreement is not health insurance and that the health care provider will not bill the patient's health insurance policy or plan for services covered under the agreement;
- State that the agreement does not qualify as minimum essential coverage to satisfy the individual responsibility provision of the Patient Protection and Affordable Care Act; and
- State that the agreement is not workers' compensation insurance and may not replace the employer's workers' compensation obligations.

Currently, individuals may only contract with allopathic physicians, osteopathic physicians, chiropractic physicians, nurses, or dentists, or a health care group practice, for health care services that are within the competency and training of the health care provider.[34] An individual may not directly contract with a podiatric physician for the provision of health care services.

Effect of Proposed Bill

Physician Assistants

HB 351 authorizes podiatric physicians to supervise and delegate tasks to physician assistants in the same manner as allopathic physicians and osteopathic physicians. Under the bill, the Board of Podiatric Medicine has the same authority and responsibilities as the Board of Medicine and Board of Osteopathic Medicine to develop the PA's scope of practice, develop a formulary of drugs that may be prescribed by a PA, and approve educational programs.

As with allopathic and osteopathic physicians, a podiatric physician may only supervise up to four PAs and is responsible and liable for the performance and the acts and omissions of a PA under his or her

[31] Section 624.27, F.S. Health care services means the screening, assessment, diagnosis, and treatment of a patient conducted within the competency and training of the health care provider for the purpose of promoting health or detecting and managing disease or injury.
[32] Section 624.27(2), F.S.
[33] Section 624.27(3), F.S.
[34] *Supra* note 31.

supervision. A PA supervised by a podiatric physician must be qualified in the medical areas in which the PA is to perform.

Medical Assistants

The bill authorizes podiatric physicians to use medical assistants in the same manner and under the same conditions as an allopathic physician.

Continuing Education

The bill requires podiatric physicians to complete two hours of continuing education on safe and effective prescribing of controlled substances, as a part of the 40 hours of continuing professional education required for each biennial licensure renewal. This will exempt podiatric physicians from the requirement in s. 456.0301, F.S., including the requirement that the course be offered only by certain physician organizations.

The bill also revises the definition of "continuing medical education" to include those courses approved by the Board of Podiatric Medicine and the American Board of Podiatric Medicine.

Direct Health Care Agreements

The bill authorizes individuals to directly contract with podiatric physicians for the provision of health care services. The bill retains the contract requirements that are currently required for other health care practitioners offering direct health care agreements.

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

B. SECTION DIRECTORY:

Section 1: Amends s. 458.347, F.S., relating to physician assistants.
Section 2: Amends s. 458.3485, F.S., relating to medical assistants.
Section 3: Amends s. 459.022, F.S., relating to physician assistants.
Section 4: Amends s. 461.007, F.S., relating to renewal of license.
Section 5: Creates s. 461.0145, F.S., relating to physician assistants.
Section 6: Creates s. 461.0155, F.S., relating to medical assistants.
Section 7: Amends s. 624.27, F.S., relating to direct health care agreements; exemption from code.
Section 8: Provides an effective date of July 1, 2020.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   DOH, the Board of Medicine, the Board of Osteopathic Medicine, and the Board of Podiatric Medicine may incur costs to amend and adopt rules to implement the bill's provisions. These costs can be absorbed within current resources.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Since additional organizations may be eligible to provide the controlled substances continuing education course, organizations currently authorized to offer the course may experience a loss in revenue.

Podiatric physicians may establish practices that use direct health care agreements to provide health care services without concern of facing regulatory action, which may increase access to podiatric care.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The Boards of Medicine, Osteopathic Medicine, and Podiatric Medicine have sufficient rulemaking authority to implement the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On November 13, 2019, the Health Quality Subcommittee adopted an amendment that removed proposed changes to the duties and composition of the Council on Physician Assistants and reported HB 351 favorably as a committee substitute.

The analysis is drafted to the committee substitute as passed by the Health Quality Subcommittee.

A bill to be entitled

An act relating to podiatric medicine; amending s. 458.347, F.S.; providing and revising definitions; amending s. 458.3485, F.S.; authorizing a medical assistant to perform specified duties under the direct supervision and responsibility of a podiatric physician; amending s. 459.022, F.S.; providing and revising definitions; amending s. 461.007, F.S.; authorizing the Board of Podiatric Medicine to require a specified number of continuing education hours related to the safe and effective prescribing of controlled substances; creating s. 461.0145, F.S.; authorizing a podiatric physician to supervise a specified number of physician assistants; providing requirements for physician assistants, podiatric physicians, and groups of podiatric physicians; creating s. 461.0155, F.S.; providing for governance of podiatric physicians who are supervising medical assistants; amending s. 624.27, F.S.; revising the definition of the term "health care provider" to include podiatric physicians; providing an effective date.

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

Section 1. Paragraphs (b) and (h) of subsection (2) of section 458.347, Florida Statutes, are amended, and paragraph (i) is added to that subsection, to read:

458.347 Physician assistants.—

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

(b) "Boards" means the Board of Medicine, ~~and~~ the Board of Osteopathic Medicine, and the Board of Podiatric Medicine.

(h) "Continuing medical education" means courses recognized and approved by the boards, the American Academy of Physician Assistants, the American Medical Association, the American Osteopathic Association, the American Podiatric Medical Association, or the Accreditation Council on Continuing Medical Education.

(i) "Physician" means a person who holds an active, unrestricted license as a physician under this chapter, an osteopathic physician under chapter 459, or a podiatric physician under chapter 461.

Section 2. Subsection (1) of section 458.3485, Florida Statutes, is amended to read:

458.3485 Medical assistant.—

(1) DEFINITIONS ~~DEFINITION~~.—As used in this section:~~,~~

(a) "Medical assistant" means a professional multiskilled person dedicated to assisting in all aspects of medical practice under the direct supervision and responsibility of a physician. This practitioner assists with patient care management, executes

administrative and clinical procedures, and often performs managerial and supervisory functions. Competence in the field also requires that a medical assistant adhere to ethical and legal standards of professional practice, recognize and respond to emergencies, and demonstrate professional characteristics.

(b) "Physician" means a person who holds an active, unrestricted license as a physician under this chapter or a podiatric physician under chapter 461.

Section 3. Paragraphs (b) and (h) of subsection (2) of section 459.022, Florida Statutes, are amended, and paragraph (i) is added to that subsection, to read:

459.022 Physician assistants.—

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

(b) "Boards" means the Board of Medicine, ~~and~~ the Board of Osteopathic Medicine, and the Board of Podiatric Medicine.

(h) "Continuing medical education" means courses recognized and approved by the boards, the American Academy of Physician Assistants, the American Medical Association, the American Osteopathic Association, the American Podiatric Medical Association, or the Accreditation Council on Continuing Medical Education.

(i) "Physician" means a person who holds an active, unrestricted license as a physician under chapter 458, an osteopathic physician under this chapter, or a podiatric physician under chapter 461.

Section 4. Subsection (3) of section 461.007, Florida Statutes, is amended to read:

461.007 Renewal of license.—

(3) The board may by rule prescribe continuing education, not to exceed 40 hours biennially, as a condition for renewal of a license, with a minimum of 2 hours of continuing education related to the safe and effective prescribing of controlled substances. The criteria for such programs or courses shall be approved by the board.

Section 5. Section 461.0145, Florida Statutes, is created to read:

461.0145 Physician assistants.—

(1) A podiatric physician or group of podiatric physicians may supervise up to four physician assistants licensed under s. 458.347 or s. 459.022. A physician assistant must be qualified in the medical areas in which the physician assistant is to perform.

(2) A physician assistant practicing under this chapter shall be governed by s. 458.347 or s. 459.022.

(3) A podiatric physician or group of podiatric physicians supervising a physician assistant shall be individually or collectively responsible and liable for the performance and the acts and omissions of the physician assistant.

Section 6. Section 461.0155, Florida Statutes, is created to read:

461.0155 Medical assistants.—A podiatric physician who is supervising a medical assistant shall be governed by s. 458.3485.

Section 7. Paragraph (b) of subsection (1) of section 624.27, Florida Statutes, is amended to read:

624.27 Direct health care agreements; exemption from code.—

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

(b) "Health care provider" means a health care provider licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 464, or chapter 466, or a health care group practice, who provides health care services to patients.

Section 8. This act shall take effect July 1, 2020.

COMMITTEE/SUBCOMMITTEE ACTION

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

Committee/Subcommittee hearing bill: Health & Human Services Committee

Representative Ponder offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Paragraph (i) is added to subsection (4) of section 458.347, Florida Statutes, to read:

458.347 Physician assistants.—

(4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—

(i) A supervising physician may authorize a licensed physician assistant to perform services under the direction of a podiatric physician licensed under chapter 461 who is a partner, shareholder, or employee of the same group practice, as defined in s. 456.053, as the supervising physician and the physician assistant. The supervising physician is liable for the

performance and the acts and omissions of any such physician assistant.

Section 2. Subsection (1) of section 458.3485, Florida Statutes, is amended to read:

458.3485 Medical assistant.—

(1) DEFINITION.—As used in this section:~~,~~

(a) "Medical assistant" means a professional multiskilled person dedicated to assisting in all aspects of medical practice under the direct supervision and responsibility of a physician. This practitioner assists with patient care management, executes administrative and clinical procedures, and often performs managerial and supervisory functions. Competence in the field also requires that a medical assistant adhere to ethical and legal standards of professional practice, recognize and respond to emergencies, and demonstrate professional characteristics.

(b) "Physician" means a person who is licensed as a physician under this chapter or a podiatric physician under chapter 461.

Section 3. Paragraph (h) is added to subsection (4) of section 459.022, Florida Statutes, to read:

459.022 Physician assistants.—

(4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—

(h) A supervising physician may authorize a licensed physician assistant to perform services under the direction of a podiatric physician licensed under chapter 461 who is a partner,

shareholder, or employee of the same group practice, as defined in s. 456.053, as the supervising physician and the physician assistant. The supervising physician is liable for the performance and the acts and omissions of any such physician assistant.

Section 4. Subsection (3) of section 461.007, Florida Statutes, is amended to read:

461.007 Renewal of license.—

(3) The board may by rule prescribe continuing education, not to exceed 40 hours biennially, as a condition for renewal of a license, with a minimum of 2 hours of continuing education related to the safe and effective prescribing of controlled substances. The criteria for such programs or courses shall be approved by the board.

Section 5. Section 461.0145, Florida Statutes, is created to read:

461.0145 Physician Assistants.— A licensed physician assistant may perform services under the direction of a podiatric physician in accordance with s. 458.347(4) and s. 459.022(4).

Section 6. Section 461.0155, Florida Statutes, is created to read:

461.0155 Medical assistants.—A podiatric physician who is supervising a medical assistant shall be governed by s. 458.3485.

Section 7. Paragraph (b) of subsection (1) of section 624.27, Florida Statutes, is amended to read:

624.27 Direct health care agreements; exemption from code.—

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

(b) "Health care provider" means a health care provider licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 464, or chapter 466, or a health care group practice, who provides health care services to patients.

Section 8. This act shall take effect July 1, 2020.

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

Remove everything before the enacting clause and insert: An act relating to podiatric medicine; amending s. 458.347, F.S.; authorizing a supervising physician to authorize a physician assistant to perform services under the direction of a podiatric physician under certain circumstances; requiring the podiatric physician to be a partner, shareholder, or employee in the same group practice as the physician assistant and supervising physician; providing the supervising physician is liable for the performance and acts and omission of the physician assistant; amending s. 458.3485, F.S.; authorizing a medical assistant to perform specified duties under the direct supervision and responsibility of a podiatric physician;

amending s. 459.022, F.S.; authorizing supervising physician to authorize a physician assistant to perform services under the direction of a podiatric physician under certain circumstances; requiring the podiatric physician to be a partner, shareholder, or employee in the same group practice as the physician assistant and supervising physician; providing the supervising physician is liable for the performance and acts and omission of the physician assistant amending s. 461.007, F.S.; authorizing the Board of Podiatric Medicine to require a specified number of continuing education hours related to the safe and effective prescribing of controlled substances; creating s. 461.0145, F.S.; authorizing a physician assistant to perform services under the direction of a podiatric physician under certain circumstances; creating s. 461.0155, F.S.; providing for governance of podiatric physicians who are supervising medical assistants; amending s. 624.27, F.S.; revising the definition of the term "health care provider" to include podiatric physicians; providing an effective date.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 409 Health Care Licensing Requirements
SPONSOR(S): Pigman
TIED BILLS: **IDEN./SIM. BILLS:** SB 780

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	14 Y, 0 N	Siples	McElroy
2) Health Care Appropriations Subcommittee	11 Y, 0 N	Mielke	Clark
3) Health & Human Services Committee		Siples	Calamas

SUMMARY ANALYSIS

Florida is home to one of the largest veteran populations in the United States. The United States Veterans Affairs (VA) provides health care services to veterans through a large health care system of hospitals and clinics throughout the state. To work at a VA health care facility, a health care practitioner must hold an active license to practice his or her healthcare profession from any state in the nation. However, if a VA health care practitioner wants to provide health care services to a veteran in a setting outside of a VA health care facility in this state, he or she must hold the appropriate Florida health care practitioner license.

HB 409 requires the Department of Health (DOH) to exempt certain VA physicians from licensure requirements. To qualify for the exemption, a VA physician must submit to DOH:

- Proof that he or she holds an active, unencumbered license to practice medicine from another state or territory of the United States;
- Proof of current employment with the VA; and
- An attestation that he or she will only provide medical services to veterans in Florida-licensed hospitals and that such services are pursuant to his or her employment with the VA.

DOH must notify the physician within 15 business of receipt of the documentation that the physician is exempt from Florida licensure requirements.

The bill has an insignificant, negative fiscal impact on DOH, which current resources are sufficient to absorb. The bill has no fiscal impact on local governments.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Physician Licensure in Florida

Allopathic Physicians

Chapter 458, F.S., governs licensure and regulation of the practice of medicine by the Florida Board of Medicine (allopathic board) in conjunction with the Department of Health (DOH). The chapter imposes requirements for licensure examination and licensure by endorsement.

An individual seeking to be licensed by examination as an allopathic physician must, among other things:[1]

- Complete 2 years of post-secondary education which includes, at a minimum, courses in fields such as anatomy, biology, and chemistry prior to entering medical school;
- Not have committed an act or offense that would constitute a basis for disciplining a physician under Florida law;
- Meet one of the following medical education and postgraduate training requirements:
  - Graduate from an allopathic medical school recognized and approved by an accrediting agency recognized by the U.S. Office of Education or recognized by an appropriate governmental body of a U.S. territorial jurisdiction, and have completed at least one year of approved residency training;
  - Graduate from an allopathic foreign medical school registered with the World Health Organization and certified pursuant to statute as meeting the standards required to accredit U.S. medical schools, and have completed at least one year of approved residency training; or
  - Graduate from an allopathic foreign medical school that has not been certified pursuant to statute; have an active, valid certificate issued by the Educational Commission for Foreign Medical Graduates (ECFMG),[2] have passed that commission's examination; and have completed an approved residency or fellowship of at least 2 years in one specialty area; and
- Obtain a passing score on:
  - The United States Medical Licensing Examination (USMLE);
  - A combination of the USMLE, the examination of the Federation of State Medical Boards of the United States, Inc. (FLEX), or the examination of the National Board of Medical Examiners up to the year 2000; or
  - The Special Purpose Examination of the Federation of State Medical Boards of the United States (SPEX), if the applicant was licensed on the basis of a state board examination, is currently licensed in at least one other jurisdiction of the United States or Canada, and has practiced for a period of at least 10 years; and
- Successfully complete a background screening.

[1] Section 458.311(1), F.S.

[2] A graduate of a foreign medical school does not need to present an ECFMG certification or pass its exam if the graduate received his or bachelor's degree from an accredited U.S. college or university, studied at a medical school recognized by the World Health Organization, and has completed all but the internship or social service requirements, has passed parts I and II of the National Board Medical Examiners licensing examination or the ECFMG equivalent examination. Section 458.311, F.S.

An individual who holds an active license to practice medicine in another jurisdiction may seek licensure by endorsement to practice medicine in Florida.[3] The applicant must meet the same requirements for licensure by examination. To qualify for licensure by endorsement, the applicant must also submit evidence of the licensed active practice of medicine in another jurisdiction for at least two of the preceding four years, or evidence of successful completion of either a board-approved postgraduate training program within two years preceding filing of an application or a board-approved clinical competency examination within the year preceding the filing of an application for licensure.

If the allopathic board determines that an applicant has failed to meet the requirements for licensure by endorsement, it may:[4]

- Refuse to certify the application for licensure to DOH;
- Certify the application for licensure to DOH with restrictions on the scope of practice of the licensee; or
- Certify the application for licensure to DOH place the physician on probation for a period of time and subject the physician to such conditions as the allopathic board may specify, including, but not limited to, requiring the physician to submit to treatment, attend continuing education courses, submit to reexamination, or work under the supervision of another physician.

Osteopathic Physicians

Chapter 459, F.S., provides for the licensure and regulation of the practice of medicine by the Florida Board of Osteopathic Medicine (osteopathic board) in conjunction with DOH. The chapter imposes requirements for licensure.

An individual seeking to be licensed as an osteopathic physician must, among other things:[5]

- Have completed at least three years of preprofessional postsecondary education;
- Has not committed an act or offense that would constitute a basis for disciplining a physician under Florida law, unless the osteopathic board determines that such act does not adversely affect the applicant's ability and fitness to practice osteopathic medicine.
- Graduate from a medical college recognized and approved by the American Osteopathic Association;
- Successfully complete a resident internship of at least 12 months in a hospital approved by the Board of Trustees of the American Osteopathic Association or any other internship approved by the osteopathic board; and
- Obtain a passing score, as established by rule of the osteopathic board, on the examination conducted by the National Board of Osteopathic Medical Examiners or other examination approved by the osteopathic board, no more than five years prior to applying for licensure;[6] and
- Successfully complete a background screening.

If an applicant for a license to practice osteopathic medicine is licensed in another state, the applicant must have actively practiced osteopathic medicine within the two years prior to applying for licensure in this state. If it has been more than two years since the applicant actively practiced osteopathic medicine, the osteopathic board may:[7]

- Deny the application;

[3] Section 458.313, F.S.
[4] Section 458.313(7), F.S.
[5] Section 459.0055(1), F.S.
[6] However, if an applicant has been actively licensed in another state, the initial licensure in the other state must have occurred no more than five years after the applicant obtained the passing score on the licensure examination.
[7] Section 459.0055(2), F.S.

- Issue a license reasonable restrictions or conditions, which may include, but is not limited to, a requirement that the applicant practice under the supervision of a physician approved by the osteopathic board; or
- Issue a license upon receipt of documentation confirming the applicant has met any conditions of the osteopathic board, which may include, but is not limited to, completing continuing education or undergoing an assessment of skills and training.

Unlicensed Practice of a Health Care Profession

An individual must meet minimum education and training requirements to become licensed and practice a health care profession.[8] Licensure is available by examination or, in many instances, by endorsement if the practitioner is licensed in another jurisdiction. Florida law prohibits an individual from practicing a regulated health care profession without a license.

An unlicensed individual providing healthcare services is subject to administrative and criminal penalties. DOH may issue a cease and desist letter to such a person and impose, by citation, an administrative penalty of up to $5,000 per offense.[9] DOH may also seek a civil penalty of up to $5,000 for each offense through the circuit court in addition to, or in lieu of, the administrative penalty.[10]

An individual practicing, attempting to practice, or offering to practice a health care profession without an active, valid Florida license is subject to criminal penalties:[11]

- A first degree misdemeanor punishable by up to one year imprisonment and a fine of up to $1,000 if the license has been inactive or delinquent for any period of time up to 12 months, with a minimum sentence of 30 days imprisonment and a $500 fine.
- A third degree felony punishable by up to five years imprisonment and a fine of up to $5,000 if the license has been inactive or delinquent for a period of time exceeding 12 months, with a minimum sentence of 30 days imprisonment and a $500 fine.
- A third degree felony punishable by up to five years imprisonment and a fine of up to $5,000, with a minimum mandatory sentence of one year imprisonment and a $1,000 fine.
- A second degree felony punishable by up to 15 years imprisonment and a fine of up to $15,000 if such practice results in serious bodily injury, with a minimum mandatory sentence of one year imprisonment and a $1,000 fine.

