Health Quality Subcommittee

Tuesday, March 21, 2017
12:30 PM – 3:30 PM
Mashburn Hall (306 HOB)

Richard Corcoran
Speaker

Cary Pigman
Chair

Committee Meeting Notice

HOUSE OF REPRESENTATIVES

Health Quality Subcommittee

Start Date and Time:	Tuesday, March 21, 2017 12:30 pm
End Date and Time:	Tuesday, March 21, 2017 03:30 pm
Location:	Mashburn Hall (306 HOB)
Duration:	3.00 hrs

Consideration of the following bill(s):

HB 211 Cosmetic Product Registration by Latvala
HB 429 Grant Program for Rural Hospitals by Williamson
HB 883 Memory Disorder Clinics by Miller, M., Plakon
HB 1253 Rights and Responsibilities of Patients by Harrison
HB 1269 Child Protection by Harrell
HB 1307 Physician Assistants by Plasencia
HB 1317 North Lake County Hospital District, Lake County by Metz

Pursuant to rule 7.11, the deadline for amendments to bills on the agenda by non-appointed members shall be 6:00 p.m., Monday, March 20, 2017.

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., Monday, March 20, 2017.

NOTICE FINALIZED on 03/17/2017 4:03PM by Iseminger.Bobbye

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 211 Cosmetic Product Registration
SPONSOR(S): Latvala
TIED BILLS: **IDEN./SIM. BILLS:** SB 114

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		Royal	McElroy
2) Government Operations & Technology Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

The federal Food and Drug Administration (FDA) regulates cosmetic products in the United States. The FDA prohibits adulterated or misbranded cosmetic products from being sold to consumers and enforces cosmetic product labeling requirements. Unlike drugs, cosmetic products are not subject to safety inspections and premarket approval. However, the FDA encourages cosmetic manufacturers to voluntarily submit information on facilities, products, and ingredients, which provides the FDA with post-market product information and assists in the assessment of product safety.

The Florida Department of Business and Professional Regulation's Division of Drugs, Devices, and Cosmetics (Division) regulates cosmetics that are manufactured and repackaged in Florida. Cosmetic manufacturers physically located in Florida must hold an active cosmetic manufacturer permit issued by the Division. In addition, each product produced or repackaged by such manufacturers must be registered with the Division. Florida is one of only three states that require cosmetic product registration.

The Division also provides certificates of free sale for cosmetic manufacturers to provide foreign customers regarding exported products. A certificate of free sale verifies that products being exported are freely marketed without restriction and are approved for sale in the United States and Florida.

HB 211 amends ch. 499, F.S., to remove the requirement that Florida cosmetic manufacturers register cosmetic products with the Division. The bill eliminates the fee to register cosmetics. The bill makes conforming changes by removing registration and renewal requirements for cosmetic products, including the requirements to submit registration applications, product labels, and registration and renewal fees. This allows cosmetic manufacturers in Florida to sell cosmetics without registering such products.

The bill removes the Division's authority to issue certificates of free sale for registered cosmetic products in s. 499.003(6), F.S.

Throughout the bill the term "Federal Drug Administration" is revised to correctly reference the federal Food and Drug Administration.

The bill has a significant negative fiscal impact on the Department of Business and Professional Regulation and no fiscal impact on local governments.

The bill provides an effective date of July 1, 2017.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Federal Regulation of Cosmetics

In the United States more than 8 billion cosmetics are sold annually which results in over $60 billion in annual sales.[1] The federal Food and Drug Administration's (FDA) definition of cosmetics covers a broad range of products. For regulatory purposes, the term includes products for the eyes, face, nails, hair, skin, and mouth, which may be in the form of products such as makeup, polish, hair dyes, fragrances, deodorants, shave gel, oral care, lotions, bath products, and products for infants and children.[2]

The FDA regulates cosmetics under the authority of the federal Food Drug and Cosmetic Act (FDCA) and the Fair Packaging and Labeling Act (FPLA). The FDCA prohibits adulterating and misbranding cosmetics and the introduction, receipt, and delivery of adulterated or misbranded cosmetics into interstate commerce.[3] A cosmetic is adulterated if it contains a substance that may cause injury to users under the conditions of use prescribed on the product's labeling or if it contains a soiled or decomposed substance.[4] A cosmetic is misbranded if its labeling is false or misleading, if it does not bear the required labeling information, if the container is made or filled in a deceptive manner, or if it does not comply with child resistant packaging requirements.[5]

The FDA is authorized to take action against a cosmetic on the market if a product is found to be adulterated or misbranded, as well as companies and individuals who market such products.[6] However, the FDA does not have the authority to require a manufacturer to recall a cosmetic product from the marketplace, although the agency has general regulations on voluntary recalls.[7]

The FPLA requires that packages and their labels provide consumers with accurate information about the quantity of contents to prevent consumer deception.[8] FPLA regulations require cosmetic product labels to disclose:[9]

- 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.

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[1] Landa, Michael. "Examining the Current State of Cosmetics," testimony on March 27, 2012, before the Subcommittee on Health Committee on Energy and Commerce, U.S. House of Representatives. Available at: http://www.fda.gov/NewsEvents/Testimony/ucm297215.htm (last visited March 14, 2017).
[2] 21 C.F.R. §720.4(c)(12) (1992).
[3] Amalia Corby-Edwards, *FDA Regulation of Cosmetics and Personal Care Products*, CONGRESSIONAL RESEARCH SERVICE, July 9, 2012. Available at: http://asbcouncil.org/sites/default/files/library/docs/crs_report_fda_regulation_of_cosmetics_and_personal_care_products.pdf (last visited March 14,2017).
[4] Id.
[5] Id.
[6] U.S. FOOD AND DRUG ADMINISTRATION, *FDA Authority over Cosmetics*. Available at: http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074162.htm (last visited March 14, 2017).
[7] *Supra*, note 3.
[8] 15 U.S.C. § 1451-1460 (2009).
[9] *Supra*, note 1.

Voluntary Regulations

The FDA's legal authority over cosmetics is less comprehensive than other products it regulates, such as drugs and medical devices, with respect to mandatory product approval, regulation, and registration. The FDA does not require registration of cosmetic manufacturers or cosmetic products, but it allows cosmetic manufacturers to voluntarily register facilities, report product ingredients, and report adverse reactions to products.

Voluntary cosmetic registration compliance is managed electronically through the FDA's Voluntary Cosmetic Registration Program (VCRP). The VCRP is an electronic reporting system for manufacturers, packers, and distributors of cosmetic products that are distributed commercially in the United States.[10] Voluntary submission to the VCRP furnishes the FDA with information on cosmetic businesses and products, which helps support product safety review processes.[11] As of February 2017, there are 4,467 active online accounts, 2,058 registered cosmetic establishments, and 57,814 product formulations on file with the VCRP.[12]

The FDA does not require good manufacturing practices (GMP) for cosmetic products as it does with drugs and medical devices, unless the product is considered both a cosmetic and a drug.[13] GMPs provide standards for product development, monitoring, and control of processes and facilities, providing assurance that products meet FDA quality and safety standards.[14] With the exception of color additives, the FDA does not require safety testing or premarket approval of the ingredients and chemicals used in cosmetic products.[15]

Product Ingredients

The FDA is not statutorily authorized to approve a premarket cosmetic product. Therefore, manufactures are responsible for verifying the safety of their products before they are sold to consumers. FDA regulations prohibit or restrict the use of 10 types of ingredients in cosmetic products including chloroform, bithioniol, methylene chloride, and mercury-containing compounds[16] and require warning statements on the labels of cosmetics that may be hazardous to consumers when misused.[17] Manufacturers must remove dangerous products from the market once a safety concern emerges. The FDA can pursue enforcement actions against such products or against firms or individuals who violate the law.[18] In general, except for color additives and those ingredients that are prohibited or restricted by regulation, a manufacturer may use any ingredient in the formulation of a cosmetic, provided that the:[19]

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[10] U.S. FOOD AND DRUG ADMINISTRATION, *Voluntary Cosmetic Registration Program*. Available at: http://www.fda.gov/Cosmetics/RegistrationProgram/default.htm (last visited March 14, 2017).

[11] Information from the VCRP is used by the Cosmetic Ingredient Review, an industry funded organization, to assess ingredient safety and determine priorities for ingredient safety review. *Id.*

[12] U.S. FOOD AND DRUG ADMINISTRATION, *Registration Reports*. Available at: http://www.fda.gov/Cosmetics/RegistrationProgram/RegistrationReports/default.htm (last visited March 14, 2017).

[13] In some cases products that are used for two purposes are considered both a cosmetic and a drug. For example, a shampoo is a cosmetic because its intended use is to cleanse the hair; however, an antidandruff treatment is a drug because its intended use is to treat dandruff. Consequently, an antidandruff shampoo is both a cosmetic and a drug and must comply with the requirements for both cosmetics and drugs. U.S. FOOD AND DRUG ADMINISTRATION, *Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?)*. Available at: http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074201.htm (last visited March 14, 2017).

[14] U.S. FOOD AND DRUG ADMINISTRATION. *Facts about the Current Good Manufacturing Practices.* Available at: https://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm169105.htm (last visited March 16,2017).

[15] *Supra*, note 3.

[16] U.S. FOOD AND DRUG ADMINISTRATION, *Prohibited and Restricted Ingredients*. Available at: http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm127406.htm (last visited March 14, 2017).

[17] Examples of such products are: cosmetics in self-pressurized containers (aerosol products), feminine deodorant sprays, and children's bubble bath products. U.S. FOOD AND DRUG ADMINISTRATION, *Summary of Labeling Requirements*. Available at: https://www.fda.gov/Cosmetics/Labeling/Regulations/ucm126438.htm#Label_Warnings (last visited March 16, 2017).

[18] *Supra*, note 1.

[19] *Supra*, note 6.

- Ingredient and the finished cosmetic are safe under labeled or customary conditions of use;
- Product is properly labeled; and
- Use of the ingredient does not otherwise cause the cosmetic to be adulterated or misbranded under the laws that FDA enforces.

State Cosmetic Laws

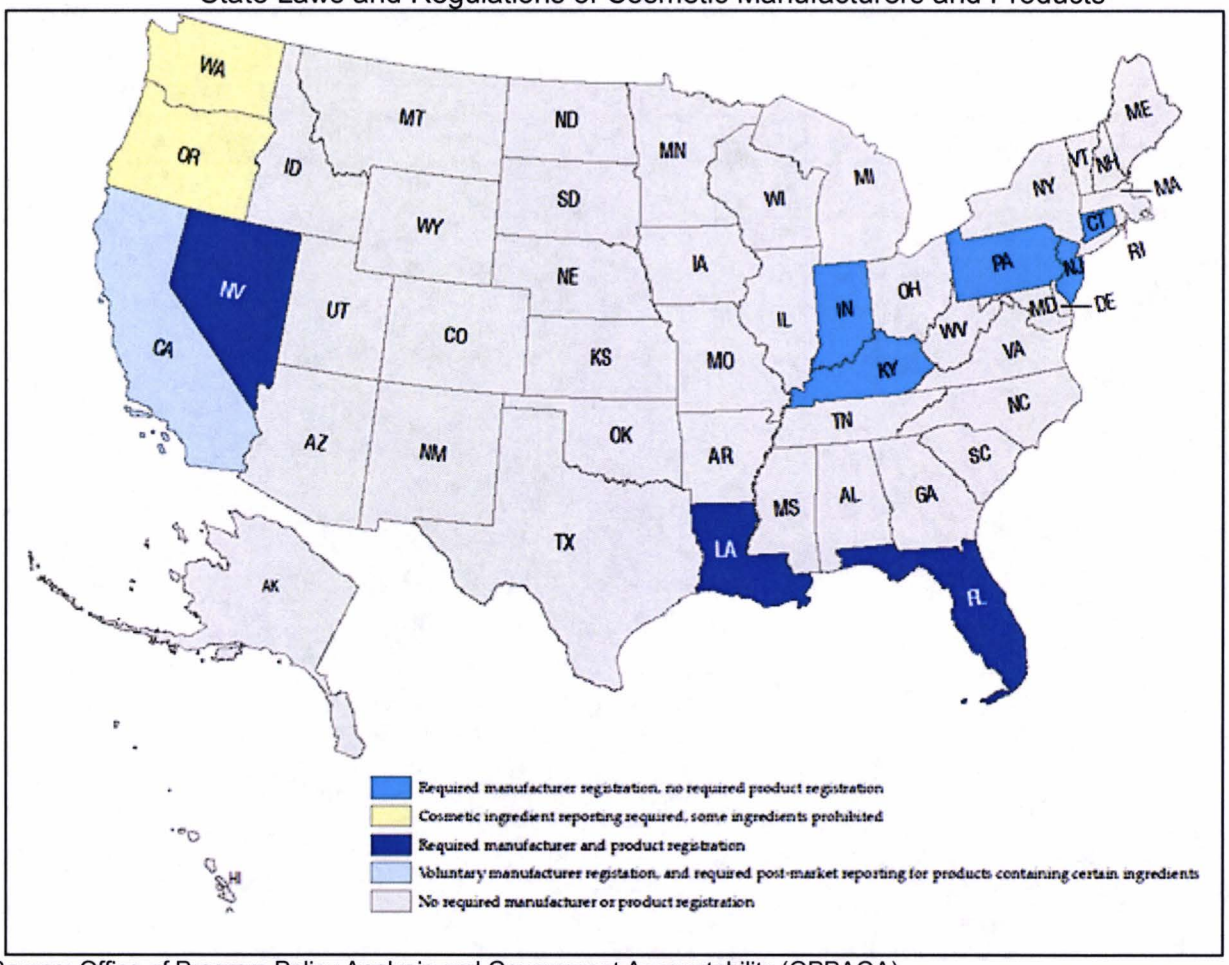
All 50 states have laws and regulations in place that conform to the FDCA, the FPLA, and FDA regulations for cosmetics.[20] Further cosmetic related laws and regulation vary state by state. Twenty-five states have enacted state food, drug and cosmetic laws similar to the federal FDCA that authorize inspections of cosmetic manufacturing facilities but do not provide any further legal authority over cosmetic manufacturers.[21] Eighteen states do not have a state food, drug, and cosmetic act, but federal law still authorizes these states to perform inspections of cosmetic manufacturing facilities.[22]

Only Louisiana, Nevada, and Florida, have mandatory registration requirements for both cosmetic manufacturers and individual cosmetic products.[23]

Seven states require only cosmetic manufacturer registration and California has a voluntary cosmetic manufacturer registration program.[24] Oregon and Washington require ingredient reporting.[25] California requires cosmetic manufacturers to notify the state of any product ingredients that are on state or federal lists of chemicals that cause cancer or birth defects.[26] Washington also requires this type notification for children's cosmetic products.[27] Other states, such as Texas and Illinois,[28] authorize the issuance of certificates of free sale for the export of in-state produced cosmetic products.

[20] U.S. FOOD AND DRUG ADMINISTRATION, *Subchapter 3.3- State Operational Authority.* Available at: https://www.fda.gov/downloads/ICECI/Inspections/IOM/UCM123506.pdf (last visited March 14, 2017).
[21] Office of Program Policy Analysis and Government Accountability (OPPAGA), *Cosmetic Regulation in Florida Research Memorandum*, February 21, 2017. (On file with the Health Quality Subcommittee staff).
[22] Id.
[23] Id.
[24] Id.
[25] Id.
[26] CALIFORNIA DEP'T OF PUBLIC HEALTH, *California Safe Cosmetic Program.* Available at: http://www.cdph.ca.gov/programs/cosmetics/Pages/default.aspx (last visited March 16,2017).
[27] WASH. REV. CODE §70.240.040 (2008)
[28] 25 Tex. Admin. Code §§ 229.301-229.306 (2010); Ill. Admin. Code Food Drug and Cosmetic 77 § 720 (2014).

State Laws and Regulations of Cosmetic Manufacturers and Products[29]



Source: Office of Program Policy Analysis and Government Accountability (OPPAGA)

Florida Cosmetic Regulation

The Department of Business and Professional Regulation's Division of Drugs, Devices, and Cosmetics (Division) administers the provisions of ch. 499, F.S., the Florida Drug and Cosmetic Act (Act), which regulates cosmetic manufacturers to prevent adulteration, contamination, and misbranding of cosmetic products.[30] The Act conforms to FDA cosmetic laws and regulations and also authorizes the Division to issue permits to Florida cosmetic manufacturers and register cosmetic products manufactured or repackaged in Florida.

Manufacturer Permit

Cosmetic manufacturers physically located in Florida must obtain a cosmetic manufacturer permit through the Division.[31] Manufacture in this context means the preparing, deriving, compounding, propagating, processing, producing, or fabricating of any cosmetic.[32] Cosmetic manufacturers also repackage products by changing the container, wrapper, or label of a product, which may include altering the quantity of a product into different containers.[33] A person that only labels or changes the

[29] *Supra*, note 21.
[30] FLORIDA DEP'T OF BUSINESS AND PROFESSIONAL REGULATION, *Division of Drugs, Devices, and Cosmetics.* Available at: http://www.myfloridalicense.com/DBPR/ddc/index.html (last visited March 15,2017).
[31] S. 499.01(2)(o), F.S.
[32] FLORIDA DEP'T OF BUSINESS AND PROFESSIONAL REGULATION, *Cosmetic Manufacturer.* Available at: http://www.myfloridalicense.com/dbpr/ddc/CosmeticManufacturer.html (last visited March 16, 2017).
[33] Id.

label of a cosmetic, but does not open the container sealed by the manufacturer of the product, is exempt from obtaining a permit.[34]

Applicants for a cosmetic manufacturer permit must complete and submit an application, pass an onsite inspection,[35] and pay a fee. Applicants must pay a fee of $800 for a biennial permit and a one-time pre-permit inspection fee of $150.[36] Currently, there are 129 establishments with cosmetic manufacturer permits.[37]

To ensure cosmetic product safety and quality and compliance with FDA laws and regulations, the Division requires cosmetic manufacturers to meet certain minimum requirements, which include: [38]

- Manufacturers must assure that personnel do not contribute to contamination or adulteration of the product;
- Any facility used for the manufacture, processing, packaging, or labeling of a cosmetic must be of suitable size and construction to produce a product that is not adulterated or misbranded;
- Any facility and equipment used in the manufacture, processing, packaging, or labeling of a cosmetic must be maintained in a clean and sanitary condition;
- Components, containers, and closures must not be reactive, additive, or absorptive so as to alter the safety or purity of the cosmetic;
- Container closure systems must provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the cosmetic product; and
- Procedures to facilitate a rapid and effective recall or market withdrawal.

Product Registration

Cosmetics manufactured, packaged, repackaged, labeled or relabeled in Florida must be registered with the Division.[39] Products that are both a cosmetic and a drug must be registered as a drug.[40] To register a cosmetic product, a manufacturer must submit a detailed application, a copy of the product labels, and a $30 fee for each product.[41] The application includes the following information:

- Manufacturer's contact and address information, type of ownership, and operating hours;
- Name of product as shown on label;
- Identification of the product, if it is for professional use only;
- Manufacturer of the product, including its name, city, and state;
- Identical cosmetic products information; and
- Signed affidavit attesting that all information in the application is true and correct.[42]

New cosmetic products must be registered prior to sale. If a manufacturer has existing registered products, its registered product list must be updated through the formal application process to include any new products.[43] Each product registration must be renewed every two years, including a $30 renewal fee.

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[34] Id.
[35] If the applicant also holds an Over-the-Counter Drug Manufacturer or Prescription Drug Manufacturer permit at the same time an inspection is not required. *Supra*, note 32.
[36] *Supra*, note 32.
[37] *Supra*, note 21.
[38] Rule 61N-1.010, F.A.C.
[39] S. 499.015(1)(a), F.S.
[40] Rule 61N-1.016(1)(a), F.A.C.
[41] S. 499.015, F.S.
[42] FLORIDA DEP'T OF BUSINESS AND PROFESSIONAL REGULATION, *Application for Product Registration-Cosmetics Form No.: DBPR-DDC-228.* Available at http://www.myfloridalicense.com/DBPR/ddc/documents/Product_Registration_Cosmetic_App-228.pdf (last visited March 16, 2017).
[43] Rule 61N-1.016(4)(b), F.A.C.

Manufacturers often produce similar products or slightly alter products from an outside manufacturer. For example, they may use a different brand name, container, or scent for an almost identical product. In these instances, for registration purposes, the product is not considered separate and distinct and is therefore, an "identical product". The registration process for "identical products" requires submission of an application and a $15 fee and biennial renewal fee for each additional size, quantity, color, flavor, and scent of a registered cosmetic product.[44]

The Division reviews applicants' product labels to determine compliance with the requirements of the FDCA.[45] The Division reviews the ingredients of the cosmetic to determine if the ingredients are approved for use in cosmetics or otherwise safe for cosmetic products.[46] Division pharmacists or drug inspectors review products that may contain ingredients that are prohibited or may change the classification of the product to a drug.[47] At the end of the fiscal year 2015-2016, there were 13,024 active cosmetic product registrations with the Division.[48]

Inspection and Investigation of Cosmetic Manufacturers

Passing an onsite inspection is a prerequisite to the issuance of a Cosmetic Manufacturer permit, unless the applicant also holds an Over-the-Counter Drug Manufacturer or Prescription Drug Manufacturer permit at the same address.[49] Additionally, once a permit has been issued to a cosmetic manufacturer, it is subject to announced or unannounced inspection and investigation by the Division and the Department of Law Enforcement.[50] Inspections and investigations may include:

- Review and copying of all records pertaining to the manufacture, advertisement, storage, holding, and distribution of any cosmetic.
- Entry to any establishment, vehicle or space therein in which cosmetics are manufactured, processed, repackaged, sold, brokered, held or transported;
- Entry to any establishment, vehicle, or space therein in which records related to cosmetics are held;
- Surveillance of procedures related to cosmetics;
- Collection of facts and information related to cosmetics;
- Questioning of persons who may have information relating to the inspection or investigation and taking sworn statements from these persons, all related to cosmetics;
- Sampling any cosmetic, including any related product (whether or not in finished form), material, component, document, literature, label, labeling or other evidence;
- Photographing any cosmetic including any related component, materials, physical plant, storage condition, article or product;
- Observations and identification of:
    - Any cosmetic consisting wholly or in part of filthy, putrid or decomposed substances;
    - Any undesirable conditions or practices bearing on filth, contamination, or decomposition which may result in a cosmetic becoming adulterated or misbranded;
    - Any unsanitary conditions or practices which may render a cosmetic injurious to health;
    - Any faulty manufacturing, processing, packaging, or holding of cosmetics as related to current GMP including recordkeeping;
    - Any deviation from recommended processing, storage or temperature requirements for any cosmetic as specified by federal or state law;
    - Any deviation from FDA requirements for the label and labeling of any cosmetic;

[44] Rule 61N-1.016(1)(b), F.A.C.
[45] FLORIDA DEP'T OF BUSINESS AND PROFESSIONAL REGULATION, 2017 Legislative Bill Analysis SB 114, March 9, 2017. (On file with Health Quality Subcommittee staff).
[46] Id.
[47] Letter from the Director of the Division of Drugs, Devices, and Cosmetics to a representative of the Florida Cosmetic Manufacturers Coalition on November 26, 2014. (On file with Health Quality Subcommittee staff).
[48] *Supra*, note 45.
[49] *Supra*, note 32.
[50] S. 499.051(1), F.S.; Rule 61N-1.019(1)-(3), F.A.C.

- Any other action to determine compliance with chapters 499 and 893[51], F.S., and chapter 61N-1, F.A.C.
- Taking of evidence related to a cosmetic that is or may be in violation of chapters 499 or 893, F.S., or any rules adopted thereunder; and
- Securing the removal of any potentially misbranded or adulterated cosmetic from commerce or public access.

Certificates of Free Sale

Manufacturers exporting products from the United States are often asked by foreign customers or foreign governments to supply a certificate of free sale (COFS) to ensure that products are in compliance with FDA laws and regulations.[52] A COFS is a document issued by a regulatory agency containing information about a product's regulatory or marketing status.[53] A COFS verifies that products being exported are freely marketed without restriction and are approved for sale in the United States and Florida.[54]

A COFS can be issued by a federal, state, city office or a non-governmental association such as a Chamber of Commerce. The Division, when requested by a cosmetic manufacturer, issues a COFS for a registered cosmetic product that is to be exported to another country.[55] Enterprise Florida will prepare a COFS for firms involved in the exporting of products manufactured in, or distributed from Florida for a $30.00 fee.[56] Although not required by law, the FDA will also issue a COFS for a cosmetic product upon request.[57]

Effect of Proposed Changes

HB 211 amends ch. 499, F.S., to remove the requirement that Florida cosmetic manufacturers register cosmetic products with the Division. As such, cosmetic manufacturers located in Florida will no longer be required to register cosmetic products with the Division. Florida cosmetic manufacturers' products would be treated the same as cosmetic products manufactured outside of Florida but distributed and sold into Florida. The bill makes conforming changes by removing registration and renewal requirements for cosmetic products, including the requirements to submit registration applications, product labels, and registration and renewal fees.

Florida cosmetic manufacturers would continue to be regulated. They would still be required to have their facilities permitted and be subject to inspection and investigation of their cosmetic products.

The bill also removes the Division's authority to issue COFSs for registered cosmetic products in s. 499.003(6), F.S. While COFSs would not be available from the Division for exported cosmetic products, they would continue to be available from other entities for exported cosmetic products, including Enterprise Florida.

Throughout the bill the term "federal Drug Administration" is revised to correctly reference the federal Food and Drug Administration.

The bill makes a recurring appropriation of $222,564 in General Revenue funds to the Division and reduces the appropriation from the Professional Regulation Trust Fund to the Division by $222,564.

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[51] Ch. 893, F.S. is The Florida Comprehensive Drug Abuse and Prevention Act.
[52] U.S. FOOD AND DRUG ADMINISTRATION, *FDA Export Certificate.* Available at: http://www.fda.gov/RegulatoryInformation/Guidances/ucm125789.htm, (last visited March 17, 2017).
[53] Id.
[54] Enterprise Florida, *Certificate of Free Sale*. Available at https://www.enterpriseflorida.com/wp-content/uploads/certificate-of-free-sale-flyer.pdf (last visited March 15, 2017).
[55] Rule 61N-1.017, F.A.C.
[56] *Supra*, note 54.
[57] *Supra,* note 52.

The bill provides an effective date of July 1, 2017.

B. SECTION DIRECTORY:

Section 1: Amends 499.015, F.S., relating to registration of drugs, devices, and cosmetics; issuance of certificates of free sale.
Section 2: Amends 499.003, F.S., relating to definitions.
Section 3: Amends 499.041, F.S., relating to schedule of fees for drug, device, and cosmetic applications and permits, product registrations, and free sale certificates.
Section 4: Amends 499.051, F.S., relating to inspections and investigations.
Section 5: Creates an unnumbered section relating appropriation of funds.
Section 6: Provides an effective date of July 1, 2017.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

The Division will experience a decrease in revenues associated with no longer receiving payment of fees for cosmetic product registration, product registration renewal, and COFS.

During Fiscal Year 2015-2016, the Division collected $2,778 in revenues associated with COFS.[58]

During Fiscal Year 2015-2016, the Division had the following revenues and expenditures for cosmetic manufacturer permits and cosmetic product registrations:[59]

Permit	Revenue	Expenditures	Surplus
Cosmetic Manufacturer	$67,957	$41,701.99	$26,254.57
Cosmetic Product Registration	$286,138	$175,590.45	$110,547.52

Assuming product registration is repealed and the Division does not receive additional appropriation of General Revenue funds, the Division projects the following revenues and expenditures for cosmetic manufacturer permits for Fiscal Year 2017-2018:[60]

Permit	Revenue	Expenditures	Deficit
Cosmetic Manufacturer	$70,296	$73,282	($2,284)

The bill makes a recurring appropriation of $222,564 in General Revenue funds to the Division and reduces the appropriation from the Professional Regulation Trust Fund to the Division by $222,564. This appears to be unnecessary given the current surplus and very minor projected deficit for Fiscal Year 2017-2018.

2. Expenditures:

See Revenues.

[58] *Supra*, note 45.
[59] FLORIDA DEP'T OF BUSINESS AND PROFESSIONAL REGULATION, DIVISION OF DRUGS, DEVICES, AND COSMETICS, *Allocation of Revenues and Expenditures Fiscal Year Ending in 2016.* (On file with the Health Quality Subcommittee).
[60] FLORIDA DEP'T OF BUSINESS AND PROFESSIONAL REGULATION, DIVISION OF DRUGS, DEVICES, AND COSMETICS, *Projected Allocation of Revenues and Expenditures Fiscal Year Ending in 2018.* (On file with the Health Quality Subcommittee).

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill has a positive fiscal impact for cosmetic manufacturers associated with no further payment of the $30 per product registration fee, $15 per identical product registration fee, and $30 and $15 biennial renewal fees to the Division.

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:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to cosmetic product registration; amending s. 499.015, F.S.; deleting the requirement that a person who manufactures, packages, repackages, labels, or relabels a cosmetic in this state register such cosmetic biennially with the Department of Business and Professional Regulation; amending ss. 499.003, 499.041, and 499.051, F.S.; conforming provisions to changes made by the act; providing an appropriation; providing an effective date.

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

Section 1. Section 499.015, Florida Statutes, is amended to read:

499.015 Registration of drugs and~~,~~ devices~~, and cosmetics~~; issuance of certificates of free sale.—

(1)(a) Except for those persons exempted from the definition of manufacturer in s. 499.003, any person who manufactures, packages, repackages, labels, or relabels a drug or~~,~~ device~~, or cosmetic~~ in this state must register such drug or~~,~~ device~~, or cosmetic~~ biennially with the department; pay a fee in accordance with the fee schedule provided by s. 499.041; and comply with this section. The registrant must list each separate and distinct drug or~~,~~ device~~, or cosmetic~~ at the time

of registration.

(b) The department may not register any product that does not comply with the Federal Food, Drug, and Cosmetic Act, as amended, or Title 21 C.F.R. Registration of a product by the department does not mean that the product does in fact comply with all provisions of the Federal Food, Drug, and Cosmetic Act, as amended.

(2) The department may require the submission of a catalog and specimens of labels at the time of application for registration of drugs or~~,~~ devices~~, and cosmetics~~ packaged and prepared in compliance with the federal act, which submission constitutes a satisfactory compliance for registration of the products. With respect to all other drugs and~~,~~ devices~~, and cosmetics~~, the department may require the submission of a catalog and specimens of labels at the time of application for registration, but the registration will not become effective until the department has examined and approved the label of the drug or~~,~~ device~~, or cosmetic product~~. This approval or denial must include written notification to the manufacturer.

(3) Except for those persons exempted from the definition of manufacturer in s. 499.003, a person may not sell any product that he or she has failed to register in conformity with this section. Such failure to register subjects such drug or~~,~~ device~~, or cosmetic product~~ to seizure and condemnation as provided in s. 499.062, and subjects such person to the penalties and

remedies provided in this part.

(4) Unless a registration is renewed, it expires 2 years after the last day of the month in which it was issued. Any product registration issued or renewed on or after July 1, 2016, shall expire on the same date as the manufacturer or repackager permit of the person seeking to register the product. If the first product registration issued to a person on or after July 1, 2016, expires less than 366 days after issuance, the fee for product registration shall be $15. If the first product registration issued to a person on or after July 1, 2016, expires more than 365 days after issuance, the fee for product registration shall be $30. The department may issue a stop-sale notice or order against a person that is subject to the requirements of this section and that fails to comply with this section within 31 days after the date the registration expires. The notice or order shall prohibit such person from selling or causing to be sold any drugs or~~,~~ devices~~, or cosmetics~~ covered by this part until he or she complies with the requirements of this section.

(5) A product regulated under this section which is not included in the biennial registration may not be sold until it is registered and complies with this section.

(6) The department may issue a certificate of free sale for any product that is required to be registered under this part.

(7) A product registration is valid only for the company named on the registration and located at the address on the registration. A person whose product is registered by the department under this section must notify the department before any change in the name or address of the establishment to which the product is registered. If a person whose product is registered ceases conducting business, the person must notify the department before closing the business.

(8) Notwithstanding any requirements set forth in this part, a manufacturer of medical devices that is registered with the federal Food and Drug Administration is exempt from this section and s. 499.041(6) if:

(a) The manufacturer's medical devices are approved for marketing by, or listed with the federal Food and Drug Administration in accordance with federal law for commercial distribution; or

(b) The manufacturer subcontracts with a manufacturer of medical devices to manufacture components of such devices.

(9) However, the manufacturer must submit evidence of such registration, listing, or approval with its initial application for a permit to do business in this state, as required in s. 499.01, and any changes to such information previously submitted at the time of renewal of the permit. Evidence of approval, listing, and registration by the federal Food and Drug Administration must include:

(a) For Class II devices, a copy of the premarket notification letter (510K);

(b) For Class III devices, a federal Food and Drug Administration premarket approval number;

(c) For a manufacturer who subcontracts with a manufacturer of medical devices to manufacture components of such devices, a federal Food and Drug Administration registration number; or

(d) For a manufacturer of medical devices whose devices are exempt from premarket approval by the federal Food and Drug Administration, a federal Food and Drug Administration registration number.

Section 2. Subsection (6) of section 499.003, Florida Statutes, is amended to read:

499.003 Definitions of terms used in this part.—As used in this part, the term:

(6) "Certificate of free sale" means a document prepared by the department which certifies a drug or~~,~~ device~~, or cosmetic,~~ that is registered with the department~~,~~ as one that can be legally sold in the state.

Section 3. Subsection (6) of section 499.041, Florida Statutes, is amended to read:

499.041 Schedule of fees for drug, device, and cosmetic applications and permits, product registrations, and free-sale certificates.—

(6) A person that is required to register drugs or~~,~~ devices~~, or cosmetic products~~ under s. 499.015 shall pay an annual product registration fee of not less than $5 or more than $15 for each separate and distinct product in package form. The registration fee is in addition to the fee charged for a free-sale certificate.

Section 4. Subsection (2) of section 499.051, Florida Statutes, is amended to read:

499.051 Inspections and investigations.—

(2) In addition to the authority set forth in subsection (1), the department and any duly designated officer or employee of the department may enter and inspect any other establishment for the purpose of determining compliance with this chapter and rules adopted under this chapter regarding any drug, device, or cosmetic ~~product~~.

Section 5. For the 2017-2018 fiscal year, the sum of $222,564 in recurring funds is appropriated from the General Revenue Fund to the Division of Drugs, Devices, and Cosmetics in the Department of Business and Professional Regulation for the purpose of implementing this act, and the appropriation from the Professional Regulation Trust Fund to the division shall be reduced by $222,564.

Section 6. This act shall take effect July 1, 2017.

COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. HB 211 (2017)

Amendment No.

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 Quality Subcommittee

Representative Latvala offered the following:

Amendment (with title amendment)

Remove lines 126-147 and insert:

(1) The department shall assess applicants requiring a manufacturing permit an annual fee ~~within the ranges~~ as established in this section for the specific type of manufacturer.

(c) The fee for a cosmetic manufacturer permit shall be sufficient to cover the costs of administering the cosmetic manufacturer program ~~may not be less than $250 or more than $400 annually~~.

(6) A person that is required to register drugs or~~,~~ devices~~, or cosmetic products~~ under s. 499.015 shall pay an

annual product registration fee of not less than $5 or more than $15 for each separate and distinct product in package form. The registration fee is in addition to the fee charged for a free-sale certificate.

Section 4. Subsection (2) of section 499.051, Florida Statutes, is amended to read:

499.051 Inspections and investigations.—

(2) In addition to the authority set forth in subsection (1), the department and any duly designated officer or employee of the department may enter and inspect any other establishment for the purpose of determining compliance with this chapter and rules adopted under this chapter regarding any drug, device, or cosmetic ~~product~~.

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

Remove lines 9-10 and insert:

Provisions to changes made by the act; providing an effective date.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 429 Grant Program for Rural Hospitals
SPONSOR(S): Williamson and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 510

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		Siples	McElroy
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

The Department of Health (DOH) administers the rural hospital capital improvement program that, subject to legislative appropriation, grants each eligible rural hospital a minimum of $100,000 annually, for projects to acquire, repair, improve, or upgrade systems, facilities, or equipment. The program has not been funded since 2008.

HB 429 repeals the current program and establishes the Florida Rural Hospital Capital Improvement Competitive Grant Program. Subject to an annual appropriation, eligible rural hospitals may apply to DOH for grants of up to $750,000, to purchase medical equipment or for facility infrastructure improvements in the rural area serviced by the grantee.

Under the bill, DOH must establish, by rule, a grant application process and the evaluation criteria by which DOH will score and rank the applications. An applicant that leverages additional private or public matching funds or in-kind contributions will be given preference. Preference will also be given to an applicant that demonstrates hospital practices aimed at reducing unnecessary emergency room visits and preventable hospitalizations through increased access to primary care.