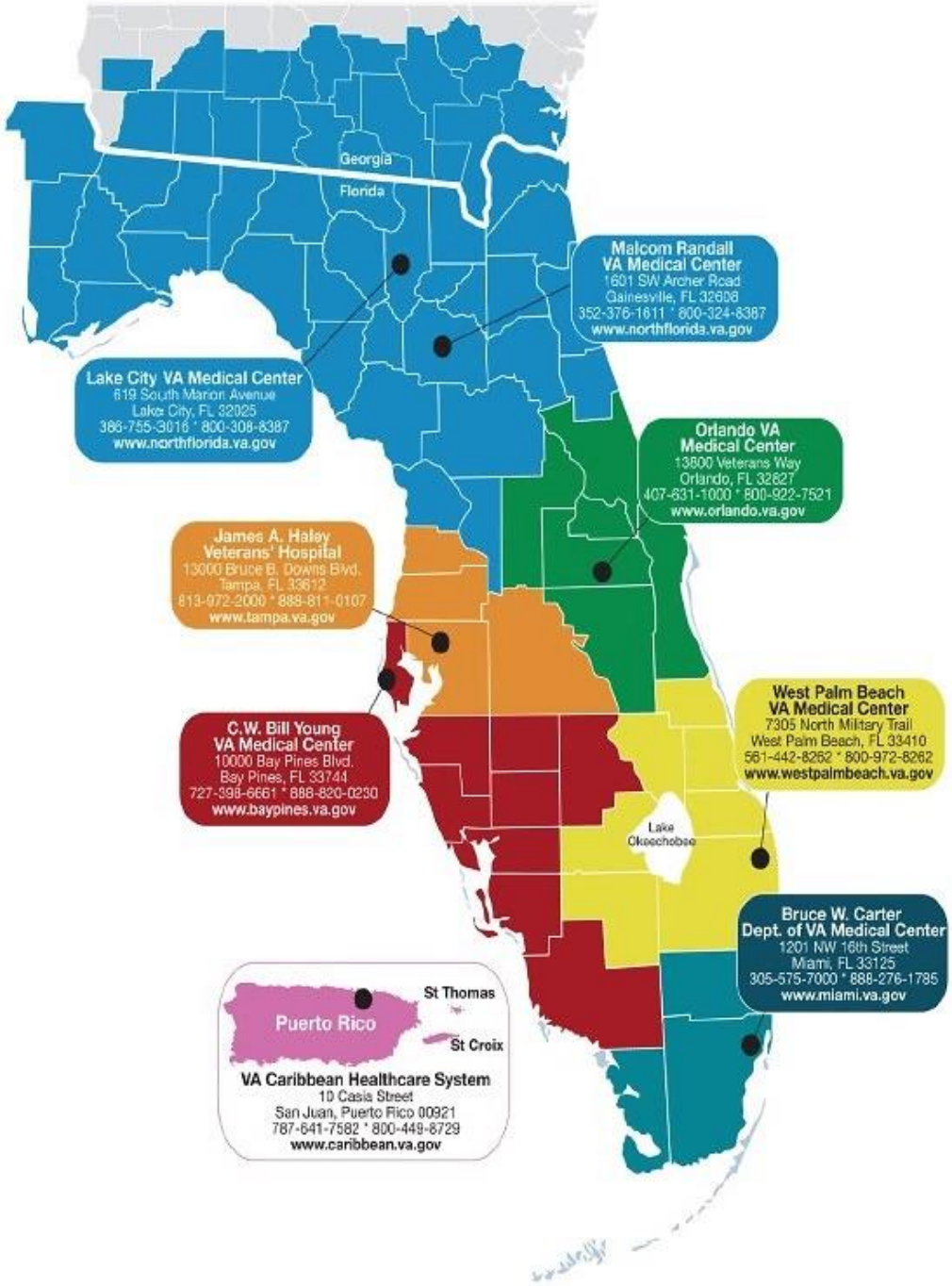
These penalties are in addition to any administrative and civil penalties incurred by the unlicensed individual.

U.S. Department of Veteran Affairs Practitioners

The Veterans Health Administration within the United States Department of Veterans Affairs (VA) operates the nation's largest integrated health care systems, providing care at 1,255 health care facilities.[12] The system is divided into 21 integrated service networks.[13] Each service network is comprised of medical centers or hospitals, which oversees the clinics in its region. Florida is a part of the Sunshine Health Network, which is comprised of eight medical centers and nearly 60 community

[8] Section 456.065(1), F.S.
[9] Section 456.065, F.S. Each day that the unlicensed practice continues after issuance of a notice to cease and desist constitutes a separate offense
[10] Section 456.065(2)(c), F.S.
[11] Section 456.065(2)(d), F.S.
[12] U.S. Department of Veterans Affairs, *Veterans Health Administration*, available at https://www.va.gov/health/ (last visited January 25, 2020).
[13] U.S. Department of Veterans Affairs, *Locations*, available at https://www.va.gov/directory/guide/map.asp (last visited January 25, 2020).

clinics, and has the fourth largest veteran population in the U.S.[14] The VA Sunshine Health Network employs 31,028, including 3,139 physicians and 6,600 nurses, and in Fiscal Year 2018, treated more than 620,000 veterans.[15]



The health care practitioners practicing in VA facilities in Florida are not required to be licensed in Florida. The VA requires that a health care practitioner have an active, unrestricted license to practice from any state to practice at any one of its facilities nationwide.[16] A VA health care practitioner may

[14] U.S. Department of Veterans Affairs, Veterans Health Administration, VA Sunshine Healthcare Network (VISN 8), *2018 Annual Report*, available at https://www.visn8.va.gov/VISN8/news/documents/V-508CLEAN_VISN8_2018AnnualReport.pdf (last visited January 25, 2020).
[15] Id at p. 4.
[16] U.S. Department of Veterans Affairs, *Physicians at VA*, available at https://www.vacareers.va.gov/Careers/Physicians/#live-work-anywhere (last visited January 25, 2020).

treat any veteran in a VA facility located in Florida, regardless of the state of licensure. However, a VA health care practitioner may not provide medical services to one of his or her veteran patients outside the VA facility unless he or she holds a Florida license. If the health care practitioner is not licensed in Florida and provides such services, the health care practitioner could be prosecuted for the unlicensed practice of a health care practitioner.

Effect of Proposed Changes

HB 409 requires DOH to exempt a VA physician from Florida licensure requirements if the VA physician:

- Holds an active, unencumbered license to practice medicine in another state, the District of Columbia, or a possession, commonwealth, or territory of the United States;
- Is currently employed with the VA;
- Attests that he or she will only provide medical services to veterans at Florida-licensed hospitals pursuant to his or her employment with the VA.

DOH must notify the physician that he or she is exempt from licensure within 15 business days of receiving documentation that a VA physician meets the requirements for an exemption. An exempt physician remains subject to prosecution for the unlicensed practice of a health care profession if the physician treats a patient who is not a veteran.

The bill authorizes DOH to adopt rules to implement its provisions.

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

B. SECTION DIRECTORY:

Section 1: Creates s. 456.0231, F.S., relating to exemption of health care license requirements for the treatment of veterans.
Section 2: Provides an effective date of July 1, 2020.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   DOH may experience a decrease in licensure revenue if a physician who works for the VA and is licensed in another state, the District of Columbia, or a possession, commonwealth, or territory of the United States is currently obtaining a Florida license to treat Florida veterans in licensed hospitals.

2. Expenditures:

   DOH will incur insignificant costs relating to rulemaking and reviewing documentation submitted by physicians seeking exemption from licensure, which current resources are adequate to absorb.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

A physician who works for the VA and is licensed in another state will no longer have to pay the fees associated with obtaining a Florida license to treat Florida veterans in licensed hospitals.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

DOH has sufficient rule-making authority to implement the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to health care licensing requirements; creating s. 456.0231, F.S.; defining the term "physician"; exempting certain health care practitioners from specified licensing requirements when providing certain services to veterans in this state; authorizing the Department of Health to adopt rules; providing an effective date.

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

Section 1. Section 456.0231, Florida Statutes, is created to read:

456.0231 Exemption of health care license requirements for the treatment of veterans.—

(1) As used in this section, the term "physician" means a person who holds an active, unencumbered license to practice allopathic medicine or osteopathic medicine issued by another state, the District of Columbia, or a possession, commonwealth, or territory of the United States.

(2) A physician must submit to the department all of the following to be exempt from the licensure requirements of chapters 458 and 459:

(a) Proof that he or she holds an active, unencumbered license to practice allopathic medicine or osteopathic medicine

issued by another state, the District of Columbia, or a possession, commonwealth, or territory of the United States.

(b) Proof of current employment with the United States Department of Veterans Affairs.

(c) An attestation that he or she will only provide medical services:

1. To veterans.

2. Pursuant to his or her employment with the United States Department of Veterans Affairs.

3. In hospitals licensed under chapter 395.

(3) The department shall notify the physician within 15 business days after receipt of the documentation required by subsection (2) that the physician is exempt from the licensure requirements of chapters 458 and 459.

(4) The department may adopt rules to administer this section.

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

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 471 Council on Physician Assistants
SPONSOR(S): Plasencia
TIED BILLS: **IDEN./SIM. BILLS:** SB 584

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	12 Y, 1 N	Siples	McElroy
2) Health Care Appropriations Subcommittee	10 Y, 0 N	Mielke	Clark
3) Health & Human Services Committee		Siples	Calamas

SUMMARY ANALYSIS

A physician assistant (PA) is licensed to perform health care services delegated by a supervising physician, in the specialty areas in which he or she has been trained. In Florida, PAs are regulated by the Council on Physician Assistants (Council), in conjunction with either the Board of Medicine for PAs licensed under ch. 458, F.S., or the Board of Osteopathic Medicine for PAs licensed under ch. 459, F.S.

The Council consists of five members including three physicians who are members of the Board of Medicine, one physician who is a member of the Board of Osteopathic Medicine, and one licensed PA appointed by the Surgeon General. The Council advises the Board of Medicine and the Board of Osteopathic Medicine on issues related to PA licensure and regulation.

HB 471 revises the composition of the Council on Physician Assistants. The bill retains the number of Council members as five, but reduces the total number of physician members from four to two and increases the number of PA members from one to three. Therefore, PAs will hold a majority of the Council membership.

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

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Physician Assistants

A physician assistant (PA) is a health care practitioner who practices under the direct or indirect supervision of an allopathic or osteopathic physician. PAs may provide a number of medical services including:[1]

- Physical examinations;
- Diagnosis and treatment of illness;
- Counsel on preventative health care;
- Assistance in surgery; and
- Prescribing of medication.

In Florida, PAs are regulated by the Council on Physician Assistants (Council), in conjunction with either the Board of Medicine for PAs licensed under ch. 458, F.S., or the Board of Osteopathic Medicine for PAs licensed under ch. 459, F.S. PAs are governed by the respective physician practice acts since PAs may only practice under the supervision of an allopathic or osteopathic physician.

Council on Physician Assistants

The Council consists of five members including three physicians who are members of the Board of Medicine, one physician who is a member of the Board of Osteopathic Medicine, and one licensed PA appointed by the Surgeon General.[2] Two of the physician members must supervise PAs in their practices.[3] Each member serves a 4-year term.[4] The Council is responsible for:[5]

- Making recommendations to the Department of Health regarding the licensure of PAs;
- Developing rules for the regulation of PAs for consideration for adoption by the boards;[6]
- Making recommendations to the boards regarding all matters relating to PAs;
- Addressing concerns and problems of practicing PAs to ensure patient safety;
- Denying, restricting, or placing conditions on the license of PA who fails to meet the licensing requirements;[7] and
- Establish a formulary of medicinal drugs that a PA may not prescribe.[8]

The Board of Medicine and the Board of Osteopathic Medicine is responsible for imposing disciplinary action against the license of a PA.[9] The Council does not discipline PAs.

[1] Florida Academy of Physician Assistance, *What is a PA*, available at https://www.fapaonline.org/page/whatisapa (last visited January 14, 2020).
[2] Sections 458.347(9)(a) and 459.022(9)(a), F.S.
[3] Sections 458.347(9)(b) and 459.022(9)(b), F.S.
[4] Id.
[5] Sections 458.347(9)(c) and 459.022(9)(c), F.S. The boards may delegate powers and duties to the Council as they deem necessary.
[6] Both the Boards of Medicine and Osteopathic Medicine must accept and approve identical language prior to rule adoption.
[7] Sections 458.347(9)(d) and 459.022(9)(d), F.S.
[8] Sections 458.347(4)(f) and 459.022(4)(e), F.S.
[9] Sections 458.347(7)(f) and 459.022(7)(f), F.S.

PA Scope of Practice

PAs may only practice under the direct or indirect supervision of an allopathic or osteopathic physician with whom they have a clinical relationship.[10] A supervising physician may only delegate tasks and procedures to the PA that are within the supervising physician's scope of practice.[11] The supervising physician is responsible and liable for any acts or omissions of the PA and may not supervise more than four PAs at any time.[12]

The Boards have established by rule that "responsible supervision" of a PA means the ability of the supervising physician to exercise control and provide direction over the services or tasks performed by the PA. Whether the supervision of a PA is adequate, is dependent upon the:

- Complexity of the task;
- Risk to the patient;
- Background, training and skill of the PA;
- Adequacy of the direction in terms of its form;
- Setting in which the tasks are performed;
- Availability of the supervising physician;
- Necessity for immediate attention; and
- Number of other persons that the supervising physician must supervise.[13]

A supervising physician decides whether to permit a PA to perform a task or procedure under direct or indirect supervision based on reasonable medical judgment regarding the probability of morbidity and mortality to the patient.[14]

Effect of Proposed Changes

HB 471 revises the composition of the Council. The total membership of the Council will remain five. However, the bill requires the appointment of one physician who is a member of the Board of Medicine, rather than three. The bill requires the appointment of three licensed PAs, rather than one. The number of osteopathic physicians on the Council does not change and remains one. Each of the physician members of the Council must supervise PAs in his or her respective practice.

The bill does not alter the duties or responsibilities of the Council.

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

B. SECTION DIRECTORY:

Section 1: Amends s. 458.347, F.S., relating to physician assistants.
Section 2: Amends s. 459.022, F.S., relating to physician assistants.
Section 3: Provides an effective date of July 1, 2020.

[10] Sections 458.347(2)(f), F.S., and 459.022(2)(f), F.S., define supervision as responsible supervision and control which requires the easy availability or physical presence of the licensed physician for consultation and direction of the PA.
[11] Rules 64B8-30.012, F.A.C., and 64B15-6.010, F.A.C.
[12] Sections 458.347(15), F.S., and 459.022(15), F.S.
[13] Rules 64B8-30.001, F.A.C., and 64B15-6.001, F.A.C.
[14] "Direct supervision" refers to the physical presence of the supervising physician so that the physician is immediately available to the PA when needed. "Indirect supervision" refers to the reasonable physical proximity of the supervising physician to the PA or availability by telecommunication. *Supra* note 13.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:
   None.

2. Expenditures:
   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:
   None.

2. Expenditures:
   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:
None.

D. FISCAL COMMENTS:
None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:
   Not applicable. The bill does not appear to affect county or municipal governments.

2. Other:
   None.

B. RULE-MAKING AUTHORITY:
Not applicable.

C. DRAFTING ISSUES OR OTHER COMMENTS:
None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to the Council on Physician Assistants; amending ss. 458.347 and 459.022, F.S.; revising requirements relating to the Council on Physician Assistants membership; 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. Paragraphs (a) and (b) of subsection (9) of section 458.347, Florida Statutes, are amended to read:

458.347 Physician assistants.—

(9) COUNCIL ON PHYSICIAN ASSISTANTS.—The Council on Physician Assistants is created within the department.

(a) The council shall consist of five members appointed as follows:

1. The chairperson of the Board of Medicine shall appoint one member ~~three members~~ who is a physician and member ~~are physicians and members~~ of the Board of Medicine who supervises~~.~~ ~~One of the physicians must supervise~~ a physician assistant in the physician's practice.

2. The chairperson of the Board of Osteopathic Medicine shall appoint one member who is a physician and ~~a~~ member of the Board of Osteopathic Medicine who supervises a physician

assistant in the physician's practice.

3. The State Surgeon General or his or her designee shall appoint three ~~a~~ fully licensed physician assistants ~~assistant~~ licensed under this chapter or chapter 459.

(b) ~~Two of the members appointed to the council must be physicians who supervise physician assistants in their practice.~~ Members shall be appointed to terms of 4 years, except that of the initial appointments, two members shall be appointed to terms of 2 years, two members shall be appointed to terms of 3 years, and one member shall be appointed to a term of 4 years, as established by rule of the boards. Council members may not serve more than two consecutive terms. The council shall annually elect a chairperson from among its members.

Section 2. Paragraphs (a) and (b) of subsection (9) of section 459.022, Florida Statutes, are amended to read:

459.022 Physician assistants.—

(9) COUNCIL ON PHYSICIAN ASSISTANTS.—The Council on Physician Assistants is created within the department.

(a) The council shall consist of five members appointed as follows:

1. The chairperson of the Board of Medicine shall appoint one member ~~three members~~ who is a physician and member ~~are physicians and members~~ of the Board of Medicine who supervises~~.~~ ~~One of the physicians must supervise~~ a physician assistant in the physician's practice.

2. The chairperson of the Board of Osteopathic Medicine shall appoint one member who is a physician and ~~a~~ member of the Board of Osteopathic Medicine who supervises a physician assistant in the physician's practice.

3. The State Surgeon General or her or his designee shall appoint three ~~a~~ fully licensed physician assistants ~~assistant~~ licensed under chapter 458 or this chapter.

(b) ~~Two of the members appointed to the council must be physicians who supervise physician assistants in their practice.~~ Members shall be appointed to terms of 4 years, except that of the initial appointments, two members shall be appointed to terms of 2 years, two members shall be appointed to terms of 3 years, and one member shall be appointed to a term of 4 years, as established by rule of the boards. Council members may not serve more than two consecutive terms. The council shall annually elect a chairperson from among its members.

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

HB 485

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 485 Athletic Trainers
SPONSOR(S): Antone
TIED BILLS: **IDEN./SIM. BILLS:** CS/SB 226

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	13 Y, 0 N	Siples	McElroy
2) Health Care Appropriations Subcommittee	10 Y, 0 N	Mielke	Clark
3) Health & Human Services Committee		Siples	Calamas

SUMMARY ANALYSIS

Athletic trainers provide service and care to individuals related to the prevention, recognition, evaluation, management, disposition, treatment, or rehabilitation of a physically active person who sustained an injury, illness, or other condition involving exercise, sport, recreation, or related physical activity. In Florida, the Board of Board of Athletic Training (Board) licenses and regulates athletic trainers. The Board of Certification, a credentialing agency, certifies athletic trainers.

Prior to 2004, athletic trainers could qualify for licensure by completing training through a Board of Certification internship program. Current law does not allow applicants who completed an internship to qualify for licensure.. Athletic trainers must show current certification from the Board of Certification for biennial licensure renewal, but there is no statutory requirement that a licensee maintain such certification without lapse and in good standing.

HB 485 revises licensure requirements, which include a new pathway to licensure and requiring athletic trainers to maintain certification for licensure renewal. The bill requires that an athletic trainer work within his or her scope of practice, as defined by Board rules, and requires the Board to adopt rules that govern the supervision of athletic training students.

The bill has an insignificant, negative fiscal impact on the Department of Health, which can be absorbed within existing resources. The bill has no fiscal impact on local governments.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Athletic Trainers

Athletic trainers provide service and care to individuals related to the prevention, recognition, evaluation, management, disposition, treatment, or rehabilitation of a physically active person who sustained an injury, illness, or other condition involving exercise, sport, recreation, or related physical activity.[1]

Board of Athletic Training

The Board of Athletic Training within the Department of Health licenses and regulates athletic trainers in this state.[2] The Board of Athletic Training must establish, by rule:[3]

- The allowable scope of practice regarding the use of equipment, procedures, and medication;
- Mandatory requirements and guidelines for communication between athletic trainers and physicians;
- Licensure requirements and examination;
- Continuing education requirements;
- Fees;
- Records and reports to be filed by licensees;
- Protocols; and
- Other requirements necessary to regulate the practice of athletic training.

Licensure Requirements

To be licensed as an athletic trainer, an applicant must:[4]

- Hold a bachelor's degree or higher from an accredited athletic training degree program and pass the national examination to be certified by the Board of Certification;[5]
- Hold a current certification from the Board of Certification, if the applicant graduated before 2004;
- Hold a current certification in both cardiopulmonary resuscitation and the use of an automated external defibrillator at the professional rescue level; and
- Pass a background screening.

Prior to 2004, athletic trainers could complete an training through a Board of Certification internship program and it was deemed sufficient for licensure.[6] Colleges and universities have established athletic training programs since 2004.[7] Completion of one of these programs is now required for licensure. Current law does not allow applicants who completed an internship prior to 2004 to qualify for licensure.

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[1] Section 468.701(2), F.S.
[2] Sections 468.703 and 468.705, F.S.
[3] Section 468.705, F.S.
[4] Section 468.707, F.S.
[5] The Board of Certification is a not-for-profit credentialing agency that provides a certification program for the entry level athletic training profession. *See* Board of Certification for the Athletic Trainer, *What is the BOC?*, available at http://www.bocatc.org/about-us#what-is-the-boc (last visited January 14, 2020).
[6] Department of Health, *2020 Agency Legislative Bill Analysis for HB 485*, (Jan. 9, 2020), on file with the Health Quality Subcommittee.
[7] Id.

An athletic trainer must renew his or her license biennially. During each biennial renewal period, an athletic trainer must complete at least 24 hours of continuing education, hold a current certification in both cardiopulmonary resuscitation and the use of an automated external defibrillator, and a current certification from the Board of Certification.[8] Although licensees must show current certification from the Board of Certification, there is no statutory requirement that a licensee maintain such certification without lapse and in good standing.

To maintain certification from the Board of Certification, an athletic trainer must:[9]

- Adhere to the Board of Certification standards of professional practice;
- Demonstrate ongoing certification in emergency cardiac care;
- Pay certification maintenance fees; and
- Biennially complete 50 hours of continuing education.

Scope of Practice

An athletic trainer must practice under the direction of a Florida-licensed allopathic, osteopathic, or chiropractic physician,[10] and may provide care such as:[11]

- Injury prevention, recognition, and evaluation;
- First aid and emergency care;
- Injury management and treatment;
- Rehabilitation through the use of safe and appropriate physical rehabilitation practices;
- Conditioning;
- Performance of tests and measurements to prevent, evaluate, and monitor acute and chronic injuries;
- Therapeutic exercises;
- Massage;
- Cryotherapy and thermotherapy;
- Therapy using other agents such as water, electricity, light, or sound; and
- The application of topical prescription medications at the direction of a physician.

The physician must communicate his or her direction through oral or written prescriptions or protocols, and the athletic trainer must provide service or care in the manner dictated by the physician.[12] A licensed athletic trainer may not provide, offer to provide, or represent that he or she is qualified to provide any care or service that he or she lacks the education, training, or experience to provide, or that he or she is otherwise prohibited by law from providing.[13]

Effect of Proposed Changes

HB 485 adds another route to licensure by authorizing individuals who hold a bachelor's degree, completed a Board of Certification internship, and hold a certification from the Board of Certification to be eligible for licensure. The bill establishes that a licensed athletic trainer must maintain his or her certification from the Board of Certification in good standing to be eligible for licensure renewal.

[8] Section 468.711, F.S.
[9] Board of Certification, *Certification Maintenance Requirements for Certified Athletic Trainers*, available at https://online.flowpaper.com/7f6907b2/201819CertMaintenanceRequirements/#page=1 (last visited January 14, 2020).
[10] Section 468.713, F.S.
[11] Rule 64B33-4.001, F.A.C.
[12] *Supra* note 10.
[13] Section 468.701(1), F.S.

The bill requires athletic trainers to work within her or his scope of practice as defined by Board of Athletic Training in rule. also requires the Board of Athletic Training to establish rules for the supervision of an athletic training student.

The bill relocates a substantive provision, which prohibits an athletic trainer from providing care or services for which the athletic trainer has not had education or training, from the definition of "athletic trainer" to a section of law that addresses the responsibilities of a licensed athletic trainer.

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

B. SECTION DIRECTORY:

Section 1: Amends s. 468.701, F.S., relating to definitions.
Section 2: Amends s. 468.707, F.S., relating to licensure requirements.
Section 3: Amends s. 468.711, F.S., relating to renewal of license; continuing education.
Section 4: Amends s. 468.713, F.S., relating to responsibilities of athletic trainers.
Section 5: Amends s. 468.723, F.S., relating to exemptions.
Section 6: Provides an effective date of July 1, 2020.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

DOH will incur insignificant costs related to rulemaking to implement the bill's provisions, which can be absorbed within existing resources.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Idividuals who hold a bachelor's degree and completed a Board of Certification internship would now be eligible for licensure.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. The bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The Board of Athletic Training has sufficient rulemaking authority to implement the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to athletic trainers; amending s. 468.701, F.S.; revising the definition of the term "athletic trainer"; deleting a requirement that is relocated to another section; amending s. 468.707, F.S.; revising athletic trainer licensure requirements; amending s. 468.711, F.S.; requiring certain licensees to maintain certification in good standing without lapse as a condition of renewal of their athletic trainer licenses; amending s. 468.713, F.S.; requiring that an athletic trainer work within a specified scope of practice; relocating an existing requirement that was stricken from another section; amending s. 468.723, F.S.; requiring the direct supervision of an athletic training student to be in accordance with rules adopted by the Board of Athletic Training; providing an effective date.

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

Section 1. Subsection (1) of section 468.701, Florida Statutes, is amended to read:

468.701 Definitions.—As used in this part, the term:

(1) "Athletic trainer" means a person licensed under this part who has met the requirements of ~~under~~ this part, including

the education requirements established ~~as set forth~~ by the Commission on Accreditation of Athletic Training Education or its successor organization and necessary credentials from the Board of Certification. ~~An individual who is licensed as an athletic trainer may not provide, offer to provide, or represent that he or she is qualified to provide any care or services that he or she lacks the education, training, or experience to provide, or that he or she is otherwise prohibited by law from providing.~~

Section 2. Section 468.707, Florida Statutes, is amended to read:

468.707 Licensure requirements.—Any person desiring to be licensed as an athletic trainer shall apply to the department on a form approved by the department. An applicant shall also provide records or other evidence, as determined by the board, to prove he or she has met the requirements of this section. The department shall license each applicant who:

(1) Has completed the application form and remitted the required fees.

(2) ~~For a person who applies on or after July 1, 2016,~~ Has submitted to background screening pursuant to s. 456.0135. The board may require a background screening for an applicant whose license has expired or who is undergoing disciplinary action.

(3)(a) Has obtained, at a minimum, a bachelor's ~~baccalaureate or higher~~ degree from a college or university

professional athletic training degree program accredited by the Commission on Accreditation of Athletic Training Education or its successor organization recognized and approved by the United States Department of Education or the Commission on Recognition of Postsecondary Accreditation, approved by the board, or recognized by the Board of Certification, and has passed the national examination to be certified by the Board of Certification; or~~.~~

(b)~~(4)~~ Has obtained, at a minimum, a bachelor's degree, has completed the Board of Certification internship requirements, and holds ~~If graduated before 2004, has~~ a current certification from the Board of Certification.

(4)~~(5)~~ Has current certification in both cardiopulmonary resuscitation and the use of an automated external defibrillator set forth in the continuing education requirements as determined by the board pursuant to s. 468.711.

(5)~~(6)~~ Has completed any other requirements as determined by the department and approved by the board.

Section 3. Subsection (3) of section 468.711, Florida Statutes, is amended to read:

468.711 Renewal of license; continuing education.—

(3) If initially licensed after January 1, 1998, the licensee must be currently certified by the Board of Certification or its successor agency and maintain that certification in good standing without lapse.

Section 4. Section 468.713, Florida Statutes, is amended to read:

468.713 Responsibilities of athletic trainers.—

(1) An athletic trainer shall practice under the direction of a physician licensed under chapter 458, chapter 459, chapter 460, or otherwise authorized by Florida law to practice medicine. The physician shall communicate his or her direction through oral or written prescriptions or protocols as deemed appropriate by the physician for the provision of services and care by the athletic trainer. An athletic trainer shall provide service or care in the manner dictated by the physician.

(2) An athletic trainer shall work within his or her allowable scope of practice as specified in board rule under s. 468.705. An athletic trainer may not provide, offer to provide, or represent that he or she is qualified to provide any care or services that he or she lacks the education, training, or experience to provide or that he or she is otherwise prohibited by law from providing.

Section 5. Subsection (2) of section 468.723, Florida Statutes, is amended to read:

468.723 Exemptions.—This part does not prohibit ~~prevent~~ or restrict:

(2) An athletic training student acting under the direct supervision of a licensed athletic trainer. For purposes of this subsection, "direct supervision" means the physical presence of

an athletic trainer so that the athletic trainer is immediately available to the athletic training student and able to intervene on behalf of the athletic training student. The supervision must comply with board rule ~~in accordance with the standards set forth by the Commission on Accreditation of Athletic Training Education or its successor~~.

Section 6. This act shall take effect July 1, 2020.

HB 575

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 575 Applied Behavior Analysis Services
SPONSOR(S): Plasencia
TIED BILLS: **IDEN./SIM. BILLS:** SB 1206

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Market Reform Subcommittee	14 Y, 0 N	Grabowski	Calamas
2) Health Care Appropriations Subcommittee	10 Y, 0 N	Nobles	Clark
3) Health & Human Services Committee		Grabowski	Calamas

SUMMARY ANALYSIS

Applied Behavioral Analysis (ABA) is an umbrella term referring to the principles and techniques used to assess, treat, and prevent challenging behaviors while promoting new, desired behaviors. ABA has been recognized as a treatment option for a range of behavioral health conditions, with an emphasis on the treatment of autism spectrum disorder. ABA services are covered under the Florida Medicaid program, when medically necessary, and also under group health insurance plans and health management organization contracts.

Research suggests that ABA interventions should generally be provided under the supervision of a trained behavioral psychologist or behavioral analyst. While the Florida Statutes do not currently require licensure for ABA providers, several levels of professional certification are available to ABA providers.

The Florida Medicaid program requires such certification to participate in Medicaid. Medicaid also requires groups or agencies providing ABA services to be licensed under the Florida Health Care Clinic Act, which includes additional fiduciary and administrative requirements for health care providers.

Current law allows certified ABA professionals and mental health professionals licensed under ch. 490 or 491, F.S., to provide services in the K-12 classroom setting. However, behavioral assistants and other non-certified professionals working under the direction of these certified or licensed professional are not allowed to provide services in the K-12 classroom setting.

HB 575 would exempt group practices that provide ABA services from the requirements of the Health Care Clinic Act.

The bill also adds paraprofessionals who practice under the supervision of either certified behavioral analysts or professionals licensed under ch. 490 or ch. 491, F.S., to the list of private instructional personnel who may provide ABA services in the classroom setting. This change would allow registered behavioral technicians and other behavioral assistants to provide ABA services to students in a public K-12 school.

The bill has significant positive fiscal impact on the Agency for Health Care Administration and no fiscal impact on local governments.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Applied Behavioral Analysis

Applied Behavioral Analysis (ABA) is an umbrella term referring to the principles and techniques used to assess, treat, and prevent challenging behaviors while promoting new, desired behaviors. ABA focuses on improving social skills, communication, reading, and academics as well as adaptive learning skills, such as fine motor dexterity, hygiene, grooming, domestic capabilities, punctuality, and job competence. ABA can be effective for children and adults with psychological disorders in a variety of settings, including schools, workplaces, homes, and clinics.[1]

ABA has been recognized as a therapeutic intervention in the treatment of autism spectrum disorder (ASD). ASD is a developmental disability that impacts the social, emotional, and communication skills of affected individuals. The disorder includes a range of conditions that were previously diagnosed separately – such as autism, Asperger syndrome, and other non-specific developmental disorders.[2]

ABA has become widely accepted among health care professionals, is used in many schools and treatment clinics, and is considered an evidence-based best practice treatment by the U.S. Surgeon General, American Psychological Association, American Academy of Child and Adolescent Psychiatry, and American Academy of Pediatrics.

Providers of ABA Services

Research suggests that ABA interventions should generally be provided under the supervision of a trained behavioral psychologist or behavioral analyst. In general, behavior analysts perform patient assessments to determine levels of adaptive and maladaptive behaviors, and develop a treatment plan. Behavior analysts supervise other professionals, such as behavior technicians, who implement the treatment plan, and monitor progress.[3]

While the Florida Statutes do not currently require licensure for behavior analysts or other types of ABA providers, several levels of professional certification are available.

The Behavior Analyst Certification Board (BACB) was established in 2008 to develop uniform standards for determining who is qualified to provide professional ABA services. It is an independent, nonprofit organization whose behavior analyst credentialing programs are accredited by the National Commission for Certifying Agencies (NCCA) of the Institute for Credentialing Excellence.[4] The BACB certifies professional practitioners at two levels: the Board Certified Behavioral Analyst (BCBA) and the Board Certified Assistant Behavioral Analyst (BCaBA). The BACB also issues a credential for paraprofessionals, known as the Registered Behavior Technician (RBT). Requirements for the three credentials are below.[5]

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[1] "Applied Behavioral Analysis", *Psychology Today*, available at https://www.psychologytoday.com/us/therapy-types/applied-behavior-analysis (last accessed December 3, 2019).
[2] U.S. Centers for Disease Control and Prevention, "What is Autism Spectrum Disorder?", available at https://www.cdc.gov/ncbddd/autism/facts.html (last accessed December 3, 2019).
[3] Association of Professional Behavior Analysts, *Identifying Applied Behavioral Analysis Interventions*, 2017, available at https://www.bacb.com/wp-content/uploads/APBA-2017-White-Paper-Identifying-ABA-Interventions1.pdf (last accessed December 4, 2019).
[4] Id.
[5] Id.

Board Certified Behavioral Analyst (BCBA)
• At least a master's degree in applied behavior analysis or a closely-related field; • Completion of 270 hours of graduate-level instruction in specified behavior analysis topics; • Completion of specified hours of supervised experiential training in ABA; and, • Passage of the BCBA examination.
Board Certified Assistant Behavioral Analyst (BCaBA)
• At least a bachelor's degree; • Completion of 180 classroom hours of instruction in specified behavior analysis topics; • Completion of specified hours of supervised experiential training in ABA; and, • Passage of the BCaBA examination.
Registered Behavioral Technician (RBT)
• At least a high school diploma; • Completion of 40 hours of training in specified behavior analysis topics; • Completion of the RBT competency assessment; and, • Passage of the RBT examination.

BACB recently added the BCBA-D distinction to recognize board certified analysts who hold doctoral degrees. The BACB specifies it is mandatory that BCaBAs practice under the supervision of a BCBA. All individuals certified BACB (whether BCBA, BCBA-D, or BCaBA) must accumulate continuing education credits to maintain their credentials.[6]

ABA Services under Florida Medicaid

Medicaid is a joint federal- and state-funded program that provides health care for low-income Floridians, administered by the Agency for Health Care Administration (AHCA) under ch. 409, F.S. Federal law establishes the mandatory services to be covered in order to receive federal matching funds.

States have some flexibility in the provision of Medicaid services. Section 1915(b) of the Social Security Act provides authority for the Secretary of the U.S. Department of Health and Human Services to waive requirements to the extent that he or she "finds it to be cost-effective and efficient and not inconsistent with the purposes of this title." Also, Section 1115 of the Social Security Act allows states to use innovative service delivery systems that improve care, increase efficiency, and reduce costs.

Medicaid reimburses health care providers that have a provider agreement with AHCA only for medically necessary goods and services that are covered by the Medicaid program and only for individuals who are eligible for medical assistance under Medicaid. Section 409.907, F.S., establishes requirements for Medicaid provider agreements, which include, among other things, background screening requirements, notification requirements for change of ownership of a Medicaid provider, authority for AHCA site visits of provider service locations and surety bond requirements.

In 2008, the Florida Legislature authorized AHCA to seek federal approval through a Medicaid waiver or state plan amendment for the provision of occupational therapy, speech therapy, physical therapy, *behavior analysis*, and *behavior assistant services* to individuals five years of age and under diagnosed with ASD or Down syndrome.[7]

[6] Behavior Analyst Certification Board, "Become Credentialed", available at https://www.bacb.com/become-credentialed/ (last accessed December 5, 2019).
[7] Ch. 2008-30, L.O.F. The bill also mandated coverage of applied behavior analysis by commercial group health insurance plans and health maintenance organizations; see ss. 627.6686, 641.31098, F.S.

Provision of ABA services under the Florida Medicaid program actually began in 2012, following a federal court order which recognized ABA as a covered service for children when medically necessary.[8] In the absence of administrative rule or formal department policy, AHCA established provider qualifications and service requirements through alerts sent to prospective providers. Between March 2012 and February 2017[9], ABA services under the Medicaid program were provided through multiple programs and provider types that included:

- Certified behavior analysts and behavior assistants enrolled under the developmental disabilities waiver program (now the iBudget waiver);
- Infant toddler developmental specialists with certification in behavior analysis enrolled as early intervention service providers; and,
- Certified behavior analysts and certified associate behavior analysts enrolled as community behavior health services providers.

In February 2017, AHCA adopted an administrative rule setting a formal classification for ABA providers that closely follows the certification hierarchy of the BACB. The rule established "lead analysts" as those professionals either holding a BCBA certification or licensed by the state under chs. 490 and 491, F.S., such as clinical social workers or school psychologists. The rule also recognizes other personnel who are permitted to provide ABA services, such as those holding BCaBA credentials, RBT credentials, and behavior assistants who have experience and training in providing services to individuals with mental health conditions or developmental or intellectual disabilities.[10]

Medicaid utilization of ABA services significantly increased 2017-2019, doubling by mid-2018.[11] AHCA implemented various additional utilization management and provider enrollment requirements, including, among other things, prior authorization requirements, service approvals by multi-disciplinary teams, and the use of a vendor to implement the requirements.

In 2019, AHCA required all ABA provider groups to be licensed as health care clinics under ch. 400, F.S., as a condition of Medicaid enrollment, effective July 1, 2020. This change will require ABA provider groups to employ a medical or clinical director and meet certain financial requirements, in addition to those required of all Medicaid enrolled providers.

Health Care Clinic Act

The Health Care Clinic Act (Act), ss. 400.990 – 400.995, F.S., was enacted in 2003 to reduce fraud and abuse in the personal injury protection (PIP) insurance system.[12] Pursuant to the Act, the Agency for Health Care Administration (AHCA) licenses health care clinics, ensures that such clinics meet basic standards, and provides administrative oversight.

Any entity that meets the definition of a health care clinic must be licensed as a health care clinic. Although all clinics must be licensed by AHCA, the Act creates many exceptions from the health care clinic licensure requirements.[13] To be licensed, an entity must submit a completed application form to AHCA[14] and must:

- Submit to a Level 2 background screening including owners and certain employees and officers of the entity;

[8] See *K.G. v. Dudek*, 839 F.Supp.2d 1254 (2011); *K.G. ex rel. Garrido v. Dudek*, 864 F. Supp. 2d 1314 (S.D. Fla. 2012); D. C. Docket No. 1:11-cv-20684-JAL.
[9] During this time period, AHCA had yet to adopt formal regulations that classified providers of ABA services.
[10] Rule 59G-4.125, F.A.C.
[11] "Florida Medicaid Behavior Analysis Services Overview", Agency for Health Care Administration, May 1, 2018, on file with subcommittee staff.
[12] Chapter 2003-411, Laws of Fla. PIP insurance is no fault auto insurance that provides certain benefits for individuals injured as a result of a motor vehicle accident. All motor vehicles registered in this state must have PIP insurance.
[13] S. 400.9905(4), F.S.
[14] S. 408.806, F.S.

- Provide a description or explanation of any exclusions, suspensions, or terminations of the applicant from the Medicare, Medicaid, or federal Clinical Laboratory Improvement Amendment programs;
- Demonstrate financial ability to operate by showing that the applicant's assets, credits, and projected revenues will meet or exceed projected liabilities and expense[15] or provide a surety bond of at least $500,000 payable to AHCA;[16]
- Provide proof of the applicant's legal right to occupy the property in which the clinic is located; and
- Provide proof of any required insurance.[17]

AHCA has 60 days after the receipt of the completed application for licensure to approve or deny the application. Licenses must be renewed biennially.

Each clinic must appoint a medical or clinical director. A medical director must be a physician employed or under contract with a clinic and who maintains an unencumbered license as an allopathic physician, osteopathic physician, chiropractor, or podiatrist.[18] In lieu of a medical director, a health care clinic may appoint a clinical director if the clinic does not provide services that are regulated by one of the aforementioned physician practice acts.

The medical or clinical director must agree in writing to accept the legal responsibility for the following activities on behalf of the clinic:

- Display signs that identify the medical or clinical director posted in a conspicuous location within the clinic readily visible to all patients;
- Ensure that all practitioners providing health care services or supplies to patients maintain a current active and unencumbered Florida license;
- Review any patient referral contracts or agreements executed by the clinic;
- Ensure that all health care practitioners at the clinic have active appropriate certification or licensure for the level of care being provided;
- Serve as the clinic records owner;
- Ensure compliance with the recordkeeping, office surgery, and adverse incident reporting requirements;
- Conduct systematic reviews of clinic billings to ensure that the billings are not fraudulent or unlawful;
- Not refer a patient to the clinic if the clinic performs magnetic resonance imaging, static radiographs, computed tomography, or positron emission tomography; and
- Ensure that the clinic publishes a schedule of charges for the medical services offered to patients.[19]

If the health care clinic's medical director is a physician, it may provide any health care service or treatment that a physician is authorized to provide. However, if the health care clinic employs another health care practitioner as its clinic director, the health care services it may offer is limited to those services within the scope of practice of that health care practitioner's license.[20]

[15] S. 408.8069, F.S. This also includes providing AHCA with financial statements, including balance sheet, income and expense statement, a statement of cash flow for the first 2 years of operation that provides evidence that the applicant has sufficient assets, credits, and projected revenues to cover liabilities and expenses, and a statement of the applicant's startup costs and sources of funds through the breakeven point.
[16] S. 408.8069, F.S.
[17] S. 408.810, F.S.
[18] S. 400.9905(5), F.S.
[19] S. 400.9935, F.S.
[20] S. 400.9905 (5), F.S.

Because providers of ABA services are not currently licensed by the state, an ABA practice would need to retain a state-licensed health care practitioner as its medical or clinical director in order to comply with the Health Care Clinic Act.

Other than the personnel requirement to have a medical or clinical director, the Health Care Clinic Act does not authorize AHCA to establish or enforce clinical standards or outcomes, and a clinic's obligations under the Act relate to PIP fraud prevention.

ABA Services in Schools

Current law requires school districts to accommodate ABA services in the school setting. Section 1003.572, F.S., defines ABA providers as "private instructional personnel", and sets parameters under which they must be allowed to enter the classroom to observe or provide services to a student in a public K-12 school. Private instructional personnel who are hired or contracted by parents to collaborate with public instructional personnel must be permitted to observe the student in the educational setting, collaborate with instructional personnel in the educational setting, and provide services in the educational setting, so long as certain requirements are met. For example, private instructional personnel must pass criminal background screening and the principal and teacher must consent to the time and place of service provision.

Among the professionals included in the definition of private instructional personnel are behavior analysts certified by BACB[21] to provide ABA services, as well as mental health professionals licensed under chapter 490 or 491 of the Florida Statutes.[22] The statute does not expressly address other behavior analysis professionals, such as RBTs, who implement the treatment plans established by behavior analysts.