DOH must submit an annual report to the Governor, President of the Senate, and the Speaker of the House of Representatives with information regarding the grants it awards.

The bill will have a significant, indeterminate negative fiscal impact on DOH and no fiscal impact on local governments.

The bill takes effect upon becoming law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Rural Hospital Capital Improvement Program

In 1999, the Legislature established the rural hospital capital improvement program that established a mechanism for a rural hospital to apply for a grant from the Department of Health (DOH).[1] Subject to legislative appropriation, each rural hospital must receive a minimum of $100,000 annually, upon application to DOH, for projects to acquire, repair, improve, or upgrade systems, facilities, or equipment.

A rural hospital is a licensed acute care hospital having 100 or fewer beds and an emergency room, which is:[2]

- The sole provider in a county with a population density or no greater than 100 persons per square mile;
- In a county with a population density no greater than 100 persons per square mile, and at least 30 minutes travel time, from any other acute care hospital in the same county;
- Supported by a tax district or sub-district whose boundaries encompass a population no greater than 100 persons per square mile;
- Classified by the Centers for Medicare and Medicaid Services (CMS) as a sole community hospital;[3]
- A hospital with a service area that has a population no greater than 100 persons per square
- mile; or
- A critical access hospital.[4]

There are currently 29 rural hospitals located throughout the state as indicated in this map:[5]

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[1] Chapter 1999-209, Laws of Fla., codified at s. 395.6061, F.S.

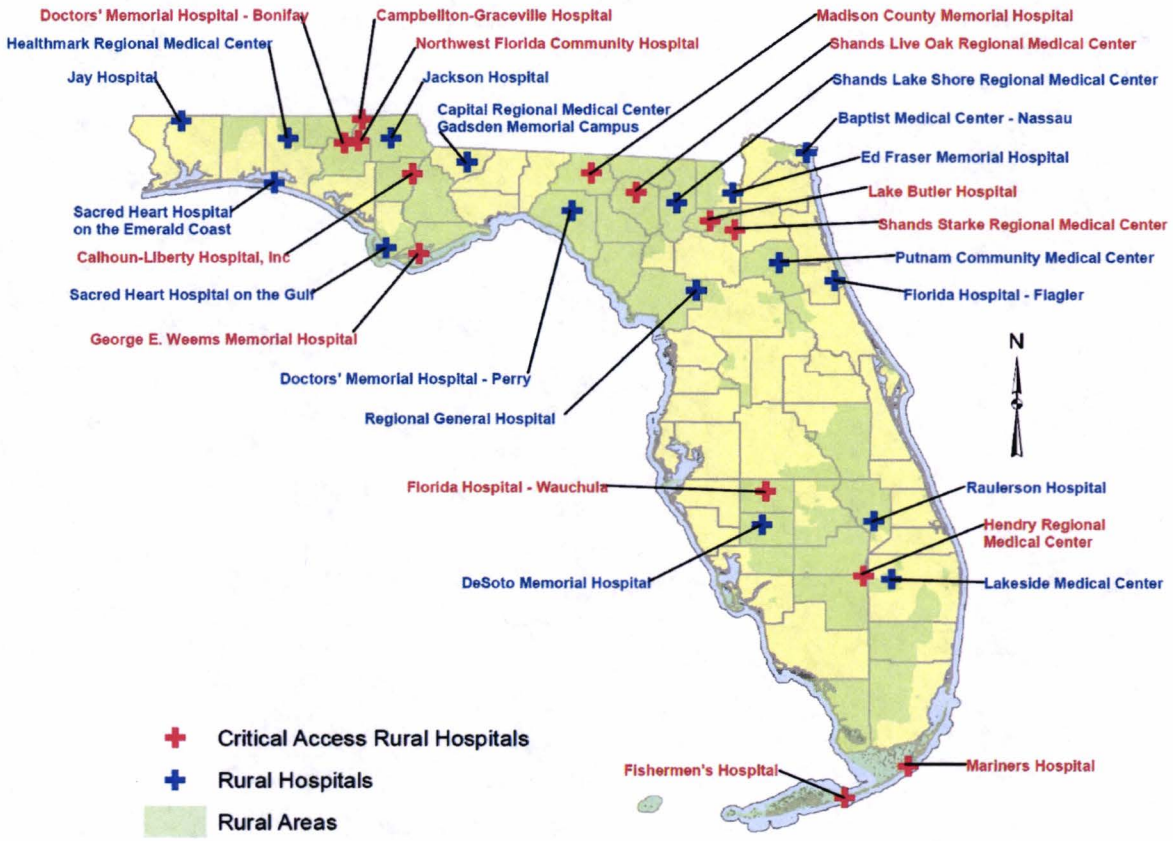
[2] Section 395.602(2)(e), F.S.

[3] A "sole community hospital" is defined by 42 C.F.R. s. 412.92, as a hospital located more than 35 miles from other like hospitals, or it is located in a rural area and meets one of the following conditions:

- The hospital is located between 25 and 35 miles from other like hospitals and meets one of the following criteria:
  - No more than 25 percent of residents who become hospital inpatients or no more than 25 percent of the Medicare beneficiaries who become hospital inpatients in the hospital's service area are admitted to other like hospitals located within a 35-mile radius of the hospital, or, if larger, within its service area;
  - The hospital has fewer than 50 beds and the intermediary certifies that the hospital would have met the criteria in listed above were it not for the fact that some beneficiaries or residents were forced to seek care outside the service area due to the unavailability of necessary specialty services at the community hospital; or
  - Because of local topography or periods of prolonged severe weather conditions, the other like hospitals are inaccessible for at least 30 days in each 2 out of 3 years;
- The hospital is located between 15 and 25 miles from other like hospitals but because of local topography or periods of prolonged severe weather conditions, the other like hospitals are inaccessible for at least 30 days in each 2 out of 3 years; or
- Because of distance, posted speed limits, and predictable weather conditions, the travel time between the hospital and the nearest like hospital is at least 45 minutes.

[4] A critical access hospital must have 25 or fewer acute care inpatient beds, be located more than 35 miles from another hospital, and have an average length of stay of 96 hours or less per patient for acute care. *See* s.408.07, F.S., and Department of Health and Human Services, Center for Medicare & Medicaid Services, *Critical Access Hospital*, (Nov. 2016), *available at* https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/CritAccessHospfctsht.pdf (last visited March 19, 2017).

[5] Florida Rural Health Association, "Map of Florida's Rural Hospitals and Rural Areas," *available at* https://static1.squarespace.com/static/50e4cd1ee4b0d83d923056bc/t/5339bc36e4b0a038333df2b6/1396292662053/FL+State+Map+v4+Rural.pdf (last visited March 19, 2017). *See also* DOH, "Florida Rural Hospital Directory 1-30-17," *available at* http://www.floridahealth.gov/programs-and-services/community-health/rural-health/ (last visited March 19, 2017).



An applicant for the rural hospital capital improvement grant program must provide DOH with the following:

- A statement of the problem the rural hospital proposes to solve with the grant funds;
- The strategy proposed to resolve the problem;
- The organizational structure, financial system, and facilities that are essential to the proposed solution;
- The projected longevity of the proposed solution after the grant funds are expended;
- Evidence of participation in the rural health network;[6]
- Evidence that the rural hospital has difficulty obtaining funding or that funds available for the proposed solution are inadequate;
- Evidence that the grant funds will assist in maintaining or returning the hospital to an economically stable condition or will involve innovative alternatives for discontinued services;
- Evidence of a satisfactory record-keeping system to account for grant fund expenditures within the rural county; and
- A rural health network plan that includes a description of how the plan was developed, the goals of the plan, the links with existing health care providers under the plan, indicators quantifying

[6] Section 381.0406, F.S., defines a "rural health network" as a nonprofit legal entity, consisting of rural and urban health care providers and others, that is organized to plan and deliver health care services on a cooperative basis in a rural area, except for some secondary and tertiary care services.

the hospital's financial well-being, measurable outcome targets, and the current physical and operational condition of the hospital.[7]

DOH must consider any information submitted in an application in determining eligibility for and the amount of the grant. None of the individual items in the application, by itself, may be used to deny grant eligibility.

DOH is required to adopt rules for annually distributing any remaining funds after eligible applicants have been awarded grants.[8] The remaining funds must be used for the support and assistance of rural hospitals and the criteria must consider the level of uncompensated care rendered by a hospital, the participation in the rural health network, and the proposed use of the grant to resolve a specific problem.[9]

Between 1999 and 2008, DOH awarded $34.45 million in grants under the program.[10] The program has not been funded since 2008.

Effect of Proposed Changes

The bill repeals the current rural hospital capital improvement grant program and replaces it with the Florida Rural Hospital Capital Improvement Competitive Grant Program. Subject to an annual appropriation, eligible rural hospitals may apply for grants of up to $750,000. Grant funds may only be used to purchase medical equipment or for facility infrastructure improvements in the rural area served by the grantee. To be eligible for a grant award, a rural hospital must demonstrate that:

- Grant funds are necessary to maintain or improve the quality of its health care services; and
- There is a return on investment to the taxpayers of this state.

Under the bill, DOH must establish, by rule, a grant application process, and the evaluation criteria by which DOH will score and rank the applications. An applicant that leverages additional private or public matching funds or in-kind contributions must be given preference. Preference will also be given to an applicant that demonstrates hospital practices aimed at reducing unnecessary emergency room visits and preventable hospitalizations through increased access to primary care.

DOH must submit an annual report to the Governor, President of the Senate, and the Speaker of the House of Representatives that includes for each grantee:

- The amount awarded;
- A brief description detailing what the funds will be used for;
- The anticipated outcomes to be achieved; and
- The return on investment to the taxpayers of this state.

The bill does not appropriate funds for the program.

The bill takes effect upon becoming law.

B. SECTION DIRECTORY:

Section 1: Amends s. 395.6061, F.S.; relating to rural hospital capital improvement.
Section 2: Provides an effective date of upon becoming law.

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[7] Section 395.6061(1) F.S.
[8] DOH repealed rules related to the grant application process on December 29, 2016, because the grant program had not been funded by the Legislature for several years and the rule was deemed no longer necessary. *See* r. 64I-3.001, F.A.C.
[9] Section 395.6061(3), F.S.
[10] DOH, *2017 Agency Legislative Bill Analysis: House Bill 429*, (Feb. 16, 2017), on file with the Health Quality Subcommittee.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   If the program is funded, DOH will incur an indeterminate negative fiscal impact associated with its administration. DOH indicates that it would need four FTEs to administer the program if it is funded to its greatest potential of approximately $21.75 million.[11]

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Rural hospitals that lack sufficient funding to be eligible to receive a grant of up to $750,000 for improvements it needs to its medical equipment or the facility infrastructure.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

[11] *Id.* In its analysis, DOH determined the total amount of the program would be $21 million if each of 28 rural hospitals received the maximum grant amount of $750,000. However, according to DOH's website, there are a total of 29 rural hospitals, so the total amount if each hospital received the maximum grant amount would be $21.75 million.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to a grant program for rural hospitals; amending s. 395.6061, F.S.; providing legislative findings and intent; requiring the Department of Health to establish and administer the Florida Rural Hospital Capital Improvement Competitive Grant Program for certain rural hospitals; revising the amount of a grant award; revising grant eligibility and preferences; establishing allowable uses of funds; requiring the department to submit an annual report to the Governor and the Legislature; deleting requirements for certain information in grant applications; deleting provisions relating to the disbursal of funds; providing an effective date.

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

Section 1. Section 395.6061, Florida Statutes, is amended to read:

395.6061 Rural hospital capital improvement.—

(1) LEGISLATIVE FINDINGS AND INTENT.—The Legislature finds that rural hospitals have limited ability to increase operating revenues or to access other public or private funding sources that are needed to maintain critical infrastructure, including, but not limited to, the replacement of high-cost medical care

equipment or improvements to facility infrastructure. Rural hospitals that do not have reasonable access to alternative sources of revenue to pay for critical infrastructure needs are at risk, and patient access, care, and quality are threatened. Therefore, the Legislature finds that it is necessary to establish the Florida Rural Hospital Capital Improvement Competitive Grant Program for eligible rural hospitals to ensure their sustainability.

(2) FLORIDA RURAL HOSPITAL CAPITAL IMPROVEMENT COMPETITIVE GRANT PROGRAM.—The Department of Health shall establish and administer the Florida Rural Hospital Capital Improvement Competitive Grant Program for rural hospitals. Subject to annual appropriation, the department shall establish grant awards up to $750,000 per each hospital that meets the eligibility requirements in subsection (3). Grants must be made available to eligible rural hospitals based on the competitive grant program and on criteria established by the agency.

(3) GRANT ELIGIBILITY.—In order to be eligible for a grant award, a hospital must be a rural hospital, as defined in s. 395.602, and must demonstrate that:

(a) Grant funds are necessary to maintain or improve the quality of its health care services; and

(b) There is a return on investment to the taxpayers of this state.

(4) AWARD OF GRANTS.—The department shall establish a

grant application process and criteria for the evaluation of applications by rule. It shall score and rank grant applications based on these criteria. Preference in grant award decisions shall be given to any applicant that leverages additional private or public matching funds or in-kind contributions. Preference in grant award decisions shall also be given to any applicant that demonstrates hospital practices targeted to reducing unnecessary emergency room visits and preventable hospitalizations through increased access to primary care services.

(5) ALLOWABLE USES OF FUNDS.—Grant awards may be used only for hospital medical equipment purchases or facility infrastructure improvements in the rural area serviced by the grantee.

(6) REPORT.—The department shall provide an annual report to the Governor, the President of the Senate, and the Speaker of the House of Representatives which includes the list of grantees and, for each grantee, the amount awarded, a brief description detailing what the funds will be used for, the anticipated outcomes to be achieved, and the return on investment to the taxpayers of this state. ~~There is established a rural hospital capital improvement grant program.~~

~~(1) A rural hospital as defined in s. 395.602 may apply to the department for a grant. The grant application must provide information that includes:~~

~~(a) A statement indicating the problem the rural hospital proposes to solve with the grant funds;~~

~~(b) The strategy proposed to resolve the problem;~~

~~(c) The organizational structure, financial system, and facilities that are essential to the proposed solution;~~

~~(d) The projected longevity of the proposed solution after the grant funds are expended;~~

~~(e) Evidence of participation in a rural health network as defined in s. 381.0406;~~

~~(f) Evidence that the rural hospital has difficulty in obtaining funding or that funds available for the proposed solution are inadequate;~~

~~(g) Evidence that the grant funds will assist in maintaining or returning the hospital to an economically stable condition or that any plan for closure or realignment of services will involve development of innovative alternatives for the discontinued services;~~

~~(h) Evidence of a satisfactory record-keeping system to account for grant fund expenditures within the rural county;~~

~~(i) A rural health network plan that includes a description of how the plan was developed, the goals of the plan, the links with existing health care providers under the plan, indicators quantifying the hospital's financial well-being, measurable outcome targets, and the current physical and operational condition of the hospital.~~

~~(2) Each rural hospital as defined in s. 395.602 shall receive a minimum of $100,000 annually, subject to legislative appropriation, upon application to the Department of Health, for projects to acquire, repair, improve, or upgrade systems, facilities, or equipment.~~

~~(3) Any remaining funds shall annually be disbursed to rural hospitals in accordance with this section. The Department of Health shall establish, by rule, criteria for awarding grants for any remaining funds, which must be used exclusively for the support and assistance of rural hospitals as defined in s. 395.602, including criteria relating to the level of uncompensated care rendered by the hospital, the participation in a rural health network as defined in s. 381.0406, and the proposed use of the grant by the rural hospital to resolve a specific problem. The department must consider any information submitted in an application for the grants in accordance with subsection (1) in determining eligibility for and the amount of the grant, and none of the individual items of information by itself may be used to deny grant eligibility.~~

~~(4) The department shall ensure that the funds are used solely for the purposes specified in this section. The total grants awarded pursuant to this section shall not exceed the amount appropriated for this program.~~

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

COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. HB 429 (2017)

Amendment No.

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 Quality Subcommittee

Representative Williamson offered the following:

Amendment (with title amendment)

Remove lines 42-60 and insert:

and on criteria established by the department.

(3) GRANT ELIGIBILITY.—In order to be eligible for a grant award, a hospital must be a rural hospital, as defined in s. 395.602, and must demonstrate that:

(a) Grant funds are necessary to maintain or improve the quality of its health care services;

(b) There is a return on investment to the taxpayers of this state; and

(c) A satisfactory recordkeeping system will be in place to account for the expenditures of grant funds within the rural

county.

(4) AWARD OF GRANTS.—The department shall establish by rule a grant application process and criteria for the evaluation of applications. The department shall score and rank grant applications based on criteria that must include, at a minimum, the following:

(a) The social and economic benefit to the surrounding community.

(b) The promotion of economic development in the surrounding community.

(c) The expansion of available services to the underserved populations in the community.

(d) The availability of private or public matching funds, or in-kind contributions, for the requested grant funds.

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

Remove lines 9-10 and insert:
eligibility; providing criteria for grant application ranking; establishing allowable use of funds; requiring the department to submit an

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 883 Memory Disorder Clinics
SPONSOR(S): Miller and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 1050

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		Royal	McElroy
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Section 430.502 establishes 15 Memory Disorder Clinics (MDCs) in the State of Florida that provide comprehensive assessments, diagnostic services, and treatment to individuals who exhibit symptoms of Alzheimer's disease and related memory disorders. MDCs also develop training programs and materials, and conduct training for caregivers, respite service providers, and health care professionals in the care of persons with Alzheimer's disease and related memory disorders. In addition, MDCs conduct service-related research projects. MDCs receive performance based funding from the General Revenue.

HB 883 establishes a 16th MDC at Florida Hospital in Orange County. Florida Hospital in Orange County established a self-funded memory disorder program in 2012. The bill does not provide any appropriation of funds to the MDC at the Florida Hospital.

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

The bill provides an effective date of July 1, 2017.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Alzheimer's Disease

Alzheimer's disease is a form of dementia, a general term for memory loss. It is a progressive brain disorder that damages and eventually destroys brain cells, leading to memory loss and changes in the functions of the brain.[1] Alzheimer's disease accounts for 60 to 80 percent of dementia cases.[2] Alzheimer's disease is a progressive disease in which dementia symptoms worsen gradually over time. In the early stages of Alzheimer's disease, memory loss is mild, but in late-stage Alzheimer's, individuals lose the ability to carry on a conversation and respond to their environment.[3] Currently, there is no cure for Alzheimer's disease, but treatments that can temporarily slow the worsening of symptoms do exist.[4]

There are an estimated 5.5 million people in the United States with Alzheimer's disease, including 5.3 million people aged 65 and older and 200,000 individuals under age 65 who have younger-onset Alzheimer's disease.[5] By 2030, the segment of the United States population aged 65 years and older is expected to double, and the estimated 71 million older Americans will make up approximately 20 percent of the total population.[6] By 2050, the number of people aged 65 and older with Alzheimer's disease is expected to nearly triple to a projected 13.8 million people.[7]

Since 2000, deaths attributed to Alzheimer's disease have increased 89 percent nationally, while deaths attributed to heart disease, the number one cause of death, decreased by 14 percent. [8] Alzheimer's disease is the sixth leading cause of death in the United States and the fifth leading cause of death age 65 and older.[9]

An estimated 520,000 Floridians have Alzheimer's disease.[10] The projected number of Floridians with Alzheimer's disease in 2025 is 720,000.[11] Alzheimer's disease is the 6th leading cause of death in Florida. The Medicaid cost of caring for people with Alzheimer's disease in Florida is 2.279 billion dollars.[12]

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[1] Alzheimer's Association. *What We Know Today About Alzheimer's Disease and Dementia.* Available at: http://www.alz.org/research/science/alzheimers_research.asp (last visited March 17, 2017).
[2] Id.
[3] Alzheimer's Association. *What is Alzheimer's?.* Available at: http://www.alz.org/alzheimers_disease_what_is_alzheimers.asp (last visited March 17, 2017).
[4] Id.
[5] Alzheimer's Association. *2017 Alzheimer's Disease Fact and Figures.* Available at http://www.alz.org/alzheimers_disease_facts_and_figures.asp (last visited March 17, 2017).
[6] Id.
[7] Id.
[8] Id
[9] Id.
[10] Alzheimer's Association. *Florida Factsheet.* Available at: http://www.alz.org/documents_custom/facts_2017/statesheet_florida.pdf?type=interior_map&facts=undefined&facts=facts (last visited March 17,2017).
[11] Id.
[12] Id.

Alzheimer's Disease Research[13]

There are several not-for-profit institutions and associations in Florida who have invested capital to support "Alzheimer's disease and related forms of dementia" (ADRD) research.[14] Research investments at the state and federal levels in institutions such as Scripps, Torrey Pines, and Burnham have added to our general research capabilities, but very few scientists at these institutions focus on ADRD.[15] The 15 state funded MDCs provide valuable ADRD research, and the majority of academic institutions in Florida have active ADRD research programs.[16]

The National Institute on Aging, within the National Institute of Health (NIH), funds 29 Alzheimer's Disease Research Centers (ADRCs) at major medical institutions across the United States.[17] NIH ADRCs serve a similar role to nationally designated cancer centers. They create infrastructure that supports clinical care for patients with ADRD.[18]

In order to be eligible for funding and recognition as an ADRC, institutions are required to have an established ongoing base of high-quality Alzheimer's disease research or research in other neurodegenerative diseases, or in aging of the nervous system.[19]

Currently, the Mayo Clinic Alzheimer's Disease Research Center and the University of Florida Alzheimer's Disease Center are the only NIH ADRCs in Florida.[20] NIH ADRCs receive $1.5 million in federal funding, annually, for five years.[21] The Mayo Clinic ADRC focuses their research on patient-oriented research and basic science research. [22] Scientists at the Mayo Clinic ADRC were among the first in the United States to identify novel genetic mutations in some families with frontotemporal dementia[23] and the three most common dominantly inherited gene mutations that cause frontotemporal dementia were discovered at the Mayo Clinic ADRC.[24]

Alzheimer's Disease Initiative

The Alzheimer's Disease Initiative (ADI)[25] was created within the Department of Elder Affairs (DOEA) to provide a continuum of services to meet the changing needs of individuals with Alzheimer's disease

[13] Department of Elder Affairs, Purple Ribbon Task Force, *2013 Final Report and Recommendation,* available at http://elderaffairs.state.fl.us/doea/purple_ribbon.php (last visited March 17, 2017).
[14] Id.
[15] Id.
[16] Id.
[17] National Institute on Aging, Alzheimer's Disease Research Centers, *see http://www.nia.nih.gov/alzheimers/alzheimers-disease-research-centers* (last visited February 28, 2014).
[18] *Supra*, note 13.
[19] National Institute of Health Funding Opportunities, *NIH Guide for Grants and Contract, Alzheimer's Disease Research Centers, Eligibility Information*, available at http://grants.nih.gov/grants/guide/rfa-files/RFA-AG-13-019.html (last visited March 17, 2017).
[20] *Supra,* note 17.
[21] *Supra*, note 13.
[22] The Mayo Clinic Alzheimer's Disease Research Center. Focus Areas. Available at: http://www.mayo.edu/research/centers-programs/alzheimers-disease-research-center/research-activities/focus-areas (last visited March 117,2017).
[23] The Mayo Clinic defines Frontotemporal dementia as: (frontotemporal lobar degeneration) is an umbrella term for a diverse group of uncommon disorders that primarily affect the frontal and temporal lobes of the brain — the areas generally associated with personality, behavior and language. In frontotemporal dementia, portions of these lobes atrophy or shrink. Signs and symptoms vary, depending upon the portion of the brain affected. Some people with frontotemporal dementia undergo dramatic changes in their personality and become socially inappropriate, impulsive or emotionally indifferent, while others lose the ability to use language. Frontotemporal dementia is often misdiagnosed as a psychiatric problem or as Alzheimer's disease. But frontotemporal dementia tends to occur at a younger age than does Alzheimer's disease, generally between the ages of 40 and 75. Available at: http://www.mayoclinic.org/diseases-conditions/frontotemporal-dementia/basics/definition/con-20023876 (last visited March 17, 2017).
[24] *Supra*, note 22.
[25] Section 430.503, F.S.

and their families.[26] In conjunction with a ten-member advisory committee appointed by the Governor[27], the initiative includes the following four programs administered by DOEA.[28]

Respite Services

ADI Respite care programs exist in all 67 Florida counties and provide in-home, facility-based, emergency and extended care (up to 30 days) respite for caregivers who serve individuals with memory disorders.[29] Additional services include caregiver training and support, education, counseling, specialized medical equipment, services and supplies, and case management.[30]
Funds for respite care programs are contracted according to an allocation formula based on the number and proportion of the county population of individuals who are 75 years of age and older.[31]

Model Day Care

Model Day Care programs[32] have been established in conjunction with Memory Disorder Clinics to test therapeutic models of care and provide day care services.[33] Model Day Care programs provide a safe environment where Alzheimer's patients gather for the day and socialize with each other, as well as receive therapeutic treatments designed to maintain or improve their cognitive functioning.[34] Model Day Care programs also provide training for health care and social service personnel that care for persons having Alzheimer's disease and related memory disorders.[35] Currently, model day care programs have been established in Gainesville, Tampa, and Miami.[36]

Brain Bank[37]

The Florida Alzheimer's disease Brain Bank is a service and research oriented network of statewide regional sites. The intent of the Brain Bank program is to collect and study the brains of deceased patients who had been clinically diagnosed with dementia. Mt. Sinai Medical Center contracts annually with the state of Florida to operate the primary Brain Bank. Coordinators at regional brain bank sites in Orlando, Tampa and Pensacola help recruit participants and act as liaisons between the Brain Bank and participants' families.

Memory Disorder Clinics

The State of Florida has designated by statute 15 MDCs[38] that provide comprehensive assessments, diagnostic services, and treatment to individuals who exhibit symptoms of Alzheimer's disease and related memory disorders.[39] MDCs also develop training programs and materials, and conduct training for caregivers, respite service providers, and health care professionals in the care of persons with Alzheimer's disease and related memory disorders.[40] In addition, MDCs conduct service-related research projects through model day care programs and respite care programs.[41] MDCs are

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[26] Chapter 95-418, L.O.F., *see also* ss. 430.501-430.504, F.S.
[27] Section 430.501,F.S., Alzheimer's Disease Advisory Committee.
[28] Florida Department of Elder Affairs. *Alzheimer's Disease Initiative*. Available at: http://elderaffairs.state.fl.us/english/alz.php (last visited March 17, 2017).
[29] Id.
[30] *Supra,* note 13.
[31] Section 430.502(5), F.S.
[32] Section 430.502(7), F.S.
[33] *Supra,* note 28.
[34] Id
[35] Id
[36] Id
[37] The Florida Brain Bank. Available at: http://elderaffairs.state.fl.us/doea/BrainBank/index.php (last visited March 18, 2017).
[38] Section 430.502(1), F.S.
[39] *Supra*, note 28
[40] Id.
[41] Supra, note 13.

established at medical schools, teaching hospitals, and public and private not-for-profit hospitals throughout the state in accordance with section s. 430.502, F.S.

MDCs receive performance based funding from the General Revenue.[42] In order to receive base level funding, MDCs must meet minimum performance measures established by DOEA. Incentive funding, subject to legislative approval, is available for MDCs that meet additional performance measures established by DOEA.[43] Performance measures are established by DOEA in its annual contracts with the MDCs.[44]

Each MDC receives $222,801 in base level funding.[45] Pursuant to the 2016-2017 contract, MDCs may receive up to $50,000 in incentive funding if the MDC meets any of the incentive performance measures.[46] The $50,000 incentive funding is allocated based on how many incentive performance measures the MDCs meet and is divided amongst all 15 MDCs.[47] For example, if all 15 MDCs achieved 10 of the incentive performance measures, the $50,000 would be divided by 10 and then by 15, resulting in each MDC receiving approximately $333.00 in incentive funding.

Section 430.502(1), F.S. expressly prohibits decreasing funding for MDCs funded as of June 30, 1995,[48] solely to accommodate subsequent MDC additions.[49]

The minimum performance measures for base level funding for Fiscal Year 2016-2017 are as follows.[50]

Quarterly Base Level Funding Measures	**Quarterly Minimum**
Unduplicated patients with symptoms of memory loss or other cognitive impairment that received diagnostic evaluation.	81
New persons with symptoms of memory loss or other cognitive impairment that received a diagnostic evaluation	25
Evaluations, reevaluations, and follow-ups	30
Referrals made	230
Percentage of patients with driving issues addressed	100%
Percentage of Silver Alerts received by MDC for which protocol forms were submitted to DOEA	100%
Percentage of patients informed of Brain Bank	100%
Percentage of patients that received information about community resources, including Silver Alert	100%
Training/education presentations, programs, events or support groups	6
Yearly Base Level Funding Measures	**Yearly Minimum**
Staff liaisons to Area Agencies on Aging/Aging and Disability Resource Centers	1
Specialized training programs provided for caregivers, caregiver groups/organizations and service providers	1
Hours of in-service training to ADI model day care and respite care providers	4
Service-related research projects	1
Percentage of subcontractors monitored	100%

[42] Section 430.502(3) and (4), F.S.; Department of Elder Affairs. *2017 Legislative Bill Analysis HB 883, March 9, 2017*. On file with Health Quality Subcommittee.
[43] Id.
[44] Section 430.502(3) and (4), F.S; Department of Elder Affairs. *Standard Contract-Alzheimer's Disease Initiative-Memory Disorder Clinic*, June 2016-July 2017. On file with the Health Quality Subcommittee.
[45] Department of Elder Affairs. *2017 Legislative Bill Analysis HB 883, March 9, 2017*. On file with Health Quality Subcommittee.
[46] *Supra*, note 44.
[47] *Supra*, note 45.
[48] Prior to 1995, MDCs were established at each of the three medical schools in the state, major private nonprofit research-oriented teaching hospital and in a public hospital that is operated by an independent special hospital taxing district that governs multiple hospitals and is located in a county with a population greater than 800,000 persons. *See s. 37, ch. 95-418 L.O.F.*
[49] Section 430.502 (1), F.S.
[50] Department of Elder Affairs. *Standard Contract-Alzheimer's Disease Initiative-Memory Disorder Clinic, June 2016-July 2017*. On file with the Health Quality Subcommittee.

To receive base level funding, MDCs must also operate Monday-Friday from 8 a.m.-5 p.m.

Fiscal Year 2016-2017 performance measures for incentive funding are as follows.[51]

Yearly Incentive Funding Measures	Yearly Minimum
Unduplicated patients with symptoms of memory loss or other cognitive impairment that received diagnostic evaluation.	486
New persons with symptoms of memory loss or other cognitive impairment that received a diagnostic evaluation	150
Evaluations, reevaluations, and follow-ups	180
Referrals made	1378
Medicaid patients that received diagnostic evaluation	12
Patients with commercial insurance policy that received diagnostic evaluation	125
In-person outreach to medical professionals to increase access to services	20
Education events conducted with community entities to increase awareness	4
Training/education presentations, programs, events or support groups	50
Outreach events in low-income or minority areas	4
Caregiver training events, programs or sessions with pre- and post-assessment	4
Caregiver trainings that included discussion of disaster preparedness	100%
Specialized training for law enforcement and/or first responders	1
Articles published in DOEA newsletter	1
Percentage of clients that would recommend MDC to others	85%
Service-related research projects	2
Research partners	4
Grants or contracts that provided additional funding	1
Total amount of institutional financial commitments received	$46,201
Newsletters, brochures, handouts by MDC; or MDC Coordinator Quarterly Meetings or ADI Advisory Committee meeting hosted by MDC; or Trainings provided in another language; or Leadership roles relating to dementia taken by MDC Coordinator/Administrator/Director	1

In the Fiscal Year 2015-2016, the MDCs:[52]

- Saw 4,745 new patients.
- Completed 9,810 medical memory evaluations.
- Conducted 1,529 free memory screenings.
- Made 26,739 referrals to medical or community services for patients and families.
- Provided 3,828 hours of training to 33,240 family caregivers, medical professionals, health students, social service workers, and the general public.
- Provided 7,131 family caregivers with educational training on how to care for a loved one at home who has dementia.
- Made 17,769 phone contacts to provide information and referrals to community resources that assist individuals affected by dementia.
- Followed up with family members upon the cancellation of 239 Silver Alerts to provide education, resources, and referrals to assist the recovered person and to help prevent future elopement.

[51] Id.
[52] Department of Elder Affairs, *Memory Disorder Clinic Statewide Report*, 2015-2016. Available at: http://elderaffairs.state.fl.us/doea/alz/MDC_Year_End_Summary_2015-2016.pdf (last visited March 18, 2017)

Florida Hospital Maturing Minds Clinic[53]

In 2012, Florida Hospital in Orange County established a self-funded memory disorder program, the Florida Hospital Maturing Minds Clinic (FHMMP). FHMMP serves patients with Alzheimer's disease and related disorders in Orange, Seminole and Osceola County. FHMMP provides early screening and diagnosis, management of symptoms, caregiver education and training, and conducts research. FHMMP conducts over 360 new patient memory loss evaluations per year.

Effect of Proposed Changes

HB 883 amends s. 430.502 by establishing a MDC at the Florida Hospital in Orange County, making it the16th MDC in Florida and the second located in Orlando. The bill does not provide any appropriation of funds to the MDC at the Florida Hospital.

The bill provides an effective date of July 1, 2017.

B. SECTION DIRECTORY:

Section 1: Amends s. 430.502 relating to Alzheimer's disease; memory disorder clinics and day care and respite care.
Section 2: Provides an effective date of July 1, 2017.

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:

The MDC at Orlando Health has a six-county service area which contains 62,684 probable persons living with Alzheimer's Disease. The Orlando Health MDC may see reduced numbers of clients served if patients begin visiting the new Florida Hospital MDC instead.[54]

D. FISCAL COMMENTS:

None.

[53] Jean Van Smith, Florida Hospital Government Relations, *Support HB 883/SB 1050, Memory Disorder Clinics*. On file with the Health Quality Subcommittee.
[54] *Supra*, note 45.

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:

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 memory disorder clinics; amending s. 430.502, F.S.; establishing a memory disorder clinic at Florida Hospital in Orange County; providing an effective date.

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

Section 1. Paragraphs (l) and (m) of subsection (1) of section 430.502, Florida Statutes, are amended, and paragraph (n) is added to that subsection, to read:

430.502 Alzheimer's disease; memory disorder clinics and day care and respite care programs.—

(1) There is established:

(l) A memory disorder clinic at Morton Plant Hospital, Clearwater, in Pinellas County; ~~and~~

(m) A memory disorder clinic at Florida Atlantic University, Boca Raton, in Palm Beach County; and~~,~~

(n) A memory disorder clinic at Florida Hospital in Orange County,

for the purpose of conducting research and training in a diagnostic and therapeutic setting for persons suffering from Alzheimer's disease and related memory disorders. However, memory disorder clinics funded as of June 30, 1995, shall not

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

receive decreased funding due solely to subsequent additions of memory disorder clinics in this subsection.

Section 2. This act shall take effect July 1, 2017.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1253 Rights and Responsibilities of Patients
SPONSOR(S): Harrison
TIED BILLS: **IDEN./SIM. BILLS:** SB 1206

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		Perdomo	McElroy
2) Health & Human Services Committee			

SUMMARY ANALYSIS

The Patient's Bill of Rights and Responsibilities, codified in s. 381.026, F.S., was created to promote better communication among patients and their health care providers and facilities while protecting patients' interests and well-being. This law requires health care providers to provide patients a general understanding of the procedures to be performed on them and with information concerning their health care so that they may make informed decisions. The Patient's Bill of Rights and Responsibilities also provides patients with a general understanding of their responsibilities toward health care providers and health care facilities.

Florida law requires health care facilities and health care providers to recognize the rights in the Patient's Bill of Rights and Responsibilities, and provide the patient with a summary of these rights if the patient requests a copy. Failure to do so can result in administrative fines imposed by the Agency for Health Care Administration, the Department of Health, or the appropriate regulatory board.

HB 1253 adds to the Patient's Bill of Rights and Responsibilities, to allow a patient to bring any person of his or her choosing to patient-accessible areas of a health care facility or a health care provider's office to accompany the patient while the patient is receiving inpatient or outpatient treatment or is consulting with his or her health care provider. The bill restricts any person or entity that may have a fiduciary interest affected by the patient's course of treatment from attending a consultation or attempting to change a prescribed course of treatment without the health care provider's consent.

In addition, the bill requires health care providers and health care facilities to include this new provision in the summary of rights and responsibilities provided to patients.