Effect of the Bill

The bill would exempt group practices that provide ABA services from licensure under the Health Care Clinic Act.

The bill also amends S. 1003.572, F.S., to add paraprofessionals who practice under the supervision of either certified behavioral analysts or professionals licensed under ch. 490 or ch. 491, F.S., to the list of private instructional personnel who may provide ABA services in the classroom setting. This change would allow RBTs and other behavioral assistants to provide ABA services to students in a public K-12 school.

B. SECTION DIRECTORY:

Section 1: Amends s. 400.9905, F.S., relating to definitions.
Section 2: Amends s. 1003.572, F.S., relating to collaboration of public and private instructional personnel.
Section 3: Provides an effective date of July 1, 2020.

[21] Or by the Agency for Persons with Disabilities (APD) pursuant to s. 393.17, F.S. APD relies on BACB for its program, and does not independently certify behavior analysts.
[22] These chapters regulate psychologists, school psychologists, mental health counselors, marriage and family therapists, and social workers.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

The bill's exemption from licensure under the Health Care Clinic Act will reduce anticipated increases in workload for the AHCA Division of Health Quality Assurance.

AHCA estimates an additional 13,000 entities, including, but not limited to, ABA providers, will seek licensure under the Act by December 2020 in compliance with the Medicaid's new contract requirement.[23] AHCA submitted four Legislative Budget Requests totaling $3.8 million and additional FTEs to cover the expense of this increased licensure work, and increased work attributable to other activity.[24] AHCA estimates 1,891 of the 13,000 entities could be ABA providers, and estimates two FTEs would be required for this work.[25] The bill would avoid this cost, making the agency request for these two FTEs unnecessary.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill may have a positive fiscal impact on providers of ABA services, since it will exempt them from the fiduciary and administrative requirements of the Health Care Clinic Act.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

AHCA has sufficient rulemaking authority to implement the bill.

[23] Agency for Health Care Administration correspondence, Nov. 27, 2019, on file with subcommittee staff.
[24] Agency for Health Care Administration, Legislative Budget Request Exhibit D-3A, Issues Codes 2000710, 3000300, 3000320, 3000340, Sept. 16, 2019.
[25] Agency for Health Care Administration correspondence, Dec. 11, 2019, on file with subcommittee staff.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to applied behavior analysis services; amending s. 400.9905, F.S.; providing an exemption from licensure requirements for certain individuals who are employed or under contract with certain entities providing applied behavior analysis services; amending s. 1003.572, F.S.; redefining the term "private instructional personnel" to include certain behavior analysts and paraprofessionals providing applied behavior analysis services; providing an effective date.

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

Section 1. Paragraph (o) is added to subsection (4) of section 400.9905, Florida Statutes, to read:

400.9905 Definitions.—

(4) "Clinic" means an entity where health care services are provided to individuals and which tenders charges for reimbursement for such services, including a mobile clinic and a portable equipment provider. As used in this part, the term does not include and the licensure requirements of this part do not apply to:

(o) A group of individuals certified under s. 393.17 or licensed under chapter 490 or chapter 491, and who are employed

by or under contract with a group practice, billing provider, or agency that provides applied behavior analysis services as defined in ss. 627.6686 and 641.31098.

Notwithstanding this subsection, an entity shall be deemed a clinic and must be licensed under this part in order to receive reimbursement under the Florida Motor Vehicle No-Fault Law, ss. 627.730-627.7405, unless exempted under s. 627.736(5)(h).

Section 2. Paragraphs (b) through (f) of subsection (1) of section 1003.572, Florida Statutes, are redesignated as paragraphs (c) through (g), respectively, paragraph (a) is amended, and a new paragraph (b) is added to that subsection, to read:

1003.572 Collaboration of public and private instructional personnel.—

(1) As used in this section, the term "private instructional personnel" means:

(a) Individuals ~~certified under s. 393.17 or~~ licensed under chapter 490 or chapter 491, or behavior analysts certified by a nonprofit credentialing entity approved by the department, for applied behavior analysis services as defined in ss. 627.6686 and 641.31098.

(b) Paraprofessionals who practice under the supervision of a professional authorized under paragraph (a) and who assist and support such professional in providing applied behavior

analysis services.

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

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 709 Guardianship
SPONSOR(S): Burton
TIED BILLS: **IDEN./SIM. BILLS:** SB 994

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Children, Families & Seniors Subcommittee	9 Y, 0 N	Morris	Brazzell
2) Justice Appropriations Subcommittee	11 Y, 0 N	Smith	Gusky
3) Health & Human Services Committee		Morris	Calamas

SUMMARY ANALYSIS

Guardianship is a concept whereby a "guardian" acts on behalf of a "ward" whom the law regards as incapable of managing his or her own person or property, or both, due to age or incapacity. A court may appoint a public or private guardian if there is no family member or friend, other person, bank, or corporation willing and qualified to serve as guardian of that ward. Before a guardian may be appointed to act for the ward, a court must determine that the ward is incapable of handling his or her affairs.

HB 709 amends sections of law relating to guardianship, addressing the appointment of a guardian, orders not to resuscitate, information required to be disclosed in petitions for appointment of a guardian, mandated guardianship reports, and conflicts of interest. The bill:

- Requires the court to inquire into and consider potential disqualifications and potential conflicts of interest prior to the appointment of a guardian;
- Prohibits a guardian from consenting to or signing on behalf of the ward an order not to resuscitate without first obtaining specific approval from the court;
- Requires the petition for appointment of a guardian to disclose whether the guardian is a professional guardian, any alternatives to guardianship being used or previously used by the alleged incapacitated person, and the reasons why a guardian advocate or alternatives to guardianship are insufficient;
- Prohibits a professional guardian from petitioning for their own appointment, unless they are a relative of the alleged incapacitated person;
- Requires certain information about preexisting advance directives and preexisting do-not-resuscitate orders to be included in the initial and annual guardianship plans;
- Requires a guardian to declare all remuneration received by the guardian in the annual guardianship report and defines "remuneration";
- Prohibits a guardian from offering, paying, soliciting, or receiving certain benefits in return for referring, soliciting, or engaging in a transaction for goods or services on behalf of an alleged incapacitated person or minor, or a ward, for past or future goods or services; and
- Prohibits a guardian from having specified interests with certain individuals unless court approval is obtained or such relationships existed prior to appointment and are disclosed to the court in the petition for appointment of a guardian.

The bill has an indeterminate fiscal impact on state and local governments.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Guardianship

When an individual is unable to make legal decisions regarding his or her person or property, a guardian may be appointed to act on his or her behalf. A guardian is someone who is appointed by the court to act on behalf of a ward (an individual who has been adjudicated incapacitated) regarding his or her person or property or both.[1] Adjudicating a person totally incapacitated and in need of a guardian deprives a person of his or her civil and legal rights.[2] The Legislature has recognized that the least restrictive form of guardianship should be used to ensure the most appropriate level of care and the protection of that person's rights.[3]

The process to determine an individual's incapacity and the subsequent appointment of a guardian begins with a verified petition detailing the factual information supporting the reasons the petitioner believes the individual to be incapacitated, including the rights the alleged incapacitated person is incapable of exercising.[4] Once a person has been adjudicated incapacitated (termed a "ward"), the court appoints a guardian, and the letters of guardianship are issued.[5] The order appointing a guardian must be consistent with the ward's welfare and safety, must be the least restrictive appropriate alternative, and must reserve to the ward the right to make decisions in all matters commensurate with his or her ability to do so.[6]

Relationship Between Guardian and Ward

The relationship between a guardian and his or her ward is a fiduciary one.[7] A fiduciary relationship exists between two persons when one of them is under a duty to act for or to give advice for the benefit of another upon matters within the scope of that relationship.[8] The guardian, as fiduciary, must:

- Act within the scope of the authority granted by the court and as provided by law;
- Act in good faith;
- Not act in a manner contrary to the ward's best interests under the circumstances; and
- Use any special skills or expertise the guardian possesses when acting on behalf of the ward.[9]

Additionally, s. 744.446, F.S., states that there is a fiduciary relationship between the guardian and the ward and that such relationship may not be used for the private gain of the guardian other than the remuneration for fees and expenses provided by law. As such, the guardian must act in the best interest of the ward and carry out his or her responsibilities in an informed and considered manner. Should a guardian breach his or her fiduciary duty to the ward, the court is authorized to intervene.[10]

[1] s. 744.102(9), F.S.
[2] s. 744.101(1), F.S.
[3] s. 744.101(2), F.S
[4] s. 744.3201, F.S.
[5] ss. 744.3371-744.345, F.S.(?)
[6] s. 744.2005, F.S.
[7] *Lawrence v. Norris,* 563 So. 2d 195, 197 (Fla. 1st DCA 1990); s. 744.361(1), F.S.
[8] *Doe v. Evans,* 814 So. 2d 370, 374 (Fla. 2002).
[9] s. 744.361(1), F.S.
[10] s. 744.446(4), F.S.

A guardian can either be a limited or plenary.[11] A limited guardian is appointed by the court to exercise the legal rights and powers specifically designated by the court after the court has found that the ward lacks the capacity to do some, but not all, of the tasks necessary to care for his or her person or property, or after the person has voluntarily petitioned for appointment of a limited guardian.[12] A plenary guardian is appointed by the court to exercise all delegable legal rights and powers of the ward after the court has found that the ward lacks the capacity to perform all of the tasks necessary to care for his or her person or property.[13]

Appointment of a Guardian

The following may be appointed guardian of a ward:

- Any resident of Florida who is 18 years of age or older and has full legal rights and capacity;
- A nonresident if he or she is related to the ward by blood, marriage, or adoption;
- A trust company, a state banking corporation, or state savings association authorized and qualified to exercise fiduciary powers in this state, or a national banking association or federal savings and loan association authorized and qualified to exercise fiduciary powers in Florida;
- A nonprofit corporation organized for religious or charitable purposes and existing under the laws of Florida;
- A judge who is related to the ward by blood, marriage, or adoption, or has a close relationship with the ward or the ward's family, and serves without compensation;
- A provider of health care services to the ward, whether direct or indirect, when the court specifically finds that there is no conflict of interest with the ward's best interests; or
- A for-profit corporation that meets certain qualifications, including being wholly owned by the person who is the circuit's public guardian in the circuit where the corporate guardian is appointed.[14]

Appointment of a Professional Guardian

A professional guardian is a guardian who has at any time rendered services to three or more wards as their guardian; however, a person serving as a guardian for two or more relatives is not considered a professional guardian. A public guardian is considered a professional guardian for purposes of regulation, education, and registration.[15]

In each case when a court appoints a professional guardian and does not use a rotation system for such appointment, the court must make specific findings of fact stating why the person was selected as guardian in the particular matter involved.[16] The findings must reference the following factors that must be considered by the court:

- Whether the guardian is related by blood or marriage to the ward;
- Whether the guardian has educational, professional, or business experience relevant to the nature of the services sought to be provided;
- Whether the guardian has the capacity to manage the financial resources involved;
- Whether the guardian has the ability to meet the requirements of the law and the unique needs of the individual case;
- The wishes expressed by an incapacitated person as to who shall be appointed guardian;
- The preference of a minor who is age 14 or over as to who should be appointed guardian;
- Any person designated as guardian in any will in which the ward is a beneficiary; and
- The wishes of the ward's next of kin, when the ward cannot express a preference.[17]

[11] s. 744.102(9), F.S.
[12] *Id.*
[13] *Id.*
[14] s. 744.309, F.S.
[15] s. 744.102(17), F.S
[16] s. 744.312(4)(a), F.S.
[17] s. 744.312(2)-(3), F.S.

Additionally, the court may not give preference to the appointment of a person based solely on the fact that such person was appointed by the court to serve as an emergency temporary guardian.[18] When a professional guardian is appointed as an emergency temporary guardian, that professional guardian may not be appointed as the permanent guardian of a ward unless one of the next of kin of the alleged incapacitated person or the ward requests that the professional guardian be appointed as permanent guardian.[19] However, the court may waive this limitation if the special requirements of the guardianship demand that the court appoint a guardian because he or she has special talent or specific prior experience.[20]

The court may not appoint a professional guardian who is not registered by the Office of Public and Professional Guardians.[21] The following are disqualified from being appointed as a guardian:

- A person convicted of a felony;
- A person who is incapable of discharging the duties of a guardian due to incapacity or illness, or is otherwise unsuitable to perform the duties of a guardian;
- A person who has been judicially determined to have committed abuse, abandonment, or neglect against a child;
- A person who has been found guilty of, regardless of adjudication, or entered a plea of nolo contendere or guilty to, any offense prohibited under s. 435.04, F.S.;
- A person who provides substantial services to the proposed ward in a professional or business capacity, or a creditor of the proposed ward, may not be appointed guardian and retain that previous professional or business relationship, with exceptions; or
- A person who is in the employ of any person, agency, government, or corporation that provides service to the proposed ward in a professional or business capacity, unless that person is the spouse, adult child, parent, or sibling of the proposed ward or the court determines that the potential conflict of interest is insubstantial and that the appointment would clearly be in the proposed ward's best interest.[22]

A court may not appoint a guardian in any other circumstance in which a conflict of interest may occur.[23]

Powers and Duties of the Guardian

The guardian of an incapacitated person may exercise only those rights removed from the ward and delegated to the guardian.[24] The guardian has a great deal of power when it comes to managing the ward's estate. Some of these powers require court approval before they may be exercised.

[18] s. 744.312(5), F.S.
[19] s. 744.312(4)(b), F.S.
[20] *Id.*
[21] s. 744.2003(9), F.S.
[22] s. 744.309(3), F.S.
[23] *Id.*
[24] s. 744.361(1), F.S.

Examples of Powers That May Be Exercised By a Guardian	
With Court Approval[25]	**Without Court Approval[26]**
• Enter into contracts that are appropriate for, and in the best interest of, the ward. • Perform, compromise, or refuse performance of a ward's existing contracts. • Alter the ward's property ownership interests, including selling, mortgaging, or leasing any real property (including the homestead), personal property, or any interest therein. • Borrow money to be repaid from the property of the ward or the ward's estate. • Renegotiate, extend, renew, or modify the terms of any obligation owing to the ward. • Prosecute or defend claims or proceedings in any jurisdiction for the protection of the estate. • Exercise any option contained in any policy of insurance payable to the ward. • Make gifts of the ward's property to members of the ward's family in estate and income tax planning. • Pay reasonable funeral, interment, and grave marker expenses for the ward.	• Retain assets owned by the ward. • Receive assets from fiduciaries or other sources. • Insure the assets of the estate against damage, loss, and liability. • Pay taxes and assessments on the ward's property. • Pay reasonable living expenses for the ward, taking into consideration the ward's current finances. • Pay incidental expenses in the administration of the estate. • Prudently invest liquid assets belonging to the ward. • Sell or exercise stock subscription or conversion rights. • Consent to the reorganization, consolidation, merger, dissolution, or liquidation of a corporation or other business enterprise of the ward. • Employ, pay, or reimburse persons, including attorneys, auditors, investment advisers, care managers, or agents, even if they are associated with the guardian, to advise or assist the guardian in the performance of his or her duties.

There are also a number of duties imposed on a guardian after they appointment to a ward in order to provide appropriate services to that ward. The guardian must:

- File an initial report within 60 days after the letters of guardianship are signed;
- File an annual report with the court consisting of an annual accounting and/or an annual guardianship plan;
- Implement the guardianship plan;
- Consult with other guardians appointed, if any;
- Protect and preserve the property of the ward; invest it prudently, apply income first to the ward before the ward's dependents, and account for it faithfully;
- Observe the standards in dealing with the guardianship property that would be observed by a prudent person dealing with the property of another; and
- If authorized by the court, take possession of all of the ward's property and of the rents, income, issues, and profits from it, whether accruing before or after the guardian's appointment, and of the proceeds arising from the sale, lease, or mortgage of the property or of any part.

Procedure for Extraordinary Authority

Some decisions made by a guardian on behalf of a ward are complex, dealing directly with the ward's interpersonal relationships, medical procedures, and life or death scenarios. Guardians are required to consider the expressed desires of the ward when making decisions that affect the ward outside any decisions that require specific authority from the court.[27] Currently, guardians are required to obtain court authority through the procedure for extraordinary authority[28] before consenting to the following actions:[29]

- Having the ward committed;
- Consenting on behalf of the ward to any experimental biomedical or behavioral procedures;
- Initiating divorce proceedings for the ward;
- Consenting on behalf of the ward to termination of the ward's parental rights; and

[25] s. 744.441, F.S.
[26] s. 744.444, F.S.
[27] s. 744.361, F.S.
[28] s. 744.3725, F.S.
[29] s. 744.3215(4), F.S.

- Consenting on behalf of the ward to a sterilization or abortion procedure on the ward.

The procedure for extraordinary authority requires the court to appoint an independent attorney to act on behalf of the incapacitated person. The attorney must have an opportunity to meet with the incapacitated person and present evidence and cross-examine witnesses at any hearing on a petition for the authority to act. The court must receive an independent medical, psychological, and social evaluation of the incapacitated person or appoint its own experts to assist in the evaluation. The court is required to meet personally with the incapacitated person in order to obtain its own impression of their capacity and give them the opportunity to express their views and wishes relating to the issue before the court. The court must find by clear and convincing evidence that the incapacitated person lacks the capacity to make decisions, that their capacity is not likely to change in the near future, and that the authority requested by the guardian is in the best interest of the incapacitated person.

Under Florida law, court approval is not currently required in order for a guardian to execute a do not resuscitate order (DNRO) on behalf of a ward.

Conflict of Interest

Unless the court gives prior approval, or such relationship existed prior to the appointment of the guardian and is disclosed to the court in the petition for appointment of a guardian, a guardian may not:

- Have any interest, financial or otherwise, direct or indirect, in any business transaction or activity with the guardianship;
- Acquire an ownership, possessory, security, or other monetary interest adverse to the ward;
- Be designated as a beneficiary on any life insurance policy, pension, or benefit plan of the ward unless such designation was made by the ward prior to adjudication of incapacity; and
- Directly or indirectly purchase, rent, lease, or sell any property or services from or to any business entity that the guardian, or the guardian's spouse or family, is an officer, partner, director, shareholder, or proprietor, or has any financial interest.[30]

A guardian found to have such conflict of interest is subject to removal from the guardianship.[31]

Office of Public and Professional Guardians

In 1999, the Legislature created the "Public Guardianship Act" and established the Statewide Public Guardianship Office (SPGO) within the Department of Elder Affairs (DOEA).[32] By December 2013, the SPGO had expanded public guardianship services to cover all 67 counties.[33] In 2016, the Legislature renamed the Statewide Public Guardianship Office within the DOEA as the Office of Public and Professional Guardians (OPPG) and required OPPG to regulate professional guardians. The OPPG appoints local public guardian offices to provide guardianship services to people who have neither adequate income nor assets to afford a private guardian, nor any willing family or friend to serve.[34]

There are 17 public guardian offices that serve all 67 counties.[35] In fiscal year 2017-2018, the public guardian offices served 3,846 wards.[36] Currently, there are 515 professional guardians registered with

[30] s. 744.446, F.S.
[31] *Id.*
[32] s. 744.701, F.S. (1999).
[33] Florida Department of Elder Affairs, Summary of Programs and Services, February 2014, *available at* http://elderaffairs.state.fl.us/doea/pubs/pubs/sops2014/2014%20SOPS_complete.pdf (last visited Dec. Jan. 24, 2020).
[34] Department of Elder Affairs, *Office of Public and Professional Guardians*, available at http://elderaffairs.state.fl.us/doea/spgo.php (last visited Jan. 24, 2020).
[35] Office of Public and Professional Guardians, *2018 Annual Report,* available at http://elderaffairs.state.fl.us/doea/SPGO/pubs/OPPG_AR_2018.pdf (last visited Jan. 24, 2020).
[36] *Id.*

the Office of Public and Professional Guardians within the Department of Elder Affairs.[37] The total number of wards served by registered professional guardians in this state is unknown by DOEA.[38]

The executive director of the OPPG is responsible for the oversight of all public and professional guardians.[39]

The executive director's oversight responsibilities for professional guardians include but are not limited to:

- Establishing standards of practice for public and professional guardians;
- Reviewing and approving the standards and criteria for the education, registration, and certification of public and professional guardians;
- Developing a guardianship training program curriculum that may be offered to all guardians;
- Developing and implementing a monitoring tool to use for periodic monitoring activities of professional guardians; however, this monitoring tool may not include a financial audit as required to be performed by the clerk of the circuit court under s. 744.368, F.S.;
- Developing procedures for the review of an allegation that a professional guardian has violated an applicable statute, fiduciary duty, standard of practice, rule, regulation, or other requirement governing the conduct of professional guardians; and
- Establishing disciplinary proceedings, conducting hearings, and taking administrative action under ch. 120, F.S.

Guardian Compensation

The guardian, or an attorney who has rendered services to the ward or to the guardian on the ward's behalf,[40] is entitled to a reasonable fee for services rendered and reimbursement for costs incurred on behalf of the assets of the guardianship estate unless the court finds the requested compensation to be substantially unreasonable.[41] Before the fees may be paid, a petition for fees or expenses must be filed with the court and accompanied by an itemized description of the services performed for the fees and expenses sought to be recovered.[42] When fees for a guardian or an attorney are submitted to the court for determination, the court shall consider:

- The time and labor required;
- The novelty and difficulty of the questions involved and the skill required to perform the services properly;
- The likelihood that the acceptance of the particular employment will preclude other employment of the person;
- The fee customarily charged in the locality for similar services;
- The nature and value of the incapacitated person's property, the amount of income earned by the estate, and the responsibilities and potential liabilities assumed by the person;
- The results obtained;
- The time limits imposed by the circumstances;
- The nature and length of the relationship with the incapacitated person; and
- The experience, reputation, diligence, and ability of the person performing the service.[43]

Alternatives to Guardianship and Types of Guardianship

Before a plenary guardian is appointed, the least restrictive form of guardianship should be made available to assist people who are only partially incapable of caring for their needs and alternatives to

[37] Email from Derek Miller, Legislative Analyst, Department of Elder Affairs, RE: HB 709 Analysis, (Jan. 24, 2020).
[38] *Id.*
[39] s. 744.2001(2)(a), F.S.
[40] Fees for legal services may include customary and reasonable charges for work performed by legal assistants employed by and working under the direction of the attorney. S. 744.108(4), F.S.
[41] s. 744.108(1), (8), F.S.
[42] s. 744.108(5), (7), F.S.
[43] s. 744.108(2), F.S.

guardianship and less restrictive means of assistance, including, but not limited to guardian advocates, should also be explored.[44]

In October 2016, Chief Justice Jorge Labarga established a Guardianship Workgroup in order to better protect vulnerable people who are subject to guardianship and guardian advocacy.[45] The workgroup was charged with examining "judicial procedures and best practices pertaining to guardianship," focusing on topics including, but not limited to, the use of least restrictive alternatives that address specific functional limitations.

The workgroup recommended requiring the petitioner, in the petition for appointment of a guardian, to explain why alternatives to guardianship are insufficient and expand the types of alternatives that must be addressed. The report specified alternatives to guardianship include supported decision making, durable powers of attorney, trusts, banking services, advance directives, medical proxies, and representative payees.[46]

Additionally, the workgroup recommended the petitioner specify whether he or she is aware of the existence of a designation of preneed guardian and to identify his or her efforts in determining whether a designation exists in the petition for appointment of a guardian. Florida law recognizes several types of guardianships, including preneed guardians, and:

- Natural guardians;
- Guardians of minors;
- Emergency temporary guardianship;
- Standby guardianship;
- Preneed guardian for a minor; and
- Foreign guardians.[47]

Do-Not-Resuscitate Orders

Florida law defines an advance directive as any witnessed, oral statements or written instructions that express a person's desires about any aspect of his or her future health care, including the designation of a health care surrogate, a living will, or an anatomical gift.[48] Designation of a health care surrogate, a living will, or an anatomical gift each serve different purposes and have their own unique requirements and specifications under the law.

One type of advance directive, a "do not resuscitate order" (DNRO) results in the withholding of cardiopulmonary resuscitation (CPR) and any other resuscitative treatment from an individual if a DNRO is presented to the health care professional treating the patient. For the DNRO to be valid, it must be on the form adopted by the Department of Health, signed by the patient's physician and by the patient, or if the patient is incapacitated, the patient's health care surrogate or proxy, court-appointed guardian, or attorney in fact under a durable power of attorney.[49] Florida's DNRO form is printed on yellow paper.[50] It is the responsibility of the Emergency Medical Services provider to ensure that the DNRO form or the patient identification device, which is a miniature version of the form, accompanies the patient.[51] A DNRO may be revoked by the patient at any time, if signed by the patient, or the patient's health care surrogate, proxy, court-appointed guardian or a person acting under a durable power of attorney.[52]

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[44] s. 744.1012(1), F.S.
[45] Judicial Management Council, *Guardianship Workgroup Final Report* (June 2018) (on file with Health and Human Services Committee staff).
[46] *Id.*
[47] ch. 744, part III, F.S.
[48] s. 765.101, F.S.
[49] s. 401.45(3), F.S.
[50] Rule 64J-2.018, F.A.C.
[51] *Id.*
[52] *Id.*

Currently, Florida law does not require a guardian to obtain any approval from the court in order to execute a (DNR) on behalf of a ward. Execution of a DNRO only requires the signatures of the guardian and a physician.

Guardian Investigations

In July 2019, Steven Stryker, a ward appointed to professional guardian Rebecca Fierle,[53] died in a Tampa hospital after choking on food.[54] Hospital staff could not perform lifesaving procedures on him due to a DNRO executed by Fierle.[55]

It was also reported that Fierle had billed AdventHealth, an Orlando area hospital, approximately $4 million for services rendered to wards[56] and developed conflicts of interest with members of appointed examining committees used to determine incapacity of a person.[57]

The Clerk of the Circuit Court and Comptroller of Okaloosa County (Clerk)[58] investigated complaints filed against Fierle with the OPPG. The Clerk found Fierle had executed a DNRO against Stryker's wishes, violating the standards of practice established by the OPPG.[59] The Clerk reported that Fierle kept a DNRO in place after a psychiatrist examined Stryker while he was admitted to St. Joseph's Hospital and determined Stryker had the ability to decide that he wanted to live and stated that Stryker wanted to be resuscitated.

The Orange County Comptroller also investigated Fierle's guardianships.[60] The Comptroller found Fierle had submitted over 6,000 invoices and charges of at least $3.9M to AdventHealth for payments between January 2009 and June 2019.[61] The payments were made on behalf of 682 patients. The Comptroller also found that in some cases Fierle had billed both AdventHealth and the wards for identical fees and services. Additionally, the Comptroller identified conflicts of interest, including several situations in which Fierle had previous relationships with wards to whom she was appointed guardian and did not disclose these relationships in the petitions for appointment of a guardian.

An Orange County judge removed Fierle from nearly 100 cases to which she had been appointed.[62] Fierle has appealed the judge's decision.[63] In a letter to the OPPG, Fierle resigned from all appointed guardianship cases (approximately 450 in 13 counties) in July, 2019.[64] As of November 2019, Fierle is under criminal investigation by the Florida Department of Law Enforcement.[65]

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[53] The Orlando Sentinel, *Florida's Troubled Guardian Program,* https://www.orlandosentinel.com/news/florida/guardians/ (last visited Dec. 6, 2019).
[54] Adrianna Iwasinski, *Orange commissioners approve new position to help monitor guardianship cases,* Click Orlando (Oct. 22, 2019), https://www.clickorlando.com/news/2019/10/23/orange-commissioners-approve-new-position-to-help-monitor-guardianship-cases/ (last visited Dec. 9, 2019).
[55] *Id.*
[56] *Supra* note 53.
[57] Monivette Cordeiro, *Florida's troubled guardianship system riddled with conflicts of interest, critics claim | Special Report,* Orlando Sentinel (Aug. 14, 2019), https://www.orlandosentinel.com/news/florida/guardians/os-ne-guardianship-examining-committee-conflicts-20190814-osbekpwlnfezneolyxttvzmrhy-story.html (last visited Dec. 9, 2019).
[58] J.D. Peacock II, Clerk of the Circuit Court and Comptroller Okaloosa County, Florida, *OPPG Investigation Case Number 19-064* (July 9, 2019), https://www.scribd.com/document/417992870/Fierle-State-Report (last visited Dec. 6, 2019).
[59] *Id.*
[60] Orange County Comptroller, *Report No. 479 – Investigation of Payments Made to Professional Guardian – Rebecca Fierle by AdventHealth,* https://occompt.com/wpfb-file/rpt479-pdf/ (last visited Dec. 6, 2019).
[61] *Id*.
[62] *Supra* note 53.
[63] *Id.*
[64] Greg Angel, *Embattled Guardian Resigns From Cases Statewide; Criminal Investigation Continues,* Spectrum News 13 (July 29, 2019), https://www.mynews13.com/fl/orlando/crime/2019/07/29/embattled-guardian-resigns-from-cases-statewide (last visited Jan. 24, 2020).
[65] Greg Angel, *Watchdog: Judge Dismisses Embattled Guardian's Appeal to Reverse Court Order,* Spectrum News 13 (Nov. 19, 2019) https://www.mynews13.com/fl/orlando/news/2019/11/19/watchdog-fierle-appeal-to-reverse-court-order-dismissed (last visited Jan. 24, 2020).

Effect of Proposed Changes

HB 709 proposes changes to chapter 744, F.S., relating to the appointment of a guardian, orders not to resuscitate, information required to be disclosed in petitions for appointment of a guardian, mandated guardianship reports, and conflicts of interest.

Appointment of a Guardian or Professional Guardian

The bill requires petitions for appointment of a guardian or professional guardian to include the following information:

- Any other type of guardianship under part III of ch. 744, F.S., or alternatives to guardianship the alleged incapacitated person has designated, is currently in or has been in previously;
- The reasons why a guardian advocate or other alternatives to guardianship are insufficient; and
- Whether the guardian is a professional guardian.

The bill defines "alternatives to guardianship," as it relates to disclosure in the petition for guardianship, as "an advance directive as defined in s. 765.101, a durable power of attorney as provided in chapter 709, a representative payee under 42 U.S.C. s. 1007, or a trust instrument as defined in s. 736.0103."

The bill requires the court to inquire into and consider potential disqualifications under s. 744.309, F.S., and potential conflicts of interest under s. 744.446, F.S., when appointing a guardian to a ward. The bill also prohibits professional guardians from petitioning for their own appointment to wards, unless they are relatives of those prospective wards.

Conflict of Interest

The bill prohibits a guardian from offering, paying, soliciting, or receiving certain benefits or engaging in split-fee arrangements in return for referring, soliciting, or engaging in a transaction for goods or services on behalf of an alleged incapacitated person, minor, or ward for past of future goods or services.

Additionally, unless prior approval is obtained by the court or such a relationship existed before appointment of the guardian and is disclosed in the petition, the bill prohibits a guardian from having any specified interest with:

- The ward;
- The judge presiding over the case;
- Any member of the appointed examining committee;
- Any court employee involved in the guardianship process; or
- The attorney for the ward.

Powers and Duties of the Guardian

The bill requires the initial guardianship plan and the annual guardianship plan to include:

- Any preexisting do-not-resuscitate orders;
- Any preexisting advance directives;
- The date an order or directive was signed;
- Whether the order or directive has been suspended by the court; and
- A description of the steps taken to identify and locate such information.

Additionally, a declaration of all remuneration received by the guardian from any source for services rendered to or on behalf of the ward must be included in the annual guardianship report. Remuneration is defined as "any payment or other benefit made directly or indirectly, overtly or covertly, or in cash or in kind to the guardian."

Do-Not-Resuscitate Orders

The bill requires a guardian to obtain specific court approval through the procedure for extraordinary authority before consenting to or signing an order not to resuscitate on behalf of a ward.

B. SECTION DIRECTORY:

Section 1: Amends s. 744.312, F.S., relating to considerations in appointment of guardian.
Section 2: Amends s. 744.3215, F.S., relating to rights of persons determined incapacitated.
Section 3: Amends s. 744.334, F.S., relating to petition for appointment of a guardian or professional guardian; contents.
Section 4: Amends s. 744.363, F.S., relating to initial guardianship plan.
Section 5: Amends s. 744.367, F.S., relating to duty to file annual guardianship report.
Section 6: Amends s. 744.3675, F.S., relating to annual guardianship plan.
Section 7: Amends s. 744.446, F.S., relating to conflicts of interest; prohibited activities; court approval; breach of fiduciary duty.
Section 8: Provides an effective date of July 1, 2020.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The bill would have an indeterminate impact on state courts workload. The State Courts Administrator estimates it is likely that there will be an increase in judicial workload due to inquiries the court would be required to make under the bill. The impact is indeterminate due to the unavailability of data needed to quantifiably establish the increase in judicial time and workload as a result of the proposed changes in the bill.[66]

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   The bill would have an indeterminate impact on the county Clerks. The Florida Court Clerks and Comptrollers Association (Clerks) estimates it is likely that there will be an increase in the number of items the Clerk's staff will have to review and will need to modify their internal procedures to accommodate the proposed changed in the bill, but the impact is indeterminate. The Clerks also estimate there will be an increase in auditing if additional complaints are received relating to "do not resuscitate orders," assuming the number of court hearings do not increase. If the number of court hearings increase, the Clerks will have an impact due to court docketing and related duties. The impact is indeterminate due to the unavailability of data needed to establish an increase in workload relating to guardianship cases.[67]

[66] Office of the State Courts Administrator, *2020 Judicial Impact Statement – HB 709*, December 5, 2019.
[67] Florida Court Clerks & Comptrollers Association, *FCCC Bill Analysis – HB 709*, December 10, 2019.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to guardianship; amending s. 744.312, F.S.; providing factors for a court to consider when appointing a guardian; amending s. 744.3215, F.S.; providing that a guardian may only consent to or authorize a do-not-resuscitate order with court approval; amending s. 744.334, F.S.; providing requirements for a petition for the appointment of a guardian; defining the term "alternatives to guardianship"; amending s. 744.363, F.S.; providing requirements of the initial guardianship plan; amending s. 744.367, F.S.; providing requirements for the annual guardianship report; defining the term "remuneration"; amending s. 744.3675, F.S.; providing requirements of the annual guardianship plan; amending s. 744.446, F.S.; revising provisions relating to conflicts of interest; providing an effective date.

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

Section 1. Paragraph (e) is added to subsection (3) of section 744.312, Florida Statutes, to read:

744.312 Considerations in appointment of guardian.—

(3) The court shall also:

(e) Inquire into and consider potential disqualifications

under s. 744.309 and potential conflicts of interest under s. 744.446.

Section 2. Paragraph (f) is added to subsection (4) of section 744.3215, Florida Statutes, to read:

744.3215 Rights of persons determined incapacitated.—

(4) Without first obtaining specific authority from the court, as described in s. 744.3725, a guardian may not:

(f) Consent to or sign on behalf of the ward an order not to resuscitate executed under s. 401.45(3).

Section 3. Section 744.334, Florida Statutes, is amended to read:

744.334 Petition for appointment of guardian or professional guardian; contents.—

(1) Every petition for the appointment of a guardian shall be verified by the petitioner and shall contain statements, to the best of petitioner's knowledge and belief, showing the name, age, residence, and post office address of the alleged incapacitated person or minor; the nature of her or his incapacity, if any; the extent of guardianship desired, either plenary or limited; the residence and post office address of the petitioner; the names and addresses of the next of kin of the alleged incapacitated person or minor, if known to the petitioner; the name of the proposed guardian and the reasons why she or he should be appointed guardian; whether the proposed guardian is a professional guardian; the relationship and

previous relationship of the proposed guardian to the alleged incapacitated person or minor ~~ward~~; any other type of guardianship under part III of this chapter or alternatives to guardianship that the alleged incapacitated person or minor has designated or is in currently or has been in previously; the reasons why a guardian advocate under s. 744.3085 or other alternatives to guardianship are insufficient to meet the needs of the alleged incapacitated person or minor; and the nature and value of property subject to the guardianship~~; and the reasons why this person should be appointed guardian~~. The petition must state whether ~~If~~ a willing and qualified guardian cannot be located~~, the petition must so state~~. As used in this subsection, the term "alternatives to guardianship" means an advance directive as defined in s. 765.101, a durable power of attorney as provided in chapter 709, a representative payee under 42 U.S.C. s. 1007, or a trust instrument as defined in s. 736.0103.

(2) If the petitioner is a professional guardian, she or he may not petition for her or his own appointment unless the petitioner is a relative of the alleged incapacitated person or minor. For purposes of this subsection, the term "relative" means an individual who would qualify to serve as a nonresident guardian under s. 744.309(2) ~~The petition for appointment of a professional guardian must comply with the provisions of subsection (1), and must state that the petitioner is a professional guardian~~.

Section 4. Subsection (1) of section 744.363, Florida Statutes, is amended to read:

744.363 Initial guardianship plan.—

(1) The initial guardianship plan shall include all of the following:

(a) The provision of medical, mental, or personal care services for the welfare of the ward.~~;~~

(b) The provision of social and personal services for the welfare of the ward.~~;~~

(c) The place and kind of residential setting best suited for the needs of the ward.~~;~~

(d) The application of health and accident insurance and any other private or governmental benefits to which the ward may be entitled to meet any part of the costs of medical, mental health, or related services provided to the ward.~~; and~~

(e) Any physical and mental examinations necessary to determine the ward's medical and mental health treatment needs.

(f) A list of any preexisting do-not-resuscitate orders executed under s. 401.45(3) or preexisting advance directives, as defined in s. 765.101, the date an order or directive was signed, whether such order or directive has been suspended by the court, and a description of the steps taken to identify and locate the preexisting do-not-resuscitate order or advance directive.

Section 5. Subsection (3) of section 744.367, Florida

Statutes, is amended to read:

744.367 Duty to file annual guardianship report.—

(3)(a) The annual guardianship report of a guardian of the property must consist of an annual accounting, and the annual guardianship report of a guardian of the person must consist of an annual guardianship plan. The annual guardianship report of a guardian of the property and the annual guardianship report of a guardian of the person must both include a declaration of all remuneration received by the guardian from any source for services rendered to or on behalf of the ward. As used in this paragraph, the term "remuneration" means any payment or other benefit made directly or indirectly, overtly or covertly, or in cash or in kind to the guardian.

(b) The annual guardianship report must ~~shall~~ be served on the ward, unless the ward is a minor or is totally incapacitated, and on the attorney for the ward, if any. The guardian shall provide a copy to any other person as the court may direct.

Section 6. Paragraph (d) is added to subsection (1) of section 744.3675, Florida Statutes, to read:

744.3675 Annual guardianship plan.—Each guardian of the person must file with the court an annual guardianship plan which updates information about the condition of the ward. The annual plan must specify the current needs of the ward and how those needs are proposed to be met in the coming year.

(1) Each plan for an adult ward must, if applicable, include:

(d) A list of any preexisting do-not-resuscitate orders executed under s. 401.45(3) or preexisting advance directives, as defined in s. 765.101, the date an order or directive was signed, whether such order or directive has been suspended by the court, and a description of the steps taken to identify and locate the preexisting do-not-resuscitate order or advance directive.

Section 7. Subsections (2), (3), and (4) of section 744.446, Florida Statutes, are renumbered as subsections (3), (4), and (5), respectively, present subsection (2) is amended, and a new subsection (2) is added to that section, to read:

744.446 Conflicts of interest; prohibited activities; court approval; breach of fiduciary duty.—

(2) A guardian may not offer, pay, solicit, or receive a commission, benefit, bonus, rebate, or kickback, directly or indirectly, overtly or covertly, in cash or in kind, or engage in a split-fee arrangement in return for referring, soliciting, or engaging in a transaction for goods or services on behalf of an alleged incapacitated person or minor, or a ward, for past or future goods or services.

(3) ~~(2)~~ Unless prior approval is obtained by court order, or unless such relationship existed before ~~prior to~~ appointment of the guardian and is disclosed to the court in the petition

for appointment of guardian, a guardian may not:

(a) Have any interest, financial or otherwise, direct or indirect, in any business transaction or activity with the ward, the judge presiding over the case, any member of the appointed examining committee, any court employee involved in the guardianship process, or the attorney for the ward;

(b) Acquire an ownership, possessory, security, or other pecuniary interest adverse to the ward;

(c) Be designated as a beneficiary on any life insurance policy, pension, or benefit plan of the ward unless such designation was validly made by the ward before ~~prior to~~ adjudication of incapacity of the ward; and

(d) Directly or indirectly purchase, rent, lease, or sell any property or services from or to any business entity of which the guardian or the guardian's spouse or any of the guardian's lineal descendants, or collateral kindred, is an officer, partner, director, shareholder, or proprietor, or has any financial interest.

Section 8. This act shall take effect July 1, 2020.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 773 Medically Essential Electric Utility Service
SPONSOR(S): Maggard
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Energy & Utilities Subcommittee	14 Y, 0 N	Keating	Keating
2) Health & Human Services Committee		Grabowski	Calamas
3) Commerce Committee			

SUMMARY ANALYSIS

Florida law, through s. 366.15, F.S., establishes procedures that each investor-owned electric utility (IOU) must follow when providing service to residential customers who depend on electric powered equipment for physician-certified medical reasons. This service is referred to as "medically essential" electric service.

The bill expands s. 366.15, F.S., to require that municipal electric utilities and rural electric cooperatives offer medically essential electric service programs on terms similar to IOUs. The bill also requires that all electric utilities provide additional consumer education about medically essential electric service programs. In particular, the bill:

- Requires each electric utility to post on its website a written explanation of the certification process, including a standard certification form.
- Requires each electric utility to provide a written explanation of the certification process to each residential customer at the time the customer opens an account and semiannually thereafter.
- Requires licensed physicians, physician assistants, and advanced registered nurse practitioners to inform eligible patients of the right to participate in medically essential electric service programs and to provide such patients a copy of s. 366.15, F.S., and, if requested, a completed medical certification.

The bill also modifies the certification and notice requirements associated with medically essential electric service programs. In particular, the bill:

- Expands the types of health care practitioners that may provide medical certification to also include licensed physician assistants and advanced registered nurse practitioners.
- Requires each medical certification to specify the time period for which service is expected to remain medically essential, up to 60 months.
- Requires the electric utility to provide recertification materials to certified customers at least 60 days prior to expiration of the customer's certification, and allows the utility to send recertification materials to the customer by e-mail if the customer has provided an email address.
- Requires an electric utility to provide additional notice to a certified customer before any disconnection of service for nonpayment, including notice by electronic means.