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

The bill provides an effective date of July 1, 2017.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Patient's Bill of Rights and Responsibilities

The Patient's Bill of Rights and Responsibilities, codified in s. 381.026, F.S, was created to promote better communication among patients and responsible health care providers and facilities while protecting patients' interests and well-being.[1] By understanding their rights and responsibilities, patients can make informed decisions concerning their health.[2] Section 381.0261(1), F.S. requires the Department of Health (DOH) to provide a summary of these rights on its website.[3]

The Patient's Bill of Rights and Responsibilities applies to health care facilities licensed under chapter 395 (hospitals, ambulatory surgical centers, and mobile surgical facilities)[4] and physicians licensed under chapter 458, 459, and 461 (allopathic, osteopathic, and podiatric physicians).[5] Health care facilities and health care providers are required to observe the following patient rights.

- **Individual dignity:** A patient has the right to be respected at all times, retains certain rights to privacy, and has a right to a prompt and reasonable response to a question or request. A health care facility shall respond in a reasonable manner to the request of a patient's health care provider for medical services to the patient. A patient also has a right in a health care facility to retain and use personal clothing or possessions as space permits.[6]
- **Information:** A patient has the right to know certain information like what patient support services are available in the facility, information concerning diagnosis, planned course of treatment, alternatives, risks, and prognosis, and the health care provider's or health care facility's procedures for expressing a grievance.[7]
- **Financial information and disclosure:** A patient has the right to certain financial information and disclosure like full information and necessary counseling on the availability of known financial resources for the patient's health care, access to a schedule of charges for the medical services that the provider offers to patients, and a copy of an itemized statement or bill upon request with an explanation upon request.[8]
- **Access to health care:** A patient has the right to impartial access to medical treatment or accommodations, regardless of race, national origin, religion, handicap, or source of payment. A patient also has the right to treatment for any emergency medical condition that will deteriorate from failure to provide such treatment as well as access any mode of treatment that is, in his or her own judgment and the judgment of his or her health care practitioner, in the best interests of the patient.[9]
- **Experimental research:** A patient has the right to know if medical treatment is for purposes of experimental research and to consent prior to participation in such experimental research. For any patient, regardless of ability to pay or source of payment for his or her care, participation

[1] S. 381.026, F.S.
[2] Id.
[3] S. 381.026(1), F.S.
[4] S. 381.026(2)(b), F.S.
[5] S. 381.026(2)(c), F.S.
[6] S. 381.026(4)(a), F.S.
[7] S. 381.026(4)(b), F.S.
[8] S. 381.026(4)(c), F.S.
[9] S. 381.026(4)(d), F.S.

must be a voluntary matter; and a patient has the right to refuse to participate. The patient's consent or refusal must be documented in the patient's care record. [10]

- **Patient's knowledge of rights and responsibilities:** In receiving health care, patients have the right to know what their rights and responsibilities are.[11]

Florida law requires that health care facilities and health care providers provide a patient with a summary of these rights if the patient requests a copy.

Enforcement

The Agency for Health Care Administration may impose an administrative fine against a health care facility when a health care facility fails to make the summary of rights available to its patients. For a first unintentional violation, the health care facility would not receive an administrative fine but would be subject to corrective action. AHCA may impose a fine against a health care facility of up to $5,000 for unintentional violations and a fine of up to $25,000 for willful and intentional violations.[12]

Regulatory boards may fine physicians when they fail to make the summary of rights available to their patients.[13] For initial unintentional violations, a health care provider would not receive an administrative fine but would be subject to corrective action.[14] A regulatory board or DOH may impose a fine of up to $100 against a health care provider for unintentional violations and a fine of up to $500 for willful violations.[15]

Health Insurance Portability and Accountability Act

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) protects personal health information. Privacy rules were initially issued in 2000 by the U.S. Department of Health and Human Services and later modified in 2002.[16] The rules address the use and disclosure of an individual's personal health information and create standards for information security. Only certain entities, "covered entities", are subject to HIPAA's provisions. Covered entities are obligated to meet HIPAA's requirements to ensure privacy and confidentiality personal health information. These "covered entities" include health plans, health care providers, health care clearinghouses, and business associates of any the preceding.[17]

HIPAA allows a covered entity to use or disclose protected health information, given that the individual is informed of the use or disclosure and has the opportunity to agree or disagree.[18] Under this section, a health care provider, using professional judgment, may discuss the patient's health information with a family member, friend or other person identified by the patient when the individual is not present, the individual does not have the opportunity to agree or disagree due to the individual's incapacity or an emergency circumstance, or the individual is deceased.[19] For example, an emergency room doctor may discuss a patient's treatment in front of the patient's friend if the patient asks that her friend come into the treatment room.[20]

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[10] S. 381.026(4)(e), F.S.
[11] S. 381.026(4)(f), F.S.
[12] S. 381.0261(4)(a), F.S.
[13] SS. 458.331, F.S., 459.015, F.S., and 461.013, F.S.
[14] S. 381.0261(4(b), F.S.
[15] Id.
[16] U.S. Department of Health and Human Services, *The Privacy Rule*, available at http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/ (last visited on March 18, 2017).
[17] U.S. Department of Health and Human Services, *For Covered Entities and Business Associates*, available at http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/ (last visited on March 18, 2017).
[18] 45 C.F.R. § 164.510.
[19] Id.
[20] U.S. Department of Health and Human Services, *Disclosures to Family and Friends*, available at https://www.hhs.gov/hipaa/for-professionals/faq/disclosures-to-family-and-friends (last visited March 19, 2017).

Alternative Decision Making

Current Florida law authorizes several ways for health care decisions to be made by someone other than the patient. Chapter 765 allows a competent individual to create a health care advance directive which allows the individual to designate a specific person to make health care decisions on his or her behalf if the individual were to become incapacitated. An advance directive can be executed by a witnessed written document or an oral statement with instructions regarding aspects of the individual's health care or health information.[21]

Surrogate

A surrogate is a competent adult who has been expressly designated to receive health information and make health care decisions by a principal, who is a competent adult executing a health care advance directive.[22] A surrogate can act on behalf of the principal regarding all health care decisions, provide informed or written consent, and receive access to appropriate health information.[23]

Durable Power of Attorney

A durable power of attorney can serve as an alternative to a health care surrogate. An agent (a person granted authority to act on behalf of the principal) can only act within the scope of authority granted.[24] The power of attorney is considered *durable* when it does not terminate by later incapacity of the principal.[25]

Proxy

A proxy is a competent adult who has not been specifically chosen to make health care decisions for a particular incapacitated patient but who is authorized to do so pursuant to s. 765.401.[26] The following individuals, in the following order of priority, would be authorized to serve as a proxy for an incapacitated or developmentally disabled patient:

- Judicially appointed guardian or guardian advocate.
- The patient's spouse.
- An adult child of the patient.
- A parent of the patient.
- An adult sibling of the patient.
- An adult relative of the patient who has demonstrated special concern and care for the patient.
- A close friend of the patient.
- A licensed clinical social worker pursuant to chapter 491.[27]

A proxy can make health care decisions on behalf of the patient based on what the proxy reasonably believes the patient would have decided under those given circumstances.[28]

National Action Plan to Improve Health Literacy

Health literacy is the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.[29] The National

[21] S. 765.101(1), F.S.
[22] S. 765.101(21), F.S.
[23] S. 765.205, F.S.
[24] S. 709.2114, F.S.
[25] S. 709.2104, F.S.
[26] S. 765.101(19), F.S.
[27] S. 765.401, F.S.
[28] Id.
[29] Id.

Action Plan to Improve Health Literacy (Plan) is an initiative by the U.S. Office of Disease Prevention and Health Promotion within the U.S. Department of Health and Human Services.[30] Among its seven goals and strategies to improve health literacy, the Plan seeks to promote changes in the health care system that improve health information, communication, informed decision-making, and access to health services.[31]

To improve communication among health care providers and patients, the Office of Disease Prevention and Health Promotion recommends that individuals volunteer to go with a family member or a friend to medical appointments, if possible, and help the patient ask questions and keep track of important notes.[32]

Effect of Proposed Changes

HB 1253 adds a new element to the Florida Patient's Bill of Rights and Responsibilities. The new provision would allow a patient to bring in any person of his or her choosing to patient-accessible areas of a health care facility or provider's office when the patient is receiving inpatient or outpatient treatment, or is consulting with his or her health care provider. The bill also requires health care facilities and health care providers to include this new element in the statement of rights and responsibilities made available to patients. The bill does not define "patient-accessible areas," so this could include any area the patient enters, like operating rooms.

The bill also restricts any person or entity that may have a fiduciary interest affected by the patient's course of treatment from attending a consultation or attempting to change a prescribed course of treatment without the health care provider's consent. It is unclear how a fiduciary interest would be verified by a health care provider or a health care facility. The bill's current language also suggests that a person or entity that does not have a fiduciary interest would have authority to change a prescribed course of treatment without the health care provider's consent.

As with the current provisions of the Patient's Bill of Rights and Responsibilities, this new element must be included in the summary required by s. 381.026(6), F.S., which hospitals, ambulatory surgery centers, and physicians must give to patients on request.

B. SECTION DIRECTORY:

Section 1: Amends s.381.026, relating to patient's bill of rights and responsibilities.
Section 2: Provides an effective date of July 1, 2017.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

[30] U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion, *National Action Plan to Improve Health Literacy*, https://health.gov/communication/HLActionPlan/pdf/Health_Literacy_Action_Plan.pdf (last visited March 18, 2017).
[31] Id.
[32] Id.

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:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to the rights and responsibilities of patients; amending s. 381.026, F.S.; requiring health care facilities and providers to authorize patients to bring in any person of the patients' choosing to specified areas of the facilities or providers' offices under certain circumstances; requiring health care facilities and providers to include such authorization as an additional patient standard in the statement of rights and responsibilities made available to patients by health care providers; providing an effective date.

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

Section 1. Paragraph (a) of subsection (4) and subsection (6) of section 381.026, Florida Statutes, are amended to read:

381.026 Florida Patient's Bill of Rights and Responsibilities.—

(4) RIGHTS OF PATIENTS.—Each health care facility or provider shall observe the following standards:

(a) *Individual dignity.*—

1. The individual dignity of a patient must be respected at all times and upon all occasions.

2. Every patient who is provided health care services

retains certain rights to privacy, which must be respected without regard to the patient's economic status or source of payment for his or her care. The patient's rights to privacy must be respected to the extent consistent with providing adequate medical care to the patient and with the efficient administration of the health care facility or provider's office. However, this subparagraph does not preclude necessary and discreet discussion of a patient's case or examination by appropriate medical personnel.

3. A patient has the right to a prompt and reasonable response to a question or request. A health care facility shall respond in a reasonable manner to the request of a patient's health care provider for medical services to the patient. The health care facility shall also respond in a reasonable manner to the patient's request for other services customarily rendered by the health care facility to the extent such services do not require the approval of the patient's health care provider or are not inconsistent with the patient's treatment.

4. A patient in a health care facility has the right to retain and use personal clothing or possessions as space permits, unless for him or her to do so would infringe upon the right of another patient or is medically or programmatically contraindicated for documented medical, safety, or programmatic reasons.

5. A patient receiving care in a health care facility or

in a provider's office has the right to bring any person of his or her choosing to the patient-accessible areas of the health care facility or provider's office to accompany the patient while the patient is receiving inpatient or outpatient treatment or is consulting with his or her health care provider. Any person or entity that may have a fiduciary interest affected by the patient's course of treatment may not attend a consultation or attempt to change a prescribed course of treatment without the health care provider's consent.

(6) SUMMARY OF RIGHTS AND RESPONSIBILITIES.—Any health care provider who treats a patient in an office or any health care facility licensed under chapter 395 that provides emergency services and care or outpatient services and care to a patient, or admits and treats a patient, shall adopt and make available to the patient, in writing, a statement of the rights and responsibilities of patients, including the following:

SUMMARY OF THE FLORIDA PATIENT'S BILL
OF RIGHTS AND RESPONSIBILITIES

Florida law requires that your health care provider or health care facility recognize your rights while you are receiving medical care and that you respect the health care provider's or health care facility's right to expect certain behavior on the part of patients. You may request a copy of the

full text of this law from your health care provider or health care facility. A summary of your rights and responsibilities follows:

A patient has the right to be treated with courtesy and respect, with appreciation of his or her individual dignity, and with protection of his or her need for privacy.

A patient has the right to a prompt and reasonable response to questions and requests.

A patient has the right to know who is providing medical services and who is responsible for his or her care.

A patient has the right to know what patient support services are available, including whether an interpreter is available if he or she does not speak English.

A patient has the right to bring any person of his or her choosing to the patient-accessible areas of the health care facility or provider's office to accompany the patient while the patient is receiving inpatient or outpatient treatment or is consulting with his or her health care provider, except that any person or entity that may have a fiduciary interest affected by the patient's course of treatment may not attend a consultation or attempt to change a prescribed course of treatment without the health care provider's consent.

A patient has the right to know what rules and regulations apply to his or her conduct.

A patient has the right to be given by the health care

provider information concerning diagnosis, planned course of treatment, alternatives, risks, and prognosis.

A patient has the right to refuse any treatment, except as otherwise provided by law.

A patient has the right to be given, upon request, full information and necessary counseling on the availability of known financial resources for his or her care.

A patient who is eligible for Medicare has the right to know, upon request and in advance of treatment, whether the health care provider or health care facility accepts the Medicare assignment rate.

A patient has the right to receive, upon request, prior to treatment, a reasonable estimate of charges for medical care.

A patient has the right to receive a copy of a reasonably clear and understandable, itemized bill and, upon request, to have the charges explained.

A patient has the right to impartial access to medical treatment or accommodations, regardless of race, national origin, religion, handicap, or source of payment.

A patient has the right to treatment for any emergency medical condition that will deteriorate from failure to provide treatment.

A patient has the right to know if medical treatment is for purposes of experimental research and to give his or her consent or refusal to participate in such experimental research.

A patient has the right to express grievances regarding any violation of his or her rights, as stated in Florida law, through the grievance procedure of the health care provider or health care facility which served him or her and to the appropriate state licensing agency.

A patient is responsible for providing to the health care provider, to the best of his or her knowledge, accurate and complete information about present complaints, past illnesses, hospitalizations, medications, and other matters relating to his or her health.

A patient is responsible for reporting unexpected changes in his or her condition to the health care provider.

A patient is responsible for reporting to the health care provider whether he or she comprehends a contemplated course of action and what is expected of him or her.

A patient is responsible for following the treatment plan recommended by the health care provider.

A patient is responsible for keeping appointments and, when he or she is unable to do so for any reason, for notifying the health care provider or health care facility.

A patient is responsible for his or her actions if he or she refuses treatment or does not follow the health care provider's instructions.

A patient is responsible for assuring that the financial obligations of his or her health care are fulfilled as promptly

as possible.

A patient is responsible for following health care facility rules and regulations affecting patient care and conduct.

Section 2. This act shall take effect July 1, 2017.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1269 Child Protection
SPONSOR(S): Harrell
TIED BILLS: **IDEN./SIM. BILLS:** SB 1454

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		Tuszynski TT	McElroy CM
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

A child protection team (CPT) is a medically directed, multidisciplinary team that supplements the child protective investigation efforts of the Department of Children and Families (DCF) and local sheriffs' offices in cases of child abuse and neglect. CPTs provide expertise in evaluating alleged child abuse and neglect, assess risk and protective factors, and provide recommendations for interventions. The Statewide Medical Director for Child Protection supervises and evaluates all child protection team medical directors for each of the 15 CPTs statewide within the 15 districts.

One of the most significant interventions into the incidence of child abuse and neglect in the U.S. is "forensic interviewing," a method to elicit accurate information from children regarding abuse and neglect during an investigation. Although national training programs in child forensic interviewing are generally based on the same body of research and practice, practice is no standardized. Differences in child forensic interviewing exist due to the blending of different models at the local level, jurisdictional expectations, state statutes, and case law.

Sections 458.3175 and 459.0066, F.S., require an expert witness who is licensed in another jurisdiction to obtain an "expert witness certificate" from DOH before providing expert testimony in medical negligence and criminal child abuse and neglect cases.

HB 1269 amends s. 39.303, F.S., to require the Surgeon General and Deputy Secretary for Children's Medical Services to consult with the Statewide Medical Director for Child Protection on decisions regarding screening, employment, and termination of child protection team medical directors at headquarters and within the 15 districts statewide. The bill also deletes a requirement for CPT and DCF to collaborate on ensuring proper referrals of mandatory cases are made to the CPT program.

The bill requires DOH to convene a task force to develop a standardized protocol for forensic interviewing for children suspected of having been abused and provide staff to support the task force, as needed. The task force must include various representatives from the disciplines of law enforcement, child welfare, and mental health treatment. The bill does not require implementation of the standardized protocol but does require DOH to provide to protocol to the legislature by January 1, 2018.

The bill expands the cases in which an expert witness certificate may be used, to include cases involving abandonment, dependency, and sexual abuse.

The bill has an insignificant positive fiscal impact on DOH, and does not have a fiscal impact on local government.