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

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Florida law, through s. 366.15, F.S., establishes procedures that each investor-owned electric utility[1] (IOU) must follow when providing service to residential customers who depend on electric powered equipment for physician-certified medical reasons. This service is referred to as "medically essential"[2] electric service.

Under the law, each IOU must:

- Designate employees who are authorized to direct the continuation or restoration of medically essential electric service.
- Provide annually to all customers a written explanation of the certification process for medically essential electric service, which includes:
  - Submittal of completed forms supplied by the utility, including a certification form completed by a physician licensed under ch. 458 or ch. 459, F.S., which states in medical and nonmedical terms why the electric service is medically essential; and
  - Recertification by a physician every 12 months.
- Provide recertification materials to a certified customer by mail at least 30 days prior to expiration of the customer's certification, and allow the customer to submit completed recertification forms within 30 days after the expiration of certification.
- Provide notice to a certified customer before any disconnection of service for nonpayment:
  - By telephone at least 24 hours before the scheduled disconnection;
  - In person at the customer's residence no later than 4 p.m. of the day before the scheduled disconnection, if the customer cannot be reached in a timely manner by telephone; and
  - By leaving written notification at the residence, if the customer cannot be reached by telephone or in person.
- Provide notice of any scheduled service interruptions to certified customers.

If a certified customer notifies its IOU of a need for financial assistance, the law requires the IOU to provide the customer with information on sources of state or local agency funding that may provide financial assistance to such customers. In addition, if an IOU operates a program to receive voluntary contributions from its customers to provide financial assistance to persons unable to pay for service, the IOU must train its customer service representatives to assist certified customers in identifying the program and any agencies to which the IOU has distributed the contributed funds.

The law provides that each certified customer maintains the responsibility to make satisfactory arrangements with the IOU to ensure payment for service consistent with the requirements of the IOU's tariff. Further, the law provides that each certified customer is solely responsible for any backup equipment or power supply and a planned course of action in the event of a power outage or interruption of service. The law specifies that an IOU may disconnect service to a residence whenever an emergency may threaten the health or safety of a person, the surrounding area, or the public utility's distribution system, provided that the IOU must promptly restore service as soon as feasible. The law states that it does not form the basis for any cause of action against an IOU.

[1] Florida's investor-owned electric utilities are Florida Power & Light Company, Duke Energy Florida, Tampa Electric Company, Gulf Power Company, and Florida Public Utilities Company. These utilities are referred to in statute as "public utilities" for purposes of regulation by the Public Service Commission. S. 366.02, F.S.

[2] The term "medically essential" is defined as "the medical dependence on electric-powered equipment that must be operated continuously or as circumstances require as specified by a physician to avoid the loss of life or immediate hospitalization of the customer or another permanent resident at the residential service address." S. 366.15(1), F.S.

The law does not apply to municipal electric utilities or rural electric cooperatives, but the majority of those utilities maintain programs for medically essential electric service, many under terms similar to the terms specified in law for IOUs.[3] The rates and service of municipal electric utilities and rural electric cooperatives are not regulated by the Public Service Commission (PSC).

Chapter 456, F.S., addresses the regulation of specified health care professions by the Department of Health. It does not address certification of patients for medically essential electric service.

Effect of Proposed Changes

In summary, the bill requires additional consumer education about medically essential electric service programs and establishes additional protections for utility customers that are certified under such programs. In addition, the bill expands the law to include municipal electric utilities and rural electric cooperatives.

The bill amends s. 366.15, F.S., to replace most references to "public utility" – the term used in ch. 366, F.S., to describe investor-owned electric utilities – with the term "electric utility." The term "electric utility" is used in ch. 366, F.S., to refer to all types of electric utilities, including investor-owned electric utilities, municipal electric utilities, and rural electric cooperatives. Thus, the bill expands the statutory requirements for medically essential electric service to all retail electric utilities in the state,[4] though it clarifies that the provision of medically essential electric service by municipal electric utilities and rural electric cooperatives will not be regulated or overseen by the PSC.

The bill requires additional consumer education about medically essential electric service. In particular, the bill:

- Requires that each electric utility post on its website a written explanation of the certification process, including a standard certification form adopted by the utility.
- Requires that each electric utility provide a written explanation of the certification process to each residential customer at the time the customer opens an account with the utility and semiannually thereafter, either through a bill insert or by electronic means.
- Creates s. 456.45, F.S., to require certain health care practitioners – licensed physicians, physician assistants, and advanced registered nurse practitioners – to inform a patient of the right to participate in medically essential electric service programs and to provide the patient with a written copy of s. 366.15, F.S., if the patient may be at risk of loss of life or immediate hospitalization due to the loss of electric service at the patient's residence. At the request of such a patient, the practitioner must provide the patient a completed medical certification using the form adopted by the utility and document the certification in the patient's record.

The bill also modifies the statutory requirements for medically essential electric service. With respect to the certification process, the bill:

- Expands the types of health care practitioners that may provide medical certification to also include licensed physician assistants and advanced registered nurse practitioners.
- Requires each utility to adopt a standard certification form and specifies the information to be included in the form, including: the customer's name, account number, service address, and contact information; the name of the permanent resident at the service address who is medically dependent on electric-powered equipment; and the name of that person's certifying health practitioner. The bill requires that the standard certification form include a separate

[3] As of December 31, 2018, IOUs served 75.5% of residential customers in the state (7,183,302), while municipal electric utilities served 13.5% (1,288,251) and rural electric cooperatives served 11% (1,043,694). *See* Florida Public Service Commission, *Statistics of the Florida Electric Utility Industry*, October 2019, at 45, *available at* http://www.psc.state.fl.us/Files/PDF/Publications/Reports/Electricgas/Statistics/2018.pdf (last visited Jan. 11, 2020).

[4] The bill does not extend certain accounting and training requirements in s. 366.15(10)(b)2., F.S., to municipal electric utilities and rural electric cooperatives.

section to be completed by the certifying health care practitioner, which must include: the name, business address, and medical license number of the certifying health care practitioner; a statement in medical and nonmedical terms that specifies why electric service is medically essential; and the time period for which the service is expected to remain medically essential.
- Allows extension of the medical certification up to 60 months.
- Requires recertification upon expiration of the current certification period but no sooner than 12 months after issuance of the current certification.
- Allows the electric utility to send recertification materials to the customer by e-mail if the customer has provided an email address to the utility.
- Requires the electric utility to provide recertification materials to certified customers at least 60 days prior to expiration of the customer's certification.
- Allows the electric utility, no more often than once every 12 months, to request verification from the customer that the person for whom service is certified continues to reside at the service address.

With respect to disconnection of service for nonpayment, the bill:
- Requires that each electric utility provide certified customers no less time than other residential customers to make payment or payment arrangements (in any event, no less than 20 days from the date a bill is mailed or delivered by the electric utility) prior to the utility scheduling disconnection of service.
- Requires the electric utility to provide, in addition to any notice provided in its normal course of business, notice to certified customers:
    - By telephone and in writing – including by electronic means if the customer has provided contact information to receive electronic communications – no later than 15 days before, and again no later than 7 days before, the scheduled disconnection;
    - In person at the customer's residence no later than 2 business days before the scheduled disconnection, if the customer cannot be reached in a timely manner by telephone; and
    - In writing by electronic means, in addition to leaving written notification at the residence, if in-person contact is not made.

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

B. SECTION DIRECTORY:

Section 1. Amends s. 366.11, F.S., related to certain exemptions from regulation under ch. 366, F.S.

Section 2. Amends s. 366.15, F.S., related to medically essential electric public utility service.

Section 3. Creates s. 456.45, F.S., related to certification of medically essential electric utility service.

Section 4. Provides an effective date of July 1, 2020.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Electric utilities that currently provide medically essential electric service programs may incur costs to modify those programs to comply with the bill. The small minority of electric utilities that do not currently provide such programs will incur costs to establish those programs in compliance with the bill.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. The bill does not appear to: require counties or municipalities to spend funds or take an action requiring the expenditure of funds; reduce the authority that counties or municipalities have to raise revenues in the aggregate; or reduce the percentage of a state tax shared with counties or municipalities.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

None.

A bill to be entitled

An act relating to medically essential electric utility service; amending s. 366.11, F.S.; specifying that the fact that certain electric utilities must provide medically essential electric service does not require them to otherwise be regulated by the Public Service Commission; amending s. 366.15, F.S.; revising and defining terms; providing notification requirements for electric utilities relating to the certification process for obtaining medically essential electric service and service disconnection; providing certification requirements for customers; specifying duties of electric utilities; revising penalties for falsification of such certification; providing construction; creating s. 456.45, F.S.; requiring certain health care practitioners to inform certain patients of such certification process; requiring such practitioners to provide patients with completed medical certifications and document the certification; providing an effective date.

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

Section 1. Subsection (1) of section 366.11, Florida Statutes, is amended to read:

366.11 Certain exemptions.—

(1) No provision of this chapter shall apply in any manner, other than as specified in ss. 366.04, 366.05(7) and (8), 366.051, 366.055, 366.093, 366.095, 366.14, 366.15, 366.80-366.83, and 366.91, to utilities owned and operated by municipalities, whether within or without any municipality, or by cooperatives organized and existing under the Rural Electric Cooperative Law of the state, or to the sale of electricity, manufactured gas, or natural gas at wholesale by any public utility to, and the purchase by, any municipality or cooperative under and pursuant to any contracts now in effect or which may be entered into in the future, when such municipality or cooperative is engaged in the sale and distribution of electricity or manufactured or natural gas, or to the rates provided for in such contracts.

Section 2. Section 366.15, Florida Statutes, is amended to read:

366.15 Medically essential electric ~~public~~ utility service.—

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

(a) "Health care practitioner" means a physician or physician assistant licensed under chapter 458 or chapter 459 or an advanced registered nurse practitioner licensed under chapter 464.

(b) "Medically essential" means the medical dependence on

electric-powered equipment that must be operated continuously or as circumstances require as specified by a health care practitioner ~~physician~~ to avoid the loss of life or immediate hospitalization of the customer or another permanent resident at the residential service address.

(2) Each electric ~~public~~ utility shall designate employees who are authorized to direct an ordered continuation or restoration of medically essential electric service. An electric ~~A public~~ utility shall not impose upon any customer any additional deposit to continue or restore medically essential electric service.

(3)(a) Each electric ~~public~~ utility shall post on its website a written explanation of the certification process for obtaining medically essential electric service. The website must include the standard certification form adopted by the utility pursuant to paragraph (b). Each electric utility shall ~~annually~~ provide a written explanation of the certification process ~~for medically essential electric service~~ to each residential utility customer:

1. When the customer opens an account for electric service with the electric utility; and

2. At least semiannually either by a written bill insert or, if the customer has provided contact information to receive electronic communications from the utility, by electronic means.

(b)1. Each electric utility must adopt a standard

certification form to be completed and signed by each residential customer who wishes to have his or her service certified as medically essential. The certification form must include the customer's service address, the customer's name and the account number for the service address, the name of the permanent resident at the service address who is medically dependent on electric-powered equipment and the name of that person's certifying health care practitioner, and the customer's contact information for purposes of receiving communications from the utility by telephone and by electronic means if the customer has provided authorization to receive electronic communications.

2. The certification form must include a separate page to be completed and signed by a health care practitioner certifying that electric service is medically essential for the customer or other permanent resident at the service address. This page of the certification form must include the name, business address, and medical license number of the certifying health care practitioner; a statement by the certifying health care practitioner, in medical and nonmedical terms, that specifies the reasons why the electric service is medically essential, as defined in subsection (1); and a specification of the time period for which the electric service is expected to remain medically essential.

(c) Certification that ~~of~~ a customer's electricity needs are ~~as~~ medically essential requires the customer ~~to complete forms supplied by the public utility and~~ to submit to the utility a completed standard certification form which includes the health care practitioner's certification ~~a form completed by a physician licensed in this state pursuant to chapter 458 or chapter 459 which states in medical and nonmedical terms why the electric service is medically essential~~. The certification may not extend beyond 60 months. Falsification of the ~~False~~ certification ~~of medically essential service by a physician~~ is a violation of s. 458.331(1)(h), ~~or~~ s. 459.015(1)(i), or s. 464.018(1)(f).

(d) ~~(b)~~ Medically essential service must ~~shall~~ be recertified at the expiration of the time period specified in the certification or ~~once every~~ 12 months after certification, whichever is later. The electric ~~public~~ utility shall send the ~~certified~~ customer by regular mail, or by e-mail if the customer has provided the utility with his or her e-mail address, a package of recertification materials, including recertification forms, at least 60 ~~30~~ days before ~~prior to~~ the expiration of the customer's certification. The materials shall advise the ~~certified~~ customer that he or she must complete and submit the recertification forms within 30 days after the expiration of the customer's existing certification. If the recertification form is ~~forms are~~ not received within this 30-day period, the

electric ~~public~~ utility may terminate the customer's certification. No more than once every 12 months during the term of the certification, the electric utility may request verification from the customer that the person for whom electric service is certified continues to reside at the service address.

(4) Each electric ~~public~~ utility must ~~shall~~ certify a customer's electric service as medically essential if the customer completes the requirements of subsection (3).

(5) Notwithstanding any other provision of this section, an electric ~~a public~~ utility may disconnect service to a residence whenever an emergency may threaten the health or safety of a person, the surrounding area, or the electric ~~public~~ utility's distribution system. The electric ~~public~~ utility shall act promptly to restore service as soon as feasible.

(6) A customer whose electric service is certified as medically essential under this section is entitled, at a minimum, to the same time period for payment of bills that applies to all other residential customers served by the electric utility. However, the time period may not be fewer than 20 days after the date the bill is mailed or delivered by the utility. If payment or a satisfactory payment arrangement has not been made within the specified time period, the electric utility may schedule disconnection of service for nonpayment of the bill. In addition to any other notice provided in the utility's normal course of business, before the electric utility

disconnects service it must provide the following notice to each customer whose electric service is certified as medically essential under this section:

(a) No later than 15 days, and again no later than 7 days, before a scheduled disconnection ~~24 hours before any scheduled disconnection of service for nonpayment of bills to a customer who requires medically essential service~~, the electric ~~a public~~ utility shall attempt to contact the customer by telephone ~~in order~~ to provide notice of the scheduled disconnection and shall provide the notice in writing, including by electronic means if the customer has provided contact information to receive electronic communications from the electric utility.

(b) If ~~the customer does not have a telephone number listed on the account or if~~ the electric ~~public~~ utility cannot reach the customer or other adult resident of the premises by telephone by the specified time, the electric ~~public~~ utility shall send a representative to the customer's residence to attempt to contact the customer~~,~~ no later than 2 business days ~~4 p.m. of the day~~ before the scheduled disconnection. If contact is not made, however, the electric ~~public~~ utility must ~~may~~ leave written notification at the residence advising the customer of the scheduled disconnection and shall provide the notice by electronic means if the customer has provided contact information to receive electronic communications from the electric utility.

Thereafter, the electric ~~public~~ utility may disconnect service on the scheduled disconnection ~~specified~~ date if payment or a satisfactory payment arrangement has not been made.

(7) Each electric ~~public~~ utility customer who requires medically essential service is responsible for making satisfactory arrangements with the electric ~~public~~ utility to ensure payment for such service, and such arrangements must be consistent with the requirements of the utility's tariff.

(8) Each electric ~~public~~ utility customer who requires medically essential service is solely responsible for any backup equipment or power supply and a planned course of action in the event of a power outage or interruption of service.

(9) Each electric ~~public~~ utility that provides electric service to any customer whose electric service is certified as medically essential pursuant to this section ~~who requires medically essential service~~ shall call, contact, or otherwise advise such customer of scheduled service interruptions.

(10)(a) Each electric ~~public~~ utility shall provide information on sources of state or local agency funding which may provide financial assistance to the ~~public~~ utility's customers who require medically essential service and who notify the ~~public~~ utility of their need for financial assistance.

(b)1. Each electric ~~public~~ utility that operates a program to receive voluntary financial contributions from the ~~public~~

utility's customers to provide assistance to persons who are unable to pay for the ~~public~~ utility's services shall maintain a list of all agencies to which the ~~public~~ utility distributes such funds for such purposes and shall make the list available to any such person who requests the list.

2. Each public utility that operates such a program shall:

a. Maintain a system of accounting for the specific amounts distributed to each such agency, and the public utility and such agencies shall maintain a system of accounting for the specific amounts distributed to persons under such respective programs.

b. Train its customer service representatives to assist any person who possesses a medically essential certification as provided in this section in identifying such agencies and programs.

(11) Nothing in this act forms ~~shall form~~ the basis for any cause of action against an electric ~~a public~~ utility. Failure to comply with any obligation created by this act does not constitute evidence of negligence on the part of the electric ~~public~~ utility.

(12) Nothing in this section shall be construed to authorize the commission to regulate or supervise the provision of medically essential electric service pursuant to this section by:

(a) Any electric utility owned and operated by a

municipality; or

(b) Any rural electric cooperative organized under chapter 425.

Section 3. Section 456.45, Florida Statutes, is created to read:

456.45 Certification of medically essential electric service.—

(1) As used in this section, the term "health care practitioner" means a physician or physician assistant licensed under chapter 458 or chapter 459 or an advanced registered nurse practitioner licensed under chapter 464.

(2) A health care practitioner who determines that a patient may be at risk of loss of life or immediate hospitalization if the patient were to lose electric service at the patient's residential service address shall inform the patient of his or her right to obtain certification under the medically essential electric service program provided by the patient's electric utility pursuant to s. 366.15, and provide the patient with a written copy of the law.

(3) Upon the request of such a patient, the health care practitioner must provide the patient with a completed medical certification using the standard certification form adopted by the patient's electric utility and made available on the utility's website pursuant to s. 366.15(3) and must document the certification in the patient's medical record.

Section 4. This act shall take effect July 1, 2020.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 1103 Electronic Prescribing
SPONSOR(S): Health Quality Subcommittee, Mariano
TIED BILLS: **IDEN./SIM. BILLS:** SB 1830

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	9 Y, 4 N, As CS	Siples	McElroy
2) Health & Human Services Committee		Siples	Calamas

SUMMARY ANALYSIS

Electronic prescribing (e-prescribing) is a method by which an authorized health care practitioner electronically transmits a prescription to a pharmacy using a secure software system. Efforts have been made by states, as well as the federal government, to increase the use of e-prescribing software. For example, Congress passed legislation mandating e-prescribing for certain medicinal drugs under the Medicare Part D program and xx states enacted mandatory e-prescribing laws.

Beginning July 1, 2021, HB 1103 requires prescribers to generate and transmit all prescriptions electronically, except when electronic prescribing is unavailable due to a temporary electrical or technological failure. In such instances, written prescriptions may be used which must meet the requirements of current law.

The bill relocates language regarding electronic prescribing from existing s. 456.43, F.S., to s. 456.42, F.S., and repeals current s. 456.43, F.S, as of July 1, 2021, to improve readability by combining several provisions related to e-prescribing in a single section of law.

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

The bill provides an effective date of July 1, 2021.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Electronic Prescribing

Electronic prescribing (e-prescribing) is a method by which health care practitioners use an electronic device such as a computer or tablet to enter and securely transmit prescriptions to pharmacies using special software and connectivity to a transmission network.[1] Numerous benefits have been attributed to e-prescribing including, improved prescription accuracy, increased patient safety, reduction of opportunities for fraud and abuse, and cost reduction.[2]

Patient Safety

An adverse drug event (ADE) is harm experienced by the patient as a result of exposure to medicine.[3] Each year, ADEs account for over 3.5 million physician office visits, an estimated one million emergency department visits, and approximately 125,000 hospitalizations.[4] Some ADEs occur without accessing hospital care, such as overdoses to opioid medications.[5] It is estimated that about half of ADEs are preventable.[6] Causes of errors include illegible handwriting, wrong dosage or dosage form, omission of information, and failure to identify drug allergies or drug-drug interactions.[7]

E-prescribing helps reduce such prescription errors.[8] E-prescribing software often includes decision support that notifies the prescriber of potential prescription errors before transmission.[9] The e-prescribing software also prompts the prescriber to verify allergies, confirm dosage accuracy, and identify drug-drug interaction before transmitting the prescription.[10]

Fraud

Individuals may illegally obtain prescription medication by using fraudulent, forged, or altered written prescriptions. In an effort to reduce fraud related to the use or misuse of controlled substances, Florida law requires prescribers to use counterfeit-proof prescription pads purchased from an authorized supplier for written prescriptions for controlled substances.[11] A counterfeit-proof prescription pad must include the following features:[12]

- A background color that is blue or green and resists reproduction;

[1] The Office of the National Coordinator for Health Information Technology, *What is Electronic Prescribing?*, available at https://www.healthit.gov/faq/what-electronic-prescribing (last visited January 14, 2020).
[2] Agency for Health Care Administration, *Florida's Annual Electronic Prescribing Reports*, available at http://www.fhin.net/eprescribing/fleprescribingRpts.shtml (last visited January 14, 2020).
[3] U.S Department of Health and Human Services, Agency for Healthcare Research and Quality, *Medication Errors and Adverse Drug Events*, (last rev. Sept. 2019), available at https://psnet.ahrq.gov/primers/primer/23/Medication-Errors-and-Adverse-Drug-Events (last visited January 14, 2020).
[4] Office of Disease Prevention and Health Promotion, *Overview: Adverse Drug Events*, (last rev. Jan. 14, 2020), available at https://health.gov/hcq/ade.asp (last visited January 14, 2020).
[5] Id.
[6] *Supra* note 3.
[7] Megan Ducker, et. al., *Pros and Cons of E-Prescribing in Community Pharmacies*, US Pharm. 2013 8(38):4-7, available at https://www.uspharmacist.com/article/pros-and-cons-of-e-prescribing-in-community-pharmacies-42392 (last visited January 14, 2020).
[8] Giampaolo P. Velo and Pietro Minuz, *Medication Errors: Prescribing Faults and Prescription Errors*, 67 British J of Clin Pharmacology, 624-628 (2009), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2723200/ (last visited January 14, 2020).
[9] *Supra* note 7.
[10] Id.
[11] Section 456.42, F.S.
[12] Rule 64B-3.005, F.A.C.