The bill provides an effective date of July 1, 2017.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

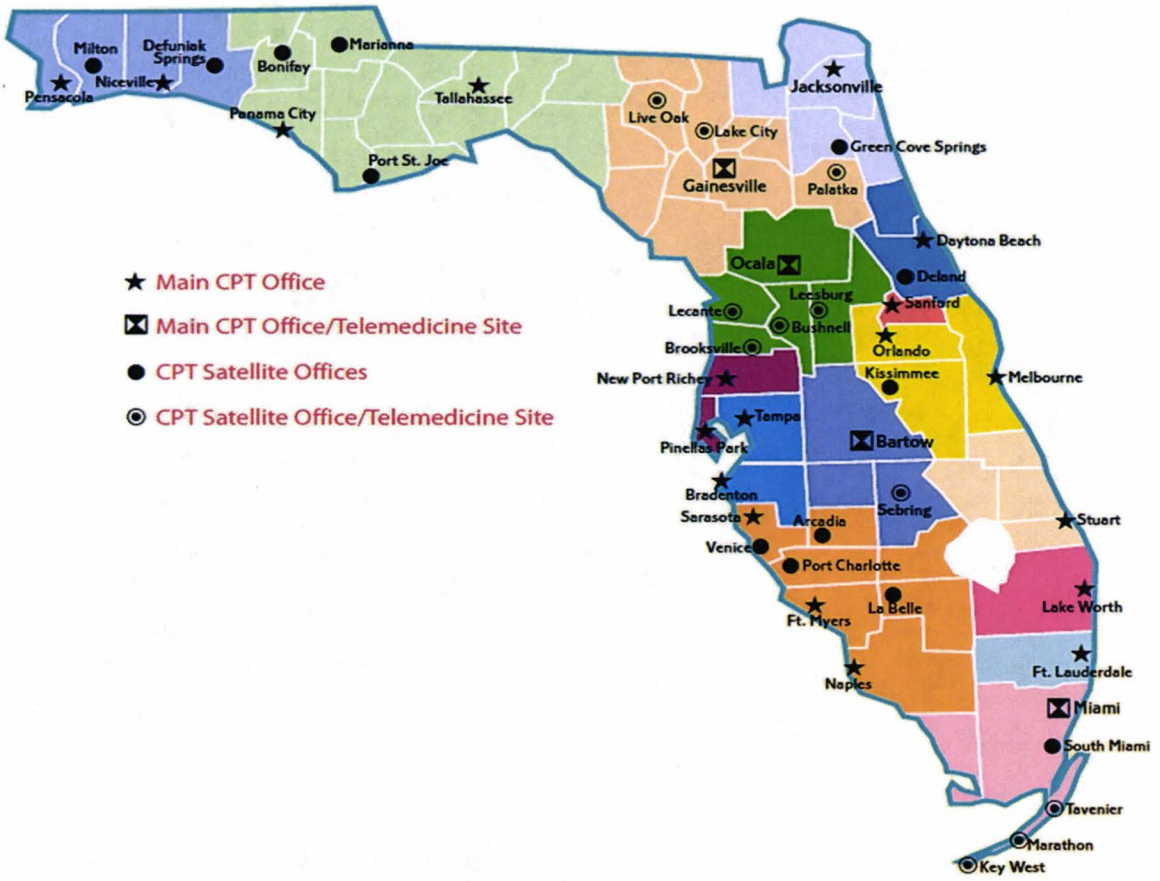
A. EFFECT OF PROPOSED CHANGES:

Background

Child Protection Teams

A child protection team (CPT) is a medically directed, multidisciplinary team that supplements the child protective investigation efforts of the Department of Children and Families (DCF) and local sheriffs' offices in cases of child abuse and neglect.[1] CPTs are independent community-based programs that provide expertise in evaluating alleged child abuse and neglect, assess risk and protective factors, and provide recommendations for interventions to protect children and enhance a caregiver's capacity to provide a safer environment when possible.[2] The Department of Health (DOH) Children's Medical Services (CMS) program contracts for CPT services with local community-based programs.[3]

CPTs across the state are divided into 15 districts and provide services to all 67counties by utilizing satellite offices and telemedicine sites.[4] Each of the 15 districts served by CPTs are supervised by one or multiple child protection team medical directors, depending on the size and subdivision of the particular district.[5]



[1] Florida Department of Health, Children's Medical Services. *Child Protection Teams* http://www.floridahealth.gov/AlternateSites/CMS-Kids/families/child_protection_safety/child_protection_teams.html (last visited March 10, 2015).
[2] Id.
[3] Section 39.303, F.S.
[4] Children's Medical Services, *Child Protection Teams: CPT Statewide Directory*, available at http://www.floridahealth.gov/alternatesites/cms-kids/home/contact/cpt.pdf (last accessed March 12, 2015).
[5] Id.

The State Surgeon General and the DOH Deputy Secretary for Children's Medical Services, in consultation with the DCF Secretary, screen, employ, and terminate the Statewide Medical Director for Child Protection as well as the district-level child protection team medical directors.[6] The Statewide Medical Director for Child Protection must be a board-certified pediatrician licensed under ch. 458 or ch. 459, F.S., with a subspecialty certification in child abuse from the American Board of Pediatrics.[7] A district child protection team medical director must be board-certified pediatrician licensed under ch. 458 or ch. 459, F.S., and within 4 years after the date of his or her employment obtain a subspecialty certification in child abuse from the American Board of Pediatrics or meet the minimum credentialing requirements established by a third-party credentialing entity recognizing specialized competence in child abuse pediatrics.[8]

Certain reports of child abuse, abandonment, and neglect to the DCF central abuse hotline must be referred to child protection teams:

- Injuries to the head, bruises to the neck or head, burns, or fractures in a child of any age.
- Bruises anywhere on a child five years of age or younger.
- Any report alleging sexual abuse of a child.
- Any sexually transmitted disease in a prepubescent child.
- Reported malnutrition or failure of a child to thrive.
- Reported medical neglect of a child.
- A sibling or other child remaining in a home where one or more children have been pronounced dead on arrival or have been injured and later died as a result of suspected abuse, abandonment or neglect.
- Symptoms of serious emotional problems in a child when emotional or other abuse, abandonment, or neglect is suspected.[9]

When a CPT accepts a referral from DCF or law enforcement, it may provide one or more of the following services:

- Medical diagnosis and evaluation;
- Child forensic interviews;
- Child and family assessments;
- Multidisciplinary staffings;
- Psychological and psychiatric evaluations;
- Community awareness campaigns; and
- Expert court testimony. [10]

CPT staff also provide training services for child protection investigators, community providers of child welfare services, and emergency room staff and other medical providers in the community.[11]

Forensic Interviewing of Child Victims of Abuse, Abandonment, and Neglect

One of the most significant developments in child abuse and neglect intervention has centered on how to elicit accurate information from children, a process commonly referred to as "forensic interviewing."[12]

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[6] Supra, FN 3.
[7] S. 39.303(2)(a), F.S.
[8] S. 39.303(2)(b), F.S.
[9] S. 39.303(4), F.S.
[10] S. 39.303(3), F.S.
[11] S. 39.303(3)(h), F.S.
[12] Saywitz, K.J., Lyon, T.D., and Goodman, G.S., Interviewing children, *The APSAC Handbook on Child Maltreatment*, 3d ed., 2011, pg. 337–360.

Forensic interviewing began after several high-profile cases in the 1980s involving allegations of daycare providers sexually abusing multiple children in their care became the subject of analysis based on the interview techniques that were used.[13] Law enforcement had relied on mental health practitioners because of their ability to establish and build rapport with children. However, these mental health practitioners used therapeutic techniques that were later deemed inappropriate for forensic purposes due to concerns of suggestibility and the encouragement of make-believe and pretend.[14]

Most child abuse investigations begin with a child forensic interview.[15] Most jurisdictions follow an established forensic interview model or protocol to guide the interviewer through various stages of a legally sound interview; these models vary in structure from highly scripted to semi-structured to flexible.[16] While there are various levels of structure, all models incorporate three general phases.

1. The **rapport-building phase** typically involves introductions with age-appropriate explanation of documentation methods, a review of the interview instructions, a discussion on the importance of telling the truth, and practice providing narrative answers and episodic memory training.
2. The **substantive phase** involves a narrative description of the events, detail-seeking strategies, clarification, and alternate hypothesis testing, when appropriate.
3. The **closure phase** that involves attention to the child's socioemotional needs, transition to nonsubstantive topics, allowing for questions, and discussion of safety or educational messages.[17]

People from multiple disciplines attend, or later review, the interview: child protective investigators; police officers and other law enforcement officials; child protection attorneys; victim advocates; and medical and mental health care practitioners. The interview provides facts and direction for those involved with the investigation and provision of services.[18]

Following two decades of research and practice, professionals have gained significant insight into how to maximize children's potential to accurately convey information about their past experiences. The multidisciplinary approach to child forensic interviews has proven to reduce fragmented and duplicative child abuse investigations, be more child-friendly, and better meet the needs of children and their families.[19] Yet, as this effort continues and practice evolves, professionals face new challenges in forensic interviewing.[20] Although national training programs in child forensic interviewing are generally based on the same body of research and practice, the field has yet to determine one standardized practice.[21] Differences in child forensic interviewing exist due to the blending of different models at the local level, jurisdictional expectations, state statute, and case law.[22] These local variations demonstrate the difficulty in creating one standard approach.

Quality Assurance Collaboration

Section 39.303(8), F.S., requires the DOH CPT quality assurance program to collaborate with DCF to ensure referrals and responses to child abuse, abandonment, and neglect reports are appropriate and review records in which there are no findings of abuse, abandonment, or neglect. Currently, the CPT program reviews every case referred to DCF and determines whether the case is of the 8 types

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[13] U.S. Department of Justice, Office of Juvenile Justice and Delinquency Prevention, Juvenile Justice Bulletin, *Child Forensic Interviewing: Best Practices*, September 2015, pg. 3, available at: https://www.ojjdp.gov/pubs/248749.pdf (last accessed March 17, 2017).
[14] Id.
[15] Id.
[16] Id.
[17] Id, at pg. 7.
[18] Id.
[19] Bonarch, K., Mabry, J.B., and Potts-Henry, C., 2010, *Exploring nonoffending caregiver satisfaction with a children's advocacy centers*, Journal of Child Sexual Abuse 19(6):687–708.
[20] Supra, FN 13 at pg. 1.
[21] Supra, FN 13 at pg. 2.
[22] Supra, FN 13 at pg. 3.

considered mandatory for CPT referral.[23] CPT tracks and reviews, as part of its quality assurance program, all cases without findings of abuse, abandonment, or neglect.

Expert Testimony in Child Abuse Cases and Expert Witness Certificates

Sections 458.3175 and 459.0066, F.S., require an expert witness who is licensed in another jurisdiction to obtain an "expert witness certificate" from DOH before providing expert testimony in medical negligence and criminal child abuse and neglect cases. The certificate has an application fee of $50, is valid for 2 years, and only authorizes the physician to do the following:

- Provide a verified written medical expert opinion;
- Provide expert testimony about the prevailing professional standard of care in connection with medical negligence litigation pending in this state against a physician licensed in Florida; and
- Provide expert testimony in criminal child abuse and neglect cases.[24]

Section 827.03(3), F.S., allows expert testimony in child abuse and neglect cases by physicians licensed under chapter 458, F.S., or 459, F.S., or by physicians who have obtained an expert witness certification. To provide expert testimony of mental injury in child abuse and neglect cases, physicians must be licensed under chapter 458, F.S., or 459, F.S., and have completed an accredited residency in psychiatry, or obtained an expert witness certification.

While s. 827.03, F.S., allows experts to testify in criminal child abuse and neglect cases if they have an expert witness certificate, ss. 458.3175(2) and 459.0066(2), F.S., only authorize a very narrow enumerated use of this certificate and does not currently allow physicians or osteopathic physicians to give expert testimony in dependency cases, which are non-criminal proceedings for children who have been abused, abandoned or neglected. The purpose of the dependency court is to protect children from further incidences of abuse while providing services to rehabilitate the family and increase the child protective capacity of parents.

Effect of the Proposed Language

Child Protection Teams

HB 1269 amends s. 39.303, F.S., to require the Surgeon General and Deputy Secretary for Children's Medical Services to consult with the Statewide Medical Director for Child Protection on decisions regarding screening, employment, and termination of child protection team medical directors at headquarters and within the 15 districts statewide.

The Statewide Medical Director for Child Protection is an employee of DOH and has the responsibility to supervise and evaluate all child protection team medical directors in the districts, including corrective actions and recommendations for termination, if appropriate.[25] This bill would expand the responsibilities of the Statewide Medical Director for Child Protection to also make recommendations on the screening and employment of child protection team medical directors.

Forensic Interviewing of Child Victims of Abuse, Abandonment, and Neglect

The bill requires CMS to convene a task force to develop a standardized protocol for forensic interviewing for children suspected of having been abused. DOH is required to provide staff to support the task force, as needed. The task force must include the Statewide Medical Director for Child protection, the executive director of the Guardian ad Litem program, and representatives from the

[23] Florida Department of Health, *Agency Analysis of 2017 House Bill 1269*, March 6, 2017, pg. 2 (on file with Health Quality Subcommittee).
[24] S. 758.3175(2), F.S.
[25] Supra, FN 23.

Florida Prosecuting Attorneys Association, the Florida Psychological Association, the Florida Public Defender Association, Children's Medical Services, a community-based care lead agency, and others designated by Children's Medical Services.

The bill requires the task force to provide the standardized protocol for forensic interviewing to the President of the Senate and the Speaker of the House by January 1, 2018. The bill does not require implementation of the protocol.

Quality Assurance Collaboration

The bill deletes s. 39.303(8), F.S., that requires the CPT quality assurance program and DCF to collaborate and ensure proper referral of mandatory cases to CPT. Section 39.303(1), F.S., requires an interagency agreement between DOH and DCF establishing the protocols for the operation of the CPT. DOH and DCF can address appropriate referrals through this agreement.[26]

Expert Testimony in Child Abuse Cases and Expert Witness Certificates

The bill expands the cases in which an expert witness certificate may be used. Sections 458.3175, 459.0066, and 827.03, F.S., are amended to include cases involving abandonment, dependency, and sexual abuse. This change allows physicians from other jurisdictions who hold an expert witness certification to provide expert testimony in criminal child abuse and neglect cases to also provide expert testimony in dependency court and cases involving sexual abuse.

The bill provides for an effective date of July 1, 2017.

B. SECTION DIRECTORY:

Section 1: Amends s. 39.303, F.S., relating to child protection teams; services; eligible cases.
Section 2: Amends s. 458.3175, F.S., relating to expert witness certificate.
Section 3: Amends s. 459.0066, F.S., relating to expert witness certificate.
Section 4: Amends s. 827.03, F.S., relating to expert testimony.
Section 5: Provides for an effective date of July 1, 2017.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   The bill has an insignificant positive fiscal impact on DOH. The number of increased witness certification applications and the amount of additional fees collected is unknown. This number is not expected to be significant.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

[26] Supra, FN 23 at pg. 3.

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 local or county government.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

Not applicable.

C. DRAFTING ISSUES OR OTHER COMMENTS:

Line 36 requires the State Surgeon General and the DOH Deputy Secretary for Children's Medical Services to consult with the Statewide Medical Director for Child Protection on the termination of the Statewide Medical Director for Child Protection.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to child protection; amending s. 39.303, F.S.; revising the entities responsible for screening, employing, and terminating child protection team medical directors to include the Statewide Medical Director for Child Protection; requiring Children's Medical Services to convene a task force to develop a protocol for forensic interviewing of children suspected of having been abused; deleting provisions requiring certain entities to collaborate to ensure referrals and responses to certain child reports are appropriate; amending ss. 458.3175, 459.0066, and 827.03, F.S.; revising provisions regarding expert testimony provided by certain entities to include neglect, abandonment, dependency, and sexual abuse cases; providing an effective date.

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

Section 1. Subsections (1) and (8) of section 39.303, Florida Statutes, are amended to read:

39.303 Child protection teams; services; eligible cases.—

(1) The Children's Medical Services Program in the Department of Health shall develop, maintain, and coordinate the services of one or more multidisciplinary child protection teams

in each of the service districts of the Department of Children and Families. Such teams may be composed of appropriate representatives of school districts and appropriate health, mental health, social service, legal service, and law enforcement agencies. The Department of Health and the Department of Children and Families shall maintain an interagency agreement that establishes protocols for oversight and operations of child protection teams and sexual abuse treatment programs. The State Surgeon General and the Deputy Secretary for Children's Medical Services, in consultation with the Statewide Medical Director for Child Protection and the Secretary of Children and Families, shall maintain the responsibility for the screening, employment, and, if necessary, the termination of child protection team medical directors, at headquarters and in the 15 districts.

(8)(a) Children's Medical Services shall convene a task force to develop a standardized protocol for forensic interviewing of children suspected of having been abused. The Department of Health shall provide staff to the task force as necessary. The task force shall include:

1. A representative from the Florida Prosecuting Attorneys Association.

2. A representative from the Florida Psychological Association.

3. The Statewide Medical Director for Child Protection.

4. A representative from the Florida Public Defender Association.

5. The executive director of the Statewide Guardian Ad Litem Office.

6. A representative from a community-based care lead agency.

7. A representative from Children's Medical Services.

8. Others designated by Children's Medical Services.

(b) Children's Medical Services shall provide the standardized protocol to the President of the Senate and the Speaker of the House of Representatives by January 1, 2018.

(c) Members of the task force are not entitled to per diem or other payment for service on the task force ~~The Department of Health child protection team quality assurance program and the Family Safety Program Office of the Department of Children and Families shall collaborate to ensure referrals and responses to child abuse, abandonment, and neglect reports are appropriate. Each quality assurance program shall include a review of records in which there are no findings of abuse, abandonment, or neglect, and the findings of these reviews shall be included in each department's quality assurance reports~~.

Section 2. Paragraph (c) of subsection (2) of section 458.3175, Florida Statutes, is amended to read:

458.3175 Expert witness certificate.—

(2) An expert witness certificate authorizes the physician

to whom the certificate is issued to do only the following:

(c) Provide expert testimony in criminal child abuse, ~~and~~ neglect, abandonment, dependency, and sexual abuse cases in this state.

Section 3. Paragraph (c) of subsection (2) of section 459.0066, Florida Statutes, is amended to read:

459.0066 Expert witness certificate.—

(2) An expert witness certificate authorizes the physician to whom the certificate is issued to do only the following:

(c) Provide expert testimony in criminal child abuse, ~~and~~ neglect, abandonment, dependency, and sexual abuse cases in this state.

Section 4. Paragraph (d) of subsection (3) of section 827.03, Florida Statutes, is amended to read:

827.03 Abuse, aggravated abuse, and neglect of a child; penalties.—

(3) EXPERT TESTIMONY.—

(d) The expert testimony requirements of this subsection apply only to criminal child abuse, neglect, abandonment, dependency, and sexual abuse cases in this state and not to family court ~~or dependency court~~ cases.

Section 5. This act shall take effect July 1, 2017.

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 Quality Subcommittee

Representative Harrell offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Section 39.303, Florida Statutes, is amended to read:

39.303 Child protection teams and sexual abuse treatment programs; services; eligible cases.—

(1) The Children's Medical Services Program in the Department of Health shall develop, maintain, and coordinate the services of one or more multidisciplinary child protection teams in each of the service circuits ~~districts~~ of the Department of Children and Families. Such teams may be composed of appropriate representatives of school districts and appropriate health,

mental health, social service, legal service, and law enforcement agencies. The Department of Health and the Department of Children and Families shall maintain an interagency agreement that establishes protocols for oversight and operations of child protection teams and sexual abuse treatment programs. The State Surgeon General and the Deputy Secretary for Children's Medical Services, in consultation with the Secretary of Children and Families and the Statewide Medical Director for Child Protection, shall maintain the responsibility for the screening, employment, and, if necessary, the termination of child protection team medical directors~~, at headquarters and~~ in the 15 circuits ~~districts~~.

(2)(a) The Statewide Medical Director for Child Protection must be a physician licensed under chapter 458 or chapter 459 who is a board-certified pediatrician with a subspecialty certification in child abuse from the American Board of Pediatrics.