- Printed on artificial watermarked paper;
- Resists erasures and alterations; and
- The word "void" or "illegal" must appear on any photocopy or reproduction;

Health care practitioners and health care facilities must return unused counterfeit-proof prescription to the vendor to be destroyed.[13] Even with these precautions, there is still the danger of a legitimate prescription pad being stolen from a health care practitioner's office or a health care facility and fraudulent prescriptions written.[14]

E-prescribing eliminates the risk of stolen prescription pads and, with the two-factor authentication required by the U.S. Drug Enforcement Administration (DEA), may further reduce unauthorized or altered prescriptions.[15]

Efficiency

E-prescribing creates efficiencies for prescribers, patients, and pharmacies. For prescribers, e-prescribing can be integrated into electronic health records, which includes patient information such as clinical notes, laboratory results, and clinical decision support functions.[16] E-prescribing also improves the accuracy of prescriptions and helps guide clinical decision-making by checking the appropriateness of a prescription and connecting to a patient's health insurance for its formulary.[17] Prescribers have also indicated that less time is spent resolving issues with pharmacies, including prior authorizations and refill requests, allowing more time to be spent on patient care.[18] The software also automates certain tasks which allows staff to perform other functions. Such efficiencies may ultimately lower overall operating costs.

Patients may also benefit from e-prescribing efficiencies due to the ability of the prescriber to check for drug interactions, drug allergies, and whether a particular drug is covered by their insurance. This may enable patients to reduce copayment expenses or inconvenience associated with requesting an alternate medication from the prescriber if the drug prescribed is not covered or too expensive.[19]

Finally, pharmacies will likely benefit from e-prescribing efficiencies because it reduces the time spent on interpreting a prescription. Pharmacists must contact prescribers if a prescription is illegible or inconsistent, which affords the pharmacist more time to counsel patients.[20]

Cost Savings

As noted above, ADEs result in many emergency room visits and hospitalizations, as well as additional visits to the prescriber's office. Although e-prescribing will not prevent all ADEs,[21] they may reduce the number of ADEs due to improved prescribing and the assistance of decision support systems.[22] The

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[13] Id.
[14] U.S. Department of Justice, Drug Enforcement Administration, Diversion Control Division, *A Pharmacist's Guide to Prescription Fraud*, (Feb. 2000), available at https://www.deadiversion.usdoj.gov/pubs/brochures/pharmguide.htm (last visited January 14, 2020).
[15] National Association of Chain Drug Stores, *Opioid Abuse Epidemic: Solutions from the Front Lines of Care*, (last rev. May 2019), available at https://www.nacds.org/pdfs/government/2017/Opioid-Policy-Oct-2017.pdf (last visited January 14, 2020).
[16] Amber Porterfield, et. al., *Electronic Prescribing: Improving the Efficiency and Accuracy of Prescribing in the Ambulatory Care Setting*, Perspect. Health Inf. Manage. 2014 Spring: 11 (Apr. 2014), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3995494/ (last visited January 14, 2020).
[17] Academy of Managed Care Pharmacy, *Concept Series Paper on Electronic Prescribing*, available at https://amcp.org/sites/default/files/2019-03/Electronic%20Prescribing.pdf (last visited January 14, 2020).
[18] *Supra* note 16.
[19] Id.
[20] *Supra* note 7.
[21] Some ADEs are unavoidable even if the medication is properly prescribed and administers. These are often known side effects of a medication. See *supra* note 3.
[22] *Supra* note 3.

efficiencies noted above may also lead to a reduction to overall operating costs. For example, one health system in Michigan estimated that it saved $3 million after implementing e-prescribing.[23]

Cost of Implementation

The cost of an e-prescribing system is based on the number of prescribers using the system and the options included in the system. It is estimated that the cost for of a full electronic health record (EHR) system that includes e-prescribing for an office with 10 full-time prescribers is approximately $42,332 for implementation and $14,725 for annual maintenance.[24] According to an industry analysis of e-prescribing software costs, the annual cost of a stand-alone e-prescribing system that meets the Drug Enforcement Administration's requirements for electronically prescribing controlled substances (EPCS) ranges from $170 to $650.[25] The fee for initial set-up of the software may be included; however, some vendors may charge additional fees for set-up and for a token for the two-factor authentication. A health IT management consulting company identified the estimated cost of adding on EPCS functionality to the most widely used EHR systems:[26]

EHR	EPCS Setup (One-time fee)	Annual Ongoing Cost
Allscripts Professional	$340 per provider	$150 per provider
Allscripts Touchworks	$6,000 per practice	$150 per provider
Amazing Charts	$0	$250 per provider
Athena	$0	$0 per provider
Cerner	Varies based upon # of providers	
DrFirst	$90 per provider	$75 per provider
eClinicalWorks	$250 per provider	$0 per provider
e-MDs	$225 per provider	$120 per provider
Epic	Varies based upon # of providers	
GE Centricity	$0	$5,988 per provider
Greenway Intergy	$150 per provider	$90 per provider
Greenway PrimeSuite	$150 per provider	$90 per provider
NewCrop	$150 per provider	$150 per provider
NextGen	$0	included in ePrescribing
Practice Fusion	$0	included in ePrescribing

[23] Annie Hahn and Annesha Lovett, *Electronic Prescribing: An Examination of Cost Effectiveness, Clinician Adoption, and Limitations*," Universal J of Clin Med (2)(1):1-24 (2014), available at http://www.hrpub.org/download/20131215/UJCM1-16900871.pdf (last visited January 14, 2020).
[24] *Supra* note 16.
[25] The U.S. Drug Enforcement Administration requires electronic prescribing software for controlled substances to have two-factor authentication to verify the identity of the prescriber and protect such credentials from misuse (21 C.F.R. 1311). *See* Eclinicworks, *E-prescribing of Controlled Substances*, available at https://www.eclinicalworks.com/wp-content/uploads/2016/11/ePrescribing-of-Controlled-Substances-Slick.pdf; RxNT, *ERX*, available at https://www.rxnt.com/eprescribing/; California Dental Association, *How to Start Prescribing Controlled Substances Electronically*, (Sept. 12, 2018), available at https://iframe.cda.org/news-events/how-to-start-prescribing-controlled-substances-electronically (last visited January 14, 2020).
[26] HealthTech Zone, *Three Factors Contributing to Lagging Provider Adoption of EPCS*, (Apr. 2018), available at http://www.healthtechzone.com/topics/healthcare/articles/2018/04/03/437665-three-factors-contributing-lagging-provider-adoption-epcs.htm (last visited January 14, 2020).

The Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009, authorized incentive payments through Medicare and Medicaid to health care practitioners and hospitals for meaningfully using EHRs to help offset some of the costs related to the adoption of electronic health record systems.[27] The incentive program consists of two stages. Stage one required the electronic capture of clinical data, including transmitting at least 40 percent of eligible prescriptions electronically.[28] In stage two, health care providers must demonstrate meaningful use for a full year; stage two retains the objective that eligible prescriptions be transmitted electronically.[29] Participants could choose to participate under Medicare or Medicaid, but could only participate in one of the programs. The maximum incentive available under Medicare was $44,000 across five years and under Medicaid, $63,750 across six years.[30]

Incentive payments for the Medicare program ended in 2016, and Medicaid will pay incentives through 2021.[31] The Centers for Medicare and Medicaid Services subsequently launched the Promoting Interoperability Program and implemented a merit-based incentive program to reward value and outcomes.[32] The focus of the program is on interoperability, improved flexibility, and placing emphasis on the use of electronic exchange of health information between patients and providers.[33] Promoting interoperability objectives, which includes the use of e-prescribing and EHRs, may account for up to 25 percent of the final score for the merit-based incentive.[34]

According to the Office of the National Coordinator for Health Information Technology (ONC), approximately 80 percent of office-based physicians in Florida have adopted EHRs that meet the criteria for meaningful use.[35] The ONC also found that, as of June 2017, 97 percent of hospitals of Florida hospitals had adopted EHRs that meet the criteria for meaningful use.[36]

E-Prescribing System Design Errors

Practitioners and researchers identify several issues related to the design of an e-prescribing system. Some systems may lack appropriate alerts and other systems may not have alerts configured in a meaningful way so that a prescriber receives an overload of alerts.[37] Other issues are related to the interface or screen design of the software. In such cases, errors may occur in the use of drop-down boxes and automatic fill functions which may lead to more manual entry and editing of prescriptions.[38] Additionally, these systems may be configured to bundle prescriptions for transmission or to transmit at

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[27] Medscape, *EHR Incentive Programs: Achieving Meaningful Use*, available at https://www.medscape.org/viewarticle/770841#content=0_0 (last visited January 14, 2020).
[28] Id.
[29] Centers for Medicare and Medicaid Services, *Stage 2 Overview Tipsheet*, (Aug. 2012), available at https://www.cms.gov/regulations-and-guidance/legislation/ehrincentiveprograms/downloads/stage2overview_tipsheet.pdf (last visited January 14, 2020). For the initial year of stage 2, CMS required providers to demonstrate meaningful use for 90 days, but in subsequent year the requirement is for a full year.
[30] Centers for Medicare and Medicaid Services, *An Introduction to the Medicare EHR Incentive Program for Eligible Professionals*, available at https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/EHR_Medicare_Stg1_BegGuide.pdf (last visited January 14, 2020).
[31] Centers for Medicare and Medicaid Services, *Medicare and Medicaid Promoting Interoperability Program Basics*, (last rev. Aug. 2019), available at https://www.cms.gov/regulations-and-guidance/legislation/ehrincentiveprograms/basics.html (last visited January 14, 2020). Participants must have enrolled to participate in the Medicaid program before 2016 to be eligible for incentive payments.
[32] Id.
[33] Id.
[34] Centers for Medicare and Medicaid Services, *Quality Payment Program*, available at https://qpp.cms.gov/participation-lookup/about?py=2019 (last visited January 14, 2020), Centers for Medicare and Medicaid Services, *Merit-based Incentive Payment System: Promoting Interoperability Requirements*, available at https://qpp.cms.gov/mips/promoting-interoperability?py=2019 (last visited January 14, 2020), and Centers for Medicare and Medicaid Services, *Quality Payment Program: Explore Measures*, available at https://qpp.cms.gov/mips/explore-measures/promoting-interoperability?py=2019#measures (last visited January 14, 2020).
[35] U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, *Florida Health IT Summary*, available at https://dashboard.healthit.gov/apps/health-information-technology-data-summaries.php?state=Florida&cat9=all+data (last visited January 14, 2020).
[36] Id.
[37] *Supra* note 16.
[38] *Supra* note 7.

a time other than the time of entry.[39] For example, the system may allow users to input prescriptions over the course of a specified duration and then send all entered prescriptions at a designated time or interval.[40]

Requirements for Electronic Prescriptions

Federal Requirements

The federal Drug Enforcement Administration (DEA) implements the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the Controlled Substances Act (CSA).[41] In 2010, the DEA adopted a rule authorizing prescribers to issue electronic prescriptions for controlled substances and permitted pharmacies to receive, dispense, and archive these electronic prescriptions.[42] To e-prescribe controlled substances, a presriber must:[43]

- Purchase or use DEA-compliant software that supports e-prescribing;
- Complete the identity-proofing process to acquire a two-factor authentication credential or digital certificate;
- Attach the authentication credential to his or her identity;
- Set access controls so that only individuals who may legally prescribe a controlled substance are allowed to do so; and
- Access the e-prescribing or electronic health record platform.

Florida Requirements

Current law requires prescriptions that are electronically generated and transmitted to contain the following: [44]

- The name of the prescriber;
- The name and strength of the drug prescribed;
- The quantity of the drug prescribed in numerical format;
- Directions for use;
- Date and electronic signature of the prescriber.

E-prescribing software may not interfere with a patient's choice of pharmacy or use any means, such as pop-up ads, advertising, or instant messaging to influence or attempt to influence the prescribing decision of the prescriber at the point of care.[45] E-prescribing software may provide formulary information, as long as nothing makes it more difficult or precludes a prescriber from selecting a specific pharmacy or drug.[46]

Florida Prescribers

The Agency for Health Care Administration (AHCA) houses a clearinghouse of information on electronic prescribing, including trends on the adoption and use of e-prescribing in the state.[47] In

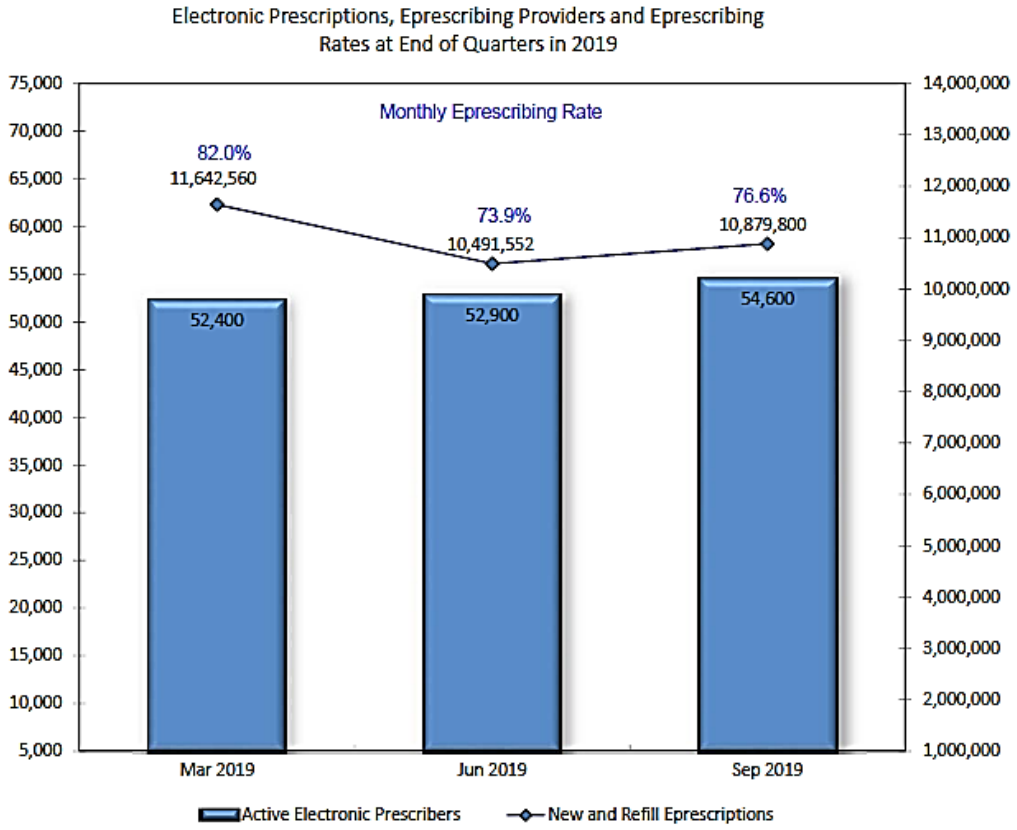
[39] Id.
[40] Id.
[41] 21 U.S.C. 801–971.
[42] U.S. Department of Justice, Drug Enforcement Administration, Diversion Control Division, *Electronic Prescriptions for Controlled Substance (EPCS)*, available at https://www.deadiversion.usdoj.gov/ecomm/e_rx/ (last visited January 14, 2020). *See also* 21 C.F.R. s. 1306.08 and 21 C.F.R. Part 1311.
[43] *Id*. *See also*, DrFirst, *EPCS: Getting Started with Electronic Prescribing of Controlled Substances*, available at http://www.drfirst.com/wp-content/uploads/EPCS_Infographic_from_DrFirst-1.png (last visited January 14, 2020).
[44] Section 456.42, F.S.
[45] Section 456.43, F.S.
[46] Id.
[47] Section 408.0611, F.S.

creating the clearinghouse, AHCA worked in collaboration with the private sector and relevant stakeholders, including representatives of health care practitioners, pharmacies, health care facilities, organizations that operate e-prescribing networks, organizations that create e-prescribing products, and regional health information organizations.[48] On its website, AHCA provides:[49]

- Information on the e-prescribing process and the availability of e-prescribing products;
- Information on the advantages of e-prescribing;
- Links to federal and private sector websites that provide guidance on selecting an appropriate e-prescribing product; and
- Links to state, federal, and private sector incentive programs for the implementation of e-prescribing.

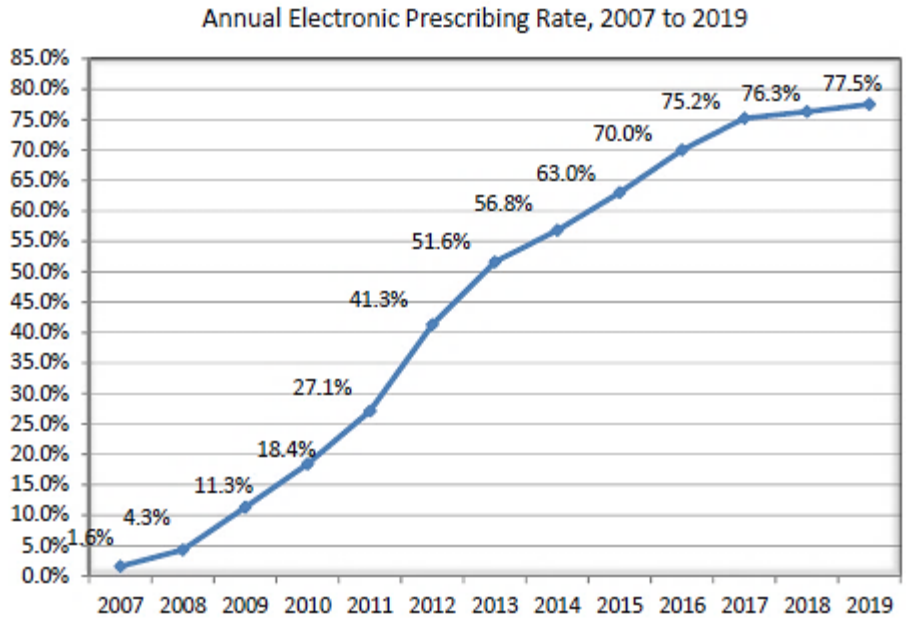
AHCA annually reports to the Governor and Legislature on the implementation of electronic prescribing by health care practitioners, facilities, and pharmacies.[50]

AHCA reports that as of the end of September 2019, the average number of e-prescribers in the state is 54,600, and that almost 10 million e-prescriptions are transmitted each month.[51]

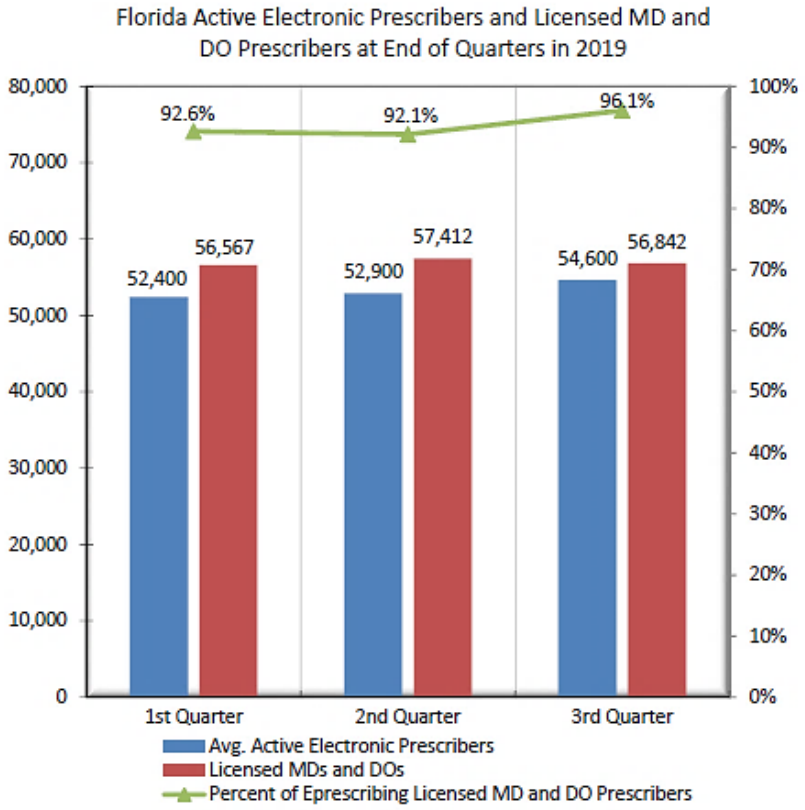


[48] Id.
[49] Id. The clearinghouse website established and maintained by AHCA is www.fhin.net (last visited January 14, 2020).
[50] Id., and Agency for Health Care Administration, Florida Center for Health Information and Transparency, *Florida Electronic Prescribing Annual Report for 2018*, (Jan. 2019), available at https://ahca.myflorida.com/SCHS/ePrescribing/docs/Florida2018ePrescribeReport.pdf (last visited January 14, 2020).
[51] Agency for Health Care Administration, Florida Center for Health Information and Transparency, *2019 Florida Electronic Prescribing Quarterly Summary*, available at https://ahca.myflorida.com/SCHS/ePrescribing/docs/2019eprescribemetrics3Q.pdf (last visited January 14, 2020).