(b) Each child protection team ~~district~~ medical director must be a physician licensed under chapter 458 or chapter 459 who is a board-certified physician in pediatrics or family medicine ~~pediatrician~~ and, within 2 ~~4~~ years after the date of ~~his or her~~ employment as a child protection team ~~district~~ medical director, obtains ~~either obtain~~ a subspecialty certification in child abuse from the American Board of Pediatrics or within 2 years meet the minimum requirements

established by a third-party credentialing entity recognizing a demonstrated specialized competence in child abuse pediatrics pursuant to paragraph (d). Each child protection team ~~district~~ medical director employed on July 1, 2015, must, within 2 ~~4~~ years, either obtain a subspecialty certification in child abuse from the American Board of Pediatrics or meet the minimum requirements established by a third-party credentialing entity recognizing a demonstrated specialized competence in child abuse pediatrics pursuant to paragraph (d). Child protection team medical directors shall be responsible for oversight of the teams in the circuits ~~districts~~.

(c) All medical personnel participating on a child protection team must successfully complete the required child protection team training curriculum as set forth in protocols determined by the Deputy Secretary for Children's Medical Services and the Statewide Medical Director for Child Protection.

(d) Contingent on appropriations, the Department of Health shall approve one or more third-party credentialing entities for the purpose of developing and administering a professional credentialing program for child protection team ~~district~~ medical directors. Within 90 days after receiving documentation from a third-party credentialing entity, the department shall approve a third-party credentialing entity that demonstrates compliance with the following minimum standards:

1. Establishment of child abuse pediatrics core competencies, certification standards, testing instruments, and recertification standards according to national psychometric standards.

2. Establishment of a process to administer the certification application, award, and maintenance processes according to national psychometric standards.

3. Demonstrated ability to administer a professional code of ethics and disciplinary process that applies to all certified persons.

4. Establishment of, and ability to maintain, a publicly accessible Internet-based database that contains information on each person who applies for and is awarded certification, such as the person's first and last name, certification status, and ethical or disciplinary history.

5. Demonstrated ability to administer biennial continuing education and certification renewal requirements.

6. Demonstrated ability to administer an education provider program to approve qualified training entities and to provide precertification training to applicants and continuing education opportunities to certified professionals.

(3) The Department of Health shall use and convene the <u>child protection</u> teams to supplement the assessment and protective supervision activities of the family safety and preservation program of the Department of Children and Families.

This section does not remove or reduce the duty and responsibility of any person to report pursuant to this chapter all suspected or actual cases of child abuse, abandonment, or neglect or sexual abuse of a child. The role of the child protection teams shall be to support activities of the program and to provide services deemed by the child protection teams to be necessary and appropriate to abused, abandoned, and neglected children upon referral. The specialized diagnostic assessment, evaluation, coordination, consultation, and other supportive services that a child protection team shall be capable of providing include, but are not limited to, the following:

(a) Medical diagnosis and evaluation services, including provision or interpretation of X rays and laboratory tests, and related services, as needed, and documentation of related findings.

(b) Telephone consultation services in emergencies and in other situations.

(c) Medical evaluation related to abuse, abandonment, or neglect, as defined by policy or rule of the Department of Health.

(d) Such psychological and psychiatric diagnosis and evaluation services for the child or the child's parent or parents, legal custodian or custodians, or other caregivers, or any other individual involved in a child abuse, abandonment, or neglect case, as the team may determine to be needed.

(e) Expert medical, psychological, and related professional testimony in court cases.

(f) Case staffings to develop treatment plans for children whose cases have been referred to the team. A child protection team may provide consultation with respect to a child who is alleged or is shown to be abused, abandoned, or neglected, which consultation shall be provided at the request of a representative of the family safety and preservation program or at the request of any other professional involved with a child or the child's parent or parents, legal custodian or custodians, or other caregivers. In every such child protection team case staffing, consultation, or staff activity involving a child, a family safety and preservation program representative shall attend and participate.

(g) Case service coordination and assistance, including the location of services available from other public and private agencies in the community.

(h) Such training services for program and other employees of the Department of Children and Families, employees of the Department of Health, and other medical professionals as is deemed appropriate to enable them to develop and maintain their professional skills and abilities in handling child abuse, abandonment, and neglect cases.

(i) Educational and community awareness campaigns on child abuse, abandonment, and neglect in an effort to enable citizens

more successfully to prevent, identify, and treat child abuse, abandonment, and neglect in the community.

(j) Child protection team assessments that include, as appropriate, medical evaluations, medical consultations, family psychosocial interviews, specialized clinical interviews, or forensic interviews.

A child protection team that is evaluating a report of medical neglect and assessing the health care needs of a medically complex child shall consult with a physician who has experience in treating children with the same condition.

(4) The child abuse, abandonment, and neglect reports that must be referred by the department to child protection teams of the Department of Health for an assessment and other appropriate available support services as set forth in subsection (3) must include cases involving:

(a) Injuries to the head, bruises to the neck or head, burns, or fractures in a child of any age.

(b) Bruises anywhere on a child 5 years of age or under.

(c) Any report alleging sexual abuse of a child.

(d) Any sexually transmitted disease in a prepubescent child.

(e) Reported malnutrition of a child and failure of a child to thrive.

(f) Reported medical neglect of a child.

(g) Any family in which one or more children have been pronounced dead on arrival at a hospital or other health care facility, or have been injured and later died, as a result of suspected abuse, abandonment, or neglect, when any sibling or other child remains in the home.

(h) Symptoms of serious emotional problems in a child when emotional or other abuse, abandonment, or neglect is suspected.

(5) All abuse and neglect cases transmitted for investigation to a circuit district by the hotline must be simultaneously transmitted to the Department of Health child protection team for review. For the purpose of determining whether face-to-face medical evaluation by a child protection team is necessary, all cases transmitted to the child protection team which meet the criteria in subsection (4) must be timely reviewed by:

(a) A physician licensed under chapter 458 or chapter 459 who holds board certification in pediatrics and is a member of a child protection team;

(b) A physician licensed under chapter 458 or chapter 459 who holds board certification in a specialty other than pediatrics, who may complete the review only when working under the direction of the child protection team medical director or a physician licensed under chapter 458 or chapter 459 who holds board certification in pediatrics and is a member of a child protection team;

(c) An advanced registered nurse practitioner licensed under chapter 464 who has a specialty in pediatrics or family medicine and is a member of a child protection team;

(d) A physician assistant licensed under chapter 458 or chapter 459, who may complete the review only when working under the supervision of the child protection team medical director or a physician licensed under chapter 458 or chapter 459 who holds board certification in pediatrics and is a member of a child protection team; or

(e) A registered nurse licensed under chapter 464, who may complete the review only when working under the direct supervision of the child protection team medical director or a physician licensed under chapter 458 or chapter 459 who holds board certification in pediatrics and is a member of a child protection team.

(6) A face-to-face medical evaluation by a child protection team is not necessary when:

(a) The child was examined for the alleged abuse or neglect by a physician who is not a member of the child protection team, and a consultation between the child protection team medical director or a child protection team board-certified pediatrician, advanced registered nurse practitioner, physician assistant working under the supervision of a child protection team medical director or a child protection team board-certified pediatrician, or registered nurse working under the direct

supervision of a child protection team medical director or a child protection team board-certified pediatrician, and the examining physician concludes that a further medical evaluation is unnecessary;

(b) The child protective investigator, with supervisory approval, has determined, after conducting a child safety assessment, that there are no indications of injuries as described in paragraphs (4)(a)-(h) as reported; or

(c) The child protection team medical director or a child protection team board-certified pediatrician, as authorized in subsection (5), determines that a medical evaluation is not required.

Notwithstanding paragraphs (a), (b), and (c), a child protection team medical director or a child protection team pediatrician, as authorized in subsection (5), may determine that a face-to-face medical evaluation is necessary.

(7) In all instances in which a child protection team is providing certain services to abused, abandoned, or neglected children, other offices and units of the Department of Health, and offices and units of the Department of Children and Families, shall avoid duplicating the provision of those services.

(8) The Department of Health child protection team quality assurance program and the Family Safety Program Office of the

Department of Children and Families shall collaborate to ensure referrals and responses to child abuse, abandonment, and neglect reports are appropriate. Each quality assurance program shall include a review of records in which there are no findings of abuse, abandonment, or neglect, and the findings of these reviews shall be included in each department's quality assurance reports.

(9) Children's Medical Services shall convene a task force to develop a standardized protocol for forensic interviewing of children suspected of having been abused. The Department of Health shall provide staff to the task force as necessary. The task force shall include:

1. A representative from the Florida Prosecuting Attorneys Association.

2. A representative from the Florida Psychological Association.

3. The Statewide Medical Director for Child Protection.

4. A representative from the Florida Public Defender Association.

5. The executive director of the Statewide Guardian Ad Litem Office.

6. A representative from a community-based care lead agency.

7. A representative from Children's Medical Services.

8. A representative from the Florida Sheriffs Association.

9. A representative from the Florida Chapter American Academy of Pediatrics.

10. A representative from the Florida Network of Children's Advocacy Centers.

11. Others designated by Children's Medical Services.

(b) Children's Medical Services must provide the standardized protocol to the President of the Senate and the Speaker of the House of Representatives by July 1, 2018.

(c) Members of the task force are not entitled to per diem or other payment for service on the task force.

(10) The Department of Health Children's Medical Services Program shall develop, maintain, and coordinate the services of one or more sexual abuse treatment programs.

(a) A child under the age of 18, who is alleged to be a victim of sexual abuse, his or her siblings, non-offending caregivers, and family members who have been impacted by sexual abuse are eligible for services.

(b) Sexual abuse treatment programs must provide specialized therapeutic treatment to child sexual abuse victims, his or her siblings, non-offending caregivers, and family members to assist in recovery from sexual abuse, to prevent developmental impairment, to restore the child's pre-abuse level of developmental functioning, and to promote healthy, non-abusive relationships. Therapeutic intervention services include crisis intervention, clinical treatment, and individual,

family, and group therapy.

(c) The sexual abuse treatment programs and child protection teams must provide referrals for child victims of sexual abuse and their families, as appropriate.

Section 2. Section 39.3031, Florida Statutes, is amended to read:

39.3031 Rules for implementation of s. 39.303.—The Department of Health, in consultation with the Department of Children and Families, shall adopt rules governing the child protection teams and sexual abuse treatment programs pursuant to s. 39.303, including definitions, organization, roles and responsibilities, eligibility, services and their availability, qualifications of staff, and a waiver-request process.

Section 3. Paragraph (c) of subsection (2) of section 458.3175, Florida Statutes, is amended to read:

458.3175 Expert witness certificate.—

(2) An expert witness certificate authorizes the physician to whom the certificate is issued to do only the following:

(c) Provide expert testimony in criminal child abuse and neglect cases pursuant to ch. 827, dependency cases pursuant to ch. 39, and cases involving sexual battery of a child pursuant to ch. 794 in this state.

Section 4. Paragraph (c) of subsection (2) of section 459.0066, Florida Statutes, is amended to read:

459.0066 Expert witness certificate.—

(2) An expert witness certificate authorizes the physician to whom the certificate is issued to do only the following:

(c) Provide expert testimony in criminal child abuse and neglect cases pursuant to ch. 827, dependency cases pursuant to ch. 39, and cases involving sexual battery of a child pursuant to ch. 794 in this state.

Section 5. Paragraph (d) of subsection (3) of section 827.03, Florida Statutes, is amended to read:

827.03 Abuse, aggravated abuse, and neglect of a child; penalties.—

(3) EXPERT TESTIMONY.—

(d) The expert testimony requirements of this subsection apply only to criminal child abuse and neglect cases pursuant to ch. 827, dependency cases pursuant to ch. 39, and cases involving sexual battery of a child pursuant to ch. 794 and not to family court ~~or dependency court~~ cases.

Section 6. This act shall take effect July 1, 2017.

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 child protection; amending s. 39.303, F.S.; revising the title; revising the title of the district medical directors to child protection team medical directors; revising the subdivision of the state from districts to circuits for the

purpose of child protection teams; revising the required board certifications for child protection team medical directors and reviewing physicians; revising the time in which a child protection team medical director must obtain certification; revising the entities responsible for screening, employing, and terminating child protection team medical directors to include the Statewide Medical Director for Child Protection; requiring Children's Medical Services to convene a task force to develop a protocol for forensic interviewing of children suspected of having been abused; requiring Children's Medical Services to develop, maintain, and coordinate one or more sexual abuse treatment programs; amending ss. 458.3175, 459.0066, and 827.03, F.S.; revising provisions regarding expert testimony provided by certain entities to include criminal cases involving abuse and neglect, dependency cases, and cases involving sexual abuse of a child; providing an effective date.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1307 Physician Assistants
SPONSOR(S): Plasencia
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		Siples	McElroy
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

A physician assistant (PA) is a person 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 medical doctors (MDs) and doctors of osteopathic medicine (DOs). A physician may supervise up to four PAs and is responsible and liable for the performance and the acts and omissions of the PA.

HB 1307 requires a PA, as a part of the biennial licensure renewal process, to respond to a survey developed by DOH. The survey will collect information regarding the PA's practice and educational background. DOH must issue a nondisciplinary citation to a PA who fails to complete the survey within 90 days after the renewal of his or her license. The citation must notify the PA who fails to complete the required survey that his or her licensure will not be subsequently renewed unless the PA completes the survey. In conjunction with a licensure renewal notice, DOH must notify each PA who failed to complete the survey of the requirement to complete such survey. DOH may not renew the license of a PA until he or she completes the required survey.

The Council on Physician Assistants (Council) advises DOH, the Board of Medicine, and the Board of Osteopathic Medicine on matters related to the licensure and regulation of PAs in this state. Currently, the Council is composed of four physicians and one PA. The bill changes the composition of the Council to two physicians and three PAs to provide PAs greater representation in developing policy that regulates the profession.

Currently, PAs must notify DOH of their supervising physician upon employment and within 30 days of a change in the supervising physician. The bill requires a PA to notify DOH of a designated supervising physician and any change of designated supervising if he or she is practicing in a facility or practice with multiple supervisory physicians. Such notice must be provided within 30 days. The requirement to have a designated supervising physician does not prevent a PA from practicing under multiple supervising physicians. The designated supervising physician must maintain a current list of all supervising physicians within the practice or facility

The bill will have an indeterminate negative fiscal impact on DOH and no fiscal impact on local governments.

The bill provides an effective date of July 1, 2017.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Under Florida law, physician assistants are governed by the physician practice acts for medical doctors and doctors of osteopathic medicine. 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. As of February 2017, there are 7,527 active licensed PAs.[1]

Council on Physician Assistants

The Council on Physician Assistants (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 physicians must be physicians who supervise physician assistants in their practice. The Council is responsible for:

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

Licensure and Regulation of Physician Assistants

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:

- Satisfactorily passes the National Commission on Certification of Physician Assistants exam;
- Completes an application form and remit the registration fee;
- Completes an approved PA training program;
- Provides an acknowledgement of any prior felony convictions;
- Provides an acknowledgement of any revocation or denial of licensure or certification in any state; and
- If the applicant wishes to apply for prescribing authority, submits of a copy of course transcripts and a copy of the course description from a PA training program describing the course content in pharmacotherapy.[3]

In Florida, a PA practices under the delegated authority of a supervising physician. A physician supervising a PA must be qualified in the medical area in which the PA is practicing and is responsible and liable for the performance, acts, and omissions of the PA.[4]

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[1] E-mail correspondence with the Department of Health dated February 2, 2017, (on file with the staff of the Health and Human Services Committee).
[2] 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 and 459.004, F.S., respectively.
[3] *See* s. 458.347 and s. 459.022, F.S.
[4] Sections 458.347(3), F.S., and 459.022(3), F.S.; and Rules 64B8-30.012, F.A.C., and 64B15-6.010, F.A.C.

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.[5]

A supervising physician may only delegate tasks and procedures to the PA which are within the supervising physician's scope of practice.[6] The decision to permit the PA to perform a task or procedure under direct or indirect supervision is made by the supervising physician based on reasonable medical judgment regarding the probability of morbidity and mortality to the patient.[7]

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;[8]
- Order any medication for administration 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.;[9] and
- Any other services that are not expressly prohibited in ch. 458, F.S., ch. 459, F.S., or the rules adopted thereunder.[10]

Health Care Professional Shortage

Florida is experiencing a health care professional shortage. This is evidenced by the fact that for just primary care, dental care, and mental health there are 655 federally designated Health Professional Shortage Areas (HPSA) within the state.[11] It would take 1,010 primary care, 1,203 dental care, and 254 mental health practitioners to eliminate these shortage areas.[12]

PAs may help alleviate the physician shortage by acting as a physician extender. PAs treat diverse patient groups and perform medical functions that are similar to the medical care provided by primary care physicians, such as performing physical examinations, diagnosing and treating illnesses, order and interpreting laboratory tests, prescribing medications, and managing patients with chronic

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[5] Rules 64B8-30.001, F.A.C., and 64B15-6.001, F.A.C.
[6] *Supra* note 3.
[7] "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* note5.
[8] 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.
[9] 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.
[10] Sections 458.347(4) and 459.022(e), F.S.
[11] U.S. Department of Health and Human Services, Health Resources and Services Administration, *Shortage Areas*, *available at* http://www.hrsa.gov/shortage/ (last visited March 19, 2017).
[12] *Id.*

conditions.[13] PAs may also assist in the care of patients needing mental health care by conducting histories and physicals, performing psychiatric evaluations and assessments, ordering and interpreting diagnostic tests, establishing and managing treatment plans, and ordering referrals.[14]

Since there is no comprehensive studies regarding the roles PAs play in the health care system in this state, the impact of their practice cannot be determined.

Effect of Proposed Changes

Physician Assistant Survey

The bill requires a PA to complete a survey, developed by DOH, as a part of the biennial licensure renewal process. The purpose of the survey is to gather information about the availability of and trends related to critically needed services, as well as licensee information. The information collected must include, at a minimum:

- The name of the approved program at which the PA received his or her education and training and the year of graduation;
- The geographic location of the PA's practice and the number of years the PA has practiced at that location; and
- Information related to the PA's practice, including but not limited to:
  - Practice setting;
  - Percentage of time spent on direct patient care;
  - Areas of specialty;
  - Salary; and
  - Whether the PA has full or partial ownership of his or her business.

The PA must acknowledge that the information he or she provides in the survey is true and accurate to the best of his or her knowledge.

If a PA fails to submit the survey within 90 days after the renewal of his or her license, DOH must issue a nondisciplinary citation notifying the PA that his or her license is not eligible for any subsequent license renewal until the survey is completed. At the time it issues the licensure renewal notice, DOH must also notify a PA that failed to complete the survey record that the PA survey must be completed.[15] The bill prohibits DOH from renewing the license of a PA until the survey is completed.