Florida's e-prescribing rate has steadily increased since 2007 with an estimated 77.5 percent of all prescriptions being e-prescribed.[52]



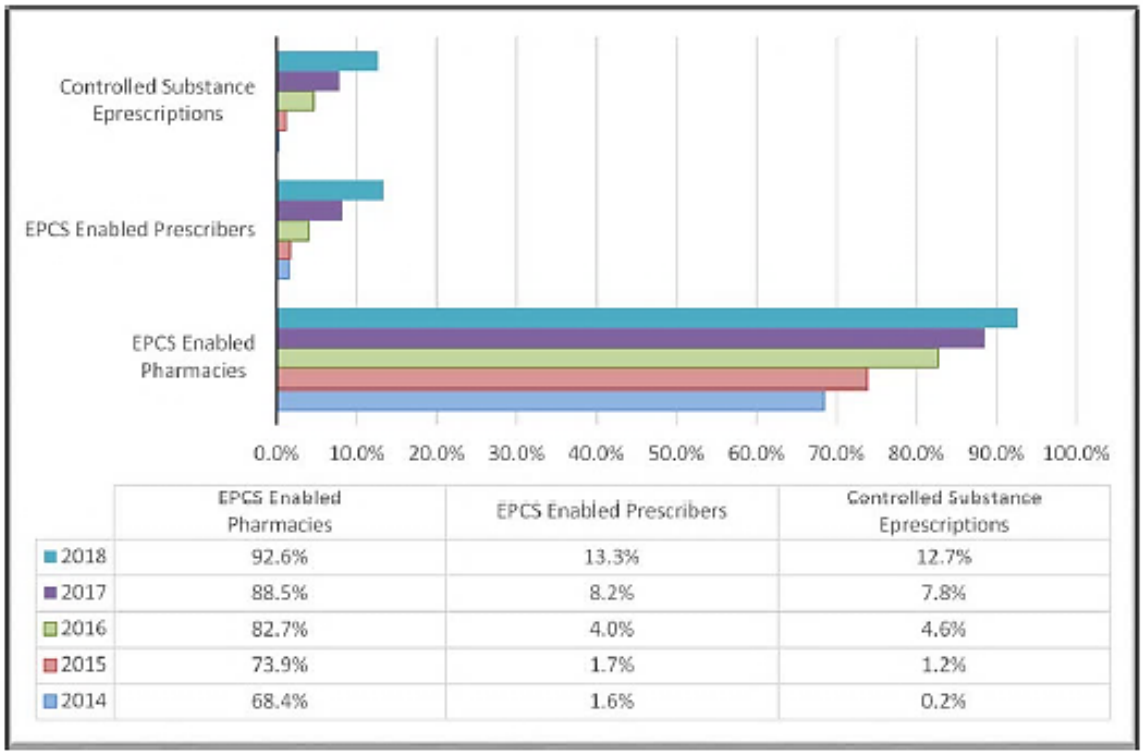
The vast majority of physicians who are actively licensed to practice in Florida have adopted e-prescribing:[53]



[52] Id. Electronic prescribing rate is defined as the amount of e-prescribing relative to all prescriptions that could have been e-prescribed.
[53] Id.

However, Florida prescribers have been slower to adopt e-prescribing for controlled substances.[54] In 2018, only12.7 percent of controlled substance prescriptions were e-prescribed.

Percent of Electronic Prescribing of Controlled Substances (EPCS), EPCS Enabled Pharmacies and EPCS Enabled Providers in Florida[1], 2014 to 2018



	EPCS Enabled Pharmacies	EPCS Enabled Prescribers	Controlled Substance Eprescriptions
2018	92.6%	13.3%	12.7%
2017	88.5%	8.2%	7.8%
2016	82.7%	4.0%	4.6%
2015	73.9%	1.7%	1.2%
2014	68.4%	1.6%	0.2%

Mandatory E-Prescribing

Medicare E-Prescribing

In 2018, Congress mandated e-prescribing for controlled substances under the Medicare Part D program by January 1, 2021, as a part of a comprehensive bill to address the opioid crisis.[55] Under the HITECH Act of 2009, the federal government provides incentive payments to those who adopt and meaningfully use electronic health record technology, including the use of e-prescribing.[56]

Florida

In 2019, the Legislature enacted legislation requiring a prescriber who maintains electronic health care records (EHR) systems, or who is an owner, employee, or contractor of a licensed health care facility or practice that maintains an EHR system, to generate and transmit all prescriptions electronically, unless the prescriber qualifies for an exemption.[57] The requirement takes effect upon the renewal of the prescriber's license or by July 1, 2021, whichever is earlier.[58]

[54] Id.
[55] Substance Use-Disorder Prevention that Promotes Opioid Recovery Treatment (SUPPORT) for Patients and Communities Act, Pub. L. No. 115-271 s. 2003 (2018).
[56] *Supra* note 27.
[57] Chapter 2019-112, L.O.F. The effective date of the law is January 1, 2020.
[58] Id. Health practitioner licenses are biennially renewed.

Laws in Other States

Over the last few years, at least 27 states have enacted mandatory e-prescribing laws.[59]

State	Effective Date	Applicable Prescriptions
Arizona	January 1, 2020	Schedule II opioids
Arkansas	January 1, 2021	Controlled substances
California	January 1, 2022	All
Colorado	July 1, 2021 for physicians, physician assistants, advance practice nurses, podiatrists, and optometrists July 1, 2023 for dentists, and rural and solo practitioners	Schedules II-IV controlled substances
Connecticut	Currently required	Controlled substances
Delaware	January 1, 2021	All
Indiana	January 1, 2021	Controlled substances
Iowa	January 1, 2020	All
Kansas	July 1, 2021	All controlled substances containing an opioid
Kentucky	January 1, 2021	Controlled substances
Maine	Currently required	All controlled substances containing opiates
Massachusetts	January 1, 2020	Controlled substances
Minnesota	Currently required	All
Missouri	January 1, 2021	Controlled substances
New York	Currently required	All
Nevada	January 1, 2021	Controlled substances
North Carolina	January 1, 2020	Schedule II and III opioids and narcotics
Oklahoma	January 1, 2020	Controlled substances
Pennsylvania	October 24, 2019	Controlled substances
Rhode Island	January 1, 2020	Controlled substances
South Carolina	January 1, 2021	Controlled substances
Tennessee	July 1, 2021	Controlled substances
Texas	January 1, 2021	Controlled substances
Virginia	July 1, 2020	All prescriptions containing opiates
Washington	January 1, 2021	Controlled substances
Wyoming	January 1, 2021	Controlled substances

The industry anticipates that additional states will introduce and pass legislation mandating e-prescribing in some fashion, whether it includes all prescriptions or is limited to controlled substances.[60]

Effect of Proposed Changes

HB 1103 requires all prescribers to generate and transmit all prescriptions electronically, and effectively prohibits written prescriptions, except when electronic prescribing is unavailable due to a temporary electrical or technological failure. The bill also eliminates all other exceptions to the mandatory electronic prescribing requirement that exist under the current law. Written prescriptions for controlled substances must meet the requirements of current law, which includes the use of counterfeit-proof prescription pads and have the quantity of the drug prescribed written in both textual and numerical formats.

[59] DrFirst, *Mandates Driving EPCS and PDMP Utilization,* available at https://www.drfirst.com/resources/e-prescribing-mandate-map/ (last visited January 14, 2020), SureScripts, *Electronic Prescribing for Controlled Substances*, available at https://surescripts.com/enhance-prescribing/e-prescribing/e-prescribing-for-controlled-substances/ (last visited January 14, 2020), and independent research by committee staff.

[60] Surescripts, *EPCS Legislation Shows Power and Promise*, (May 3, 2018), available at https://surescripts.com/news-center/intelligence-in-action/opioids/epcs-legislation-shows-power-and-promise/ (last visited January 14, 2020).

The bill relocates language regarding electronic prescribing from existing s. 456.43, F.S., to s. 456.42, F.S., and repeals current s. 456.43, F.S. These provisions regulates the use of e-prescribing software. The bill does not amend these provisions but simply relocates them.

The bill makes conforming changes.

The bill provides an effective date of July 1, 2021.

B. SECTION DIRECTORY:

Section 1: Amends s. 456.42, F.S., relating to written prescriptions for medicinal drugs.
Section 2: Repeals: s. 456.43, F.S., relating to electronic prescribing for medicinal drugs.
Section 3: Amends s. 458.347, F.S., relating to physician assistants.
Section 4: Amends s. 459.022, F.S., relating to physician assistants.
Section 5: Provides an effective date of July 1, 2021.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Prescribers may achieve savings in operating costs based on the efficiencies offered by using e-prescribing software. However, prescribers who do not have such software will incur costs associated with the initial installation and ongoing maintenance. Pharmacies may also achieve cost savings related to the efficiencies provided by e-prescribing.

Vendors currently authorized to sell the counterfeit-proof prescription pads will experience a decrease in demand, which may result in a financial loss.

Vendors of e-prescribing software will experience an increase in demand.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

   The bill provides sufficient rulemaking authority to implement its provisions.

C. DRAFTING ISSUES OR OTHER COMMENTS:

   None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On January 15, 2020, the Health Quality Subcommittee adopted an amendment and reported the bill favorably as a committee substitute. The amendment replaced the term “subsection” with “section” to clarify the authority of the health care regulatory boards to adopt rules for electronic prescribing.

This analysis is drafted to the committee substitute as pass by the Health Quality Subcommittee.

A bill to be entitled

An act relating to electronic prescribing; amending s. 456.42, F.S.; requiring all prescriptions for medicinal drugs to be electronically generated and transmitted to the pharmacist filling the prescription; providing an exception; deleting a requirement that a health care practitioner may only electronically transmit prescriptions for certain drugs; prohibiting electronic prescribing from interfering with a patient's freedom to choose a pharmacy; providing definitions; authorizing electronic prescribing software to display information regarding a payor's formulary under certain circumstances; providing rulemaking authority; repealing s. 456.43, F.S., relating to electronic prescribing for medicinal drugs; amending ss. 458.347 and 459.022, 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. Section 456.42, Florida Statutes, is amended to read:

456.42 ~~Written~~ Prescriptions for medicinal drugs.—

(1) Any ~~A written~~ prescription for a medicinal drug issued

by a health care practitioner licensed by law to prescribe such drug must be electronically generated and transmitted to the pharmacist filling the prescription. ~~legibly printed or typed so as to be capable of being understood by the pharmacist filling the prescription; must contain the name of the prescribing practitioner, the name and strength of the drug prescribed, the quantity of the drug prescribed, and the directions for use of the drug; must be dated; and must be signed by the prescribing practitioner on the day when issued. However,~~ A prescription ~~that is electronically generated and transmitted~~ must contain the name of the prescribing practitioner, the name and strength of the drug prescribed, the quantity of the drug prescribed in numerical format, and the directions for use of the drug and must contain the date and an electronic signature, as defined in s. 668.003(4), by the prescribing practitioner only on the day issued.

(2) A prescriber may issue a written prescription only when electronic prescribing is not available due to a temporary technological or electrical failure that is not reasonably within the control of the prescribing practitioner, and such failure is documented in the patient record. A written prescription for a controlled substance listed in chapter 893 must have the quantity of the drug prescribed in both textual and numerical formats, must be dated in numerical, month/day/year format, or with the abbreviated month written

out, or the month written out in whole, and must be ~~either~~ written on a standardized counterfeit-proof prescription pad produced by a vendor approved by the department ~~or electronically prescribed as that term is used in s. 408.0611~~. As a condition of being an approved vendor, a prescription pad vendor must submit a monthly report to the department that, at a minimum, documents the number of prescription pads sold and identifies the purchasers. The department may, by rule, require the reporting of additional information.

(3) Electronic prescribing may not interfere with a patient's freedom to choose a pharmacy. ~~A health care practitioner licensed by law to prescribe a medicinal drug who maintains a system of electronic health records as defined in s. 408.051(2)(a), or who prescribes medicinal drugs as an owner, an employee, or a contractor of a licensed health care facility or practice that maintains such a system and who is prescribing in his or her capacity as such an owner, an employee, or a contractor, may only electronically transmit prescriptions for such drugs. This requirement applies to such a health care practitioner upon renewal of the health care practitioner's license or by July 1, 2021, whichever is earlier, but does not apply if:~~

~~(a) The practitioner and the dispenser are the same entity;~~

~~(b) The prescription cannot be transmitted electronically~~

~~under the most recently implemented version of the National Council for Prescription Drug Programs SCRIPT Standard;~~

~~(c) The practitioner has been issued a waiver by the department, not to exceed 1 year in duration, from the requirement to use electronic prescribing due to demonstrated economic hardship, technological limitations that are not reasonably within the control of the practitioner, or another exceptional circumstance demonstrated by the practitioner;~~

~~(d) The practitioner reasonably determines that it would be impractical for the patient in question to obtain a medicinal drug prescribed by electronic prescription in a timely manner and such delay would adversely impact the patient's medical condition;~~

~~(e) The practitioner is prescribing a drug under a research protocol;~~

~~(f) The prescription is for a drug for which the federal Food and Drug Administration requires the prescription to contain elements that may not be included in electronic prescribing;~~

~~(g) The prescription is issued to an individual receiving hospice care or who is a resident of a nursing home facility; or~~

~~(h) The practitioner determines that it is in the best interest of the patient, or the patient determines that it is in his or her own best interest, to compare prescription drug prices among area pharmacies. The practitioner must document~~

~~such determination in the patient's medical record.~~

(4) Electronic prescribing software may not use any means or permit any other person to use any means to influence, through economic incentives or otherwise, the prescribing decision of a prescribing practitioner or his or her agent at the point of care, including but not limited to, means such as advertising, instant messaging, pop-up ads, or similar means triggered by or in specific response to the input, selection, or act of a prescribing practitioner or his or her agent in prescribing a certain medicinal drug or directing a patient to a certain pharmacy. For purposes of this subsection, the term:

(a) "Point of care" means the time at which a prescribing practitioner or his or her agent prescribes any medicinal drug.

(b) "Prescribing decision" means a prescribing practitioner's or his or her agent's decision to prescribe any medicinal drug.

(5) Electronic prescribing software may display information regarding a payor's formulary if nothing is designed to preclude or make more difficult the selection of any particular pharmacy by a patient or the selection of any certain medicinal drug by a prescribing practitioner or his or her agent.

The department, in consultation with the Board of Medicine, the Board of Osteopathic Medicine, the Board of Podiatric Medicine,

the Board of Dentistry, the Board of Nursing, and the Board of Optometry, may adopt rules to implement this section ~~subsection~~.

Section 2. Section 456.43, Florida Statutes, is repealed.

Section 3. Paragraph (e) of subsection (4) of section 458.347, Florida Statutes, is amended to read:

458.347 Physician assistants.—

(4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—

(e) A supervising physician may delegate to a fully licensed physician assistant the authority to prescribe or dispense any medication used in the supervising physician's practice unless such medication is listed on the formulary created pursuant to paragraph (f). A fully licensed physician assistant may only prescribe or dispense such medication under the following circumstances:

1. A physician assistant must clearly identify to the patient that he or she is a physician assistant and inform the patient that the patient has the right to see the physician before a prescription is prescribed or dispensed by the physician assistant.

2. The supervising physician must notify the department of his or her intent to delegate, on a department-approved form, before delegating such authority and of any change in prescriptive privileges of the physician assistant. Authority to dispense may be delegated only by a supervising physician who is registered as a dispensing practitioner in compliance with s.

465.0276.

3. The physician assistant must complete a minimum of 10 continuing medical education hours in the specialty practice in which the physician assistant has prescriptive privileges with each licensure renewal. Three of the 10 hours must consist of a continuing education course on the safe and effective prescribing of controlled substance medications which is offered by a statewide professional association of physicians in this state accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award Category 1 credit or designated by the American Academy of Physician Assistants as a Category 1 credit.

4. The department may issue a prescriber number to the physician assistant granting authority for the prescribing of medicinal drugs authorized within this paragraph upon completion of the requirements of this paragraph. The physician assistant is not required to independently register pursuant to s. 465.0276.

5. The prescription ~~may be in paper or electronic form but~~ must comply with ss. 456.0392(1) and 456.42 ~~ss. 456.0392(1) and 456.42(1)~~ and chapter 499 and must contain, in addition to the supervising physician's name, address, and telephone number, the physician assistant's prescriber number. Unless it is a drug or drug sample dispensed by the physician assistant, the prescription must be filled in a pharmacy permitted under

chapter 465 and must be dispensed in that pharmacy by a pharmacist licensed under chapter 465. The inclusion of the prescriber number creates a presumption that the physician assistant is authorized to prescribe the medicinal drug and the prescription is valid.

6. The physician assistant must note the prescription or dispensing of medication in the appropriate medical record.

Section 4. Paragraph (e) of subsection (4) of section 459.022, Florida Statutes, is amended to read:

459.022 Physician assistants.—

(4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—

(e) A supervising physician may delegate to a fully licensed physician assistant the authority to prescribe or dispense any medication used in the supervising physician's practice unless such medication is listed on the formulary created pursuant to s. 458.347. A fully licensed physician assistant may only prescribe or dispense such medication under the following circumstances:

1. A physician assistant must clearly identify to the patient that she or he is a physician assistant and must inform the patient that the patient has the right to see the physician before a prescription is prescribed or dispensed by the physician assistant.

2. The supervising physician must notify the department of her or his intent to delegate, on a department-approved form,

before delegating such authority and of any change in prescriptive privileges of the physician assistant. Authority to dispense may be delegated only by a supervising physician who is registered as a dispensing practitioner in compliance with s. 465.0276.

3. The physician assistant must complete a minimum of 10 continuing medical education hours in the specialty practice in which the physician assistant has prescriptive privileges with each licensure renewal.

4. The department may issue a prescriber number to the physician assistant granting authority for the prescribing of medicinal drugs authorized within this paragraph upon completion of the requirements of this paragraph. The physician assistant is not required to independently register pursuant to s. 465.0276.

5. The prescription ~~may be in paper or electronic form but~~ must comply with ss. 456.0392(1) and 456.42 ~~ss. 456.0392(1) and 456.42(1)~~ and chapter 499 and must contain, in addition to the supervising physician's name, address, and telephone number, the physician assistant's prescriber number. Unless it is a drug or drug sample dispensed by the physician assistant, the prescription must be filled in a pharmacy permitted under chapter 465, and must be dispensed in that pharmacy by a pharmacist licensed under chapter 465. The inclusion of the prescriber number creates a presumption that the physician

assistant is authorized to prescribe the medicinal drug and the prescription is valid.

6. The physician assistant must note the prescription or dispensing of medication in the appropriate medical record.

Section 5. This act shall take effect July 1, 2021.

COMMITTEE/SUBCOMMITTEE ACTION

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

Committee/Subcommittee hearing bill: Health & Human Services Committee

Representative Mariano offered the following:

Amendment (with title amendment)

Remove lines 27-59 and insert:

drug must be telephonically transmitted or electronically generated and transmitted to the pharmacist filling the prescription. ~~legibly printed or typed so as to be capable of being understood by the pharmacist filling the prescription; must contain the name of the prescribing practitioner, the name and strength of the drug prescribed, the quantity of the drug prescribed, and the directions for use of the drug; must be dated; and must be signed by the prescribing practitioner on the day when issued. However,~~ A prescription ~~that is electronically generated and transmitted~~ must contain the name of the

prescribing practitioner, the name and strength of the drug prescribed, the quantity of the drug prescribed in numerical format, and the directions for use of the drug and must contain the date and an electronic signature, as defined in s. 668.003(4), by the prescribing practitioner only on the day issued.

(2) A prescriber may issue a written prescription only in the following circumstances:

(a) Electronic prescribing is not available due to a temporary technological or electrical failure that is not reasonably within the control of the prescribing practitioner, and such failure is documented in the patient record;

(b) The prescription is issued to a patient receiving services in a free clinic as defined in s. 766.1115, or a patient receiving services for which the health care practitioner will not bill or accept payment; or

(c) The prescription is issued to a patient of a hospital emergency department.

A written prescription for a controlled substance listed in chapter 893 must have the quantity of the drug prescribed in both textual and numerical formats, must be dated in numerical, month/day/year format, or with the abbreviated month written out, or the month written out in whole, and must be ~~either~~ written on a standardized counterfeit-proof prescription pad

produced by a vendor approved by the department ~~or electronically prescribed as that term is used in s. 408.0611~~. As a condition of being an approved vendor, a prescription pad vendor must submit a monthly report to the department that, at a minimum, documents the number of prescription pads sold and identifies the purchasers. The department may, by rule, require the reporting of additional information.

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

Remove lines 4-6 and insert:
medicinal drugs to be telephonically transmitted or electronically generated and transmitted to the pharmacist filling the prescription; providing exceptions; deleting a