The bill authorizes DOH to develop rules to implement the PA survey.

Designated Supervising Physician

Under current law, a PA must notify DOH of his or her employment and the name of the supervising, within 30 days of commencing such employment or at any time his or her supervising physician changes. The bill requires that a PA notifies DOH of the designated supervising physician and any change in a designated supervising physician within 30 days.[16] If a PA has a designated supervising physician, he or she may still practice under the supervision of another physician.

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[13] American Academy of Physician Assistants, *Specialty Practice: PAs in Primary Care*, (Jan. 2010), *available at* https://www.aapa.org/wp-content/uploads/2016/12/SP_PAs_PrimaryCare.pdf (last visited March 19, 2017).

[14] American Academy of Physician Assistants, *Specialty Practice: PAs in Psychiatry* (Jan. 2010), *available at* https://www.aapa.org/wp-content/uploads/2016/12/SP_PAs_Psychiatry.pdf (last visited March 19, 2017).

[15] DOH sends a renewal notification to a licensee at least 90 days before the end of a licensure period. (Section 456.038, F.S.)

[16] The bill defines "designated supervising physician" as a physician designated by the facility or practice to be the primary contact and supervising physician for the PAs in the practice where PAs are supervised by multiple supervising physicians.

The designated supervising physician must maintain a list of all approved supervising physicians at the practice or facility, which includes each supervising physician's name and area of practice. This list must be kept current and must be available upon written request by DOH.

Council on Physician Assistants

The bill changes the constitution of the Council to one physician who is a member of the Board of Medicine, one physician who is a member of the Board of Osteopathic Medicine, and three licensed physician assistants appointed by the Surgeon General. The bill clarifies that each of the physicians on the Council must supervise a physician assistant in his or her practice. Physician assistants will have a greater opportunity to assist in the development of policy for the regulation of their profession.

The bill provides an effective date of July 1. 2017.

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, 2017.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   DOH will incur an indeterminate negative fiscal impact related to enforcement of the PA survey requirement, including changes to its Licensure and Enforcement Information Database System. DOH will incur an insignificant, indeterminate negative fiscal impact for costs related to rulemaking, which current budget authority is adequate to absorb.

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 local or municipal governments.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

Although the bill requires DOH to collect this information, the bill does not instruct DOH to do anything with the information it collects, such as develop a report or otherwise process the information and make it available in some format.

The bill requires DOH to collect certain information that PAs or physician offices or facilities employing PAs may consider sensitive such as salary and ownership structure. This information, once in the possession of DOH, becomes available for public inspection.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to physician assistants; amending ss. 458.347 and 459.022, F.S.; revising licensure renewal requirements to include a physician assistant survey; requiring the Department of Health to issue a nondisciplinary citation to a physician assistant who fails to complete the survey; requiring rulemaking; providing requirements relating to designated supervising physicians; revising membership of the Council on Physician Assistants; providing an effective date.

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

Section 1. Paragraphs (b) and (d) of subsection (7) and paragraphs (a) and (b) of subsection (9) of section 458.347, Florida Statutes, are amended to read:

458.347 Physician assistants.—

(7) PHYSICIAN ASSISTANT LICENSURE.—

(b) The license must be renewed biennially. Each renewal must include:

1. A renewal fee not to exceed $500 as set by the boards.

2. Acknowledgment of no felony convictions in the previous 2 years.

3. Completion of a physician assistant survey developed

and conducted by the department that includes information on the availability of and trends relating to critically needed services, licensee information, and an acknowledgement that the information provided in the survey is true and accurate to the best of the licensee's knowledge and does not contain any knowingly false information.

a. Licensee information must include, but is not limited to:

(I) The name of the approved program at which the physician assistant received his or her education and training and the year he or she graduated from such program.

(II) The geographic location of the physician assistant's practice and the number of years he or she has practiced in such location.

(III) Information relating to the physician assistant and his or her practice, including, but not limited to, practice setting, percentage of time spent in direct patient care, areas of specialty, salary, and whether the physician assistant has full or partial ownership in his or her practice.

b.(I) The department shall issue a nondisciplinary citation to a physician assistant licensed under this chapter or chapter 459 who fails to complete the physician assistant survey within 90 days after the renewal of his or her license.

(II) The citation must notify a physician assistant who fails to complete the physician assistant survey that his or her

license is not eligible for any subsequent license renewal until he or she completes such survey.

c. In conjunction with the issuance of the license renewal notice required by s. 456.038, the department shall notify, at his or her last known address, each physician assistant who has failed to complete the physician assistant survey of the requirement to complete such survey. The department may not renew the license of a physician assistant until he or she completes such survey.

d. The department shall adopt rules pursuant to ss. 120.536(1) and 120.54 necessary to implement this subparagraph.

(d)1. Upon employment as a physician assistant, a licensed physician assistant must notify the department in writing within 30 days after such employment or after any subsequent changes in the supervising physician. The notification must include the full name, Florida medical license number, specialty, and address of a designated ~~the~~ supervising physician. A physician assistant shall report any subsequent changes in the designated supervising physician to the department within 30 days after the change. The assignment of a designated supervising physician does not preclude a physician assistant from practicing under the supervision of a physician other than the designated supervising physician.

2. A designated supervising physician shall be a physician designated by a facility or practice to be the primary contact

and supervising physician for the physician assistants in a practice in which physician assistants are supervised by multiple physicians. The designated supervising physician shall maintain a list of all approved supervising physicians at the facility or practice, including each physician's name and area of practice, and shall update the list as needed. The designated supervising physician shall provide the list to the department in a timely manner upon written request.

(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 ~~are physicians~~ and a member ~~members~~ of the Board of Medicine. ~~One of~~ The physician appointed by the Board of Medicine ~~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. The physician appointed by the Board of Osteopathic Medicine must supervise 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 (b) and (d) of subsection (7) and paragraphs (a) and (b) of subsection (9) of section 459.022, Florida Statutes, are amended to read:

459.022 Physician assistants.—

(7) PHYSICIAN ASSISTANT LICENSURE.—

(b) The licensure must be renewed biennially. Each renewal must include:

1. A renewal fee not to exceed $500 as set by the boards.

2. Acknowledgment of no felony convictions in the previous 2 years.

3. Completion of a physician assistant survey developed and conducted by the department that includes information on the availability of and trends relating to critically needed services, licensee information, and an acknowledgement that the information provided in the survey is true and accurate to the best of the licensee's knowledge and does not contain any

knowingly false information.

a. Licensee information must include, but is not limited to:

(I) The name of the approved program at which the physician assistant received his or her education and training and the year he or she graduated from such program.

(II) The geographic location of the physician assistant's practice and the number of years he or she has practiced in such location.

(III) Information relating to the physician assistant and his or her practice, including, but not limited to, practice setting, percentage of time spent in direct patient care, areas of specialty, salary, and whether the physician assistant has full or partial ownership in his or her practice.

b.(I) The department shall issue a nondisciplinary citation to a physician assistant licensed under this chapter or chapter 458 who fails to complete the physician assistant survey within 90 days after the renewal of his or her license.

(II) The citation must notify a physician assistant who fails to complete the physician assistant survey that his or her license is not eligible for any subsequent license renewal until he or she completes such survey.

c. In conjunction with issuance of the license renewal notice required by s. 456.038, the department shall notify, at his or her last known address, each physician assistant who has

failed to complete the physician assistant survey of the requirement to complete such survey. The department may not renew the license of a physician assistant until he or she completes such survey.

d. The department shall adopt rules pursuant to ss. 120.536(1) and 120.54 necessary to implement this subparagraph.

(d)1. Upon employment as a physician assistant, a licensed physician assistant must notify the department in writing within 30 days after such employment or after any subsequent changes in the supervising physician. The notification must include the full name, Florida medical license number, specialty, and address of a designated ~~the~~ supervising physician. A physician assistant shall report any subsequent changes in the designated supervising physician to the department within 30 days after the change. The assignment of a designated supervising physician does not preclude a physician assistant from practicing under the supervision of a physician other than the designated supervising physician.

2. A designated supervising physician shall be a physician designated by a facility or practice to be the primary contact and supervising physician for the physician assistants in a practice in which physician assistants are supervised by multiple physicians. The designated supervising physician shall maintain a list of all approved supervising physicians at the facility or practice, including each physician's name and area

of practice, and shall update the list as needed. The designated supervising physician shall provide the list to the department in a timely manner upon written request.

(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 ~~are physicians~~ and a member ~~members~~ of the Board of Medicine. ~~One of~~ The physician appointed by the Board of Medicine ~~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. The physician appointed by the Board of Osteopathic Medicine must supervise 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, 2017.

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 Quality Subcommittee

Representative Plasencia offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Paragraphs (d), (e), (f), (g), and (h) of subsection (2) are redesignated as paragraphs (e), (f), (g), (h), and (i), and new paragraph (c) is added to that subsection, and paragraphs (b) and (d) of subsection (7) and paragraphs (a) and (b) of subsection (9) of section 458.347, Florida Statutes, are amended to read:

458.347 Physician assistants.—

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

(d) "Designated supervising physician" means a physician designated by a facility or practice to be the primary contact

and supervising physician for the physician assistants in a practice in which physician assistants are supervised by multiple physicians.

(7) PHYSICIAN ASSISTANT LICENSURE.—

(b) The license must be renewed biennially. Each renewal must include:

1. A renewal fee not to exceed $500 as set by the boards.

2. Acknowledgment of no felony convictions in the previous 2 years.

3. Completion of a physician assistant workforce survey which shall be administered in the same manner and have the same content as the physician workforce survey required under s. 458.3191.

a. The department shall issue a nondisciplinary citation to a physician assistant licensed under this chapter or chapter 458 who fails to complete the physician assistant workforce survey within 90 days after the renewal of his or her license.

b. The citation must notify a physician assistant who fails to complete the physician assistant workforce survey that his or her license is not eligible for any subsequent license renewal until he or she completes such survey.

c. In conjunction with issuance of the license renewal notice required by s. 456.038, the department shall notify each physician assistant who has failed to complete the physician assistant workforce survey at his or her last known address of

record with the department of the requirement that the physician assistant workforce survey be completed prior to subsequent license renewal. The department may not subsequently renew the license of a physician assistant until he or she completes the survey required under this paragraph.

d. Beginning July 1, 2018, and every two years thereafter, the department must report the data collected to the boards.

e. The department shall adopt rules pursuant to ss. 120.536(1) and 120.54 necessary to implement this subparagraph.

(d)1. Upon employment as a physician assistant, a licensed physician assistant must notify the department in writing within 30 days after such employment that provides ~~or after any subsequent changes in the supervising physician. The notification must include~~ the full name, Florida medical license number, specialty, and address of supervising physician or a designated ~~the~~ supervising physician. A physician assistant shall report any subsequent changes in the supervising physician or designated supervising physician to the department within 30 days after the change. The assignment of a designated supervising physician does not preclude a physician assistant from practicing under the supervision of a physician other than the designated supervising physician.

2. The designated supervising physician shall maintain a list of all approved supervising physicians at the facility or practice, including each physician's name and area of practice,

and shall update the list as needed. The designated supervising physician shall provide the list to the department in a timely manner upon written request.

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

(a) Beginning October 1, 2017, 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 ~~are physicians~~ and a member ~~members~~ of the Board of Medicine. ~~One of~~ The physician appointed by the Board of Medicine ~~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. The physician appointed by the Board of Osteopathic Medicine must supervise 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 (d), (e), (f), (g), and (h) of subsection (2) are redesignated as paragraphs (e), (f), (g), (h), and (i), and new paragraph (c) is added to that subsection, and paragraphs (b) and (d) of subsection (7) and paragraphs (a) and (b) of subsection (9) of section 459.022, Florida Statutes, are amended to read:

459.022 Physician assistants.—

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

(d) "Designated supervising physician" means a physician designated by a facility or practice to be the primary contact and supervising physician for the physician assistants in a practice in which physician assistants are supervised by multiple physicians.

(7) PHYSICIAN ASSISTANT LICENSURE.—

(b) The licensure must be renewed biennially. Each renewal must include:

1. A renewal fee not to exceed $500 as set by the boards.

2. Acknowledgment of no felony convictions in the previous 2 years.

3. Completion of a physician assistant workforce survey which shall be administered in the same manner and have the same

content as the physician workforce survey required under s. 459.0081.

a. The department shall issue a nondisciplinary citation to a physician assistant licensed under this chapter or chapter 458 who fails to complete the physician assistant workforce survey within 90 days after the renewal of his or her license.

b. The citation must notify a physician assistant who fails to complete the physician assistant workforce survey that his or her license is not eligible for any subsequent license renewal until he or she completes such survey.

c. In conjunction with issuance of the license renewal notice required by s. 456.038, the department shall notify each physician assistant who has failed to complete the physician assistant workforce survey at his or her last known address of record with the department of the requirement that the physician assistant workforce survey be completed prior to subsequent license renewal. The department may not subsequently renew the license of a physician assistant until he or she completes the survey required under this paragraph.

d. Beginning July 1, 2018, and every two years thereafter, the department must report the data collected to the boards.

d. The department shall adopt rules pursuant to ss. 120.536(1) and 120.54 necessary to implement this subparagraph.

(d)1. Upon employment as a physician assistant, a licensed physician assistant must notify the department in

writing within 30 days after such employment that provides ~~or after any subsequent changes in the supervising physician. The notification must include~~ the full name, Florida medical license number, specialty, and address of supervising physician or a designated ~~the~~ supervising physician. A physician assistant shall report any subsequent changes in the supervising physician or designated supervising physician to the department within 30 days after the change. The assignment of a designated supervising physician does not preclude a physician assistant from practicing under the supervision of a physician other than the designated supervising physician.

2. The designated supervising physician shall maintain a list of all approved supervising physicians at the facility or practice, including each physician's name and area of practice, and shall update the list as needed. The designated supervising physician shall provide the list to the department in a timely manner upon written request.

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

(a) Beginning October 1, 2017, 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 ~~are physicians~~ and a member ~~members~~ of the Board of Medicine. ~~One of~~ The physician

appointed by the Board of Medicine ~~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. The physician appointed by the Board of Osteopathic Medicine must supervise 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, 2017

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

Remove everything before the enacting clause and insert:

An act a relating to physician assistants; amending ss. 458.347 and 459.022, F.S.; defining designated supervising physician; revising licensure renewal requirements to include a physician assistant workforce survey; requiring the Department of Health to issue a nondisciplinary citation to a physician assistant who fails to complete a survey; requiring rulemaking; requiring a report; providing requirements related to designated supervising physicians; revising the membership of the Council on Physician Assistants as of a specified date; providing an effective date.

HOUSE OF REPRESENTATIVES LOCAL BILL STAFF ANALYSIS

BILL #: HB 1317 North Lake County Hospital District, Lake County
SPONSOR(S): Metz
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Local, Federal & Veterans Affairs Subcommittee	12 Y, 0 N	Renner	Miller
2) Health Quality Subcommittee		Roth DR	McElroy CM
3) Government Accountability Committee			

SUMMARY ANALYSIS

The North Lake County Hospital District (district) is an independent special district that was created by the Florida Legislature in ch. 95-508, Laws of Florida, to provide a means to pay for indigent care delivered by local hospitals and clinics.

Chapter 2012-258, Laws of Florida, revised and codified the district's charter to, among other matters, sunset the district in 2017 unless a majority of Lake County voters approved its continuation through a referendum placed on the ballot in the 2016 general election. If approved, the district would be subject to a continuation vote every 10 years thereafter.

On November 8, 2016, a referendum on the continuation of the North Lake Hospital District was placed on the general election ballot for Lake County. Lake County voters approved the continuation of the district for an additional 10 years.

The bill aligns the law with the results of the 2016 referendum. It extends the expiration date of the district to the end of its fiscal year in 2027 without further legislative action, and provides for a referendum which would be held on November 3, 2026, or such other general election date as provided by general law.

The bill takes effect upon becoming law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Special Districts

A "special district" is a unit of local government created for a particular purpose, with jurisdiction to operate within a limited geographic boundary. Special districts are created by general law,[1] special act,[2] local ordinance,[3] or by rule of the Governor and Cabinet.[4] A special district has only those powers expressly provided by, or reasonably implied from, the authority provided in the district's charter. Special districts provide specific municipal services in addition to, or in place of, those provided by a municipality or county.[5]

An "independent special district" is characterized by having a governing board comprised of members which are not identical in membership to, nor all appointed by, nor any removable at will by, the governing body of a single county or municipality, and the district budget cannot be affirmed or vetoed by the governing body of a single county or municipality.[6] Additionally, a district that includes more than one county is an independent special district unless the district lies wholly within the boundaries of a single municipality.

North Lake County Hospital District

The North Lake County Hospital District (district) is an independent special district that was created by the Florida Legislature in ch. 95-508, Laws of Florida. This special act ratified the merger of the Northwest Lake County Hospital District (created by ch. 78-546, Laws of Florida) and the Northeast Lake County Hospital District (created by ch. 63-1509, Laws of Florida), which were combined into a single independent taxing district by concurrent resolutions on February 9, 1990.[7] The district has the authority to levy an ad valorem tax each year not to exceed 1 mill[8], to fund the indigent care to qualified residents.[9]

In 2012, the district's charter was codified and revised.[10] The purpose of the district is to:[11]

> ...provide a means to pay for indigent care. Indigent care may be provided to residents of the district through the use of health care facilities not owned and operated by the board of trustees. The provision of such indigent care[12] is found and

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[1] Section 189.031(3), F.S.
[2] *Id.*
[3] Section 189.02(1), F.S.
[4] Section 190.005(1), F.S. *See*, generally, s. 189.012(6), F.S.
[5] *2017 – 2018 Local Gov't Formation Manual*, p. 67, available at http://www.myfloridahouse.gov/Sections/Committees/committeesdetail.aspx?CommitteeId=2911 (last viewed 3/1/2017)
[6] Section 189.012(3), F.S.
[7] In 1989, the Uniform Special District Accountability Act provided for the merger of special districts through adoption of concurrent resolutions by the governing bodies of each special district pursuant to s. 189.073, F.S.
[8] A mill rate (millage rate), is a figure representing the amount per $1,000 of the assessed value of property. In this case $1.00 per $1,000.
[9] Email from Jerry Foster, Assistant Supervisor of Elections, Lake County Supervisor of Elections, RE: Requested Ballot Language (March 17, 2017) on file with the Health Quality Subcommittee staff.
[10] Ch. 2012-258, Laws of Fla.
[11] Ch. 2012-258, Section 3, Laws of Fla.
[12] Ch. 2012-258, Laws of Fla., Charter defines "indigent care" as medically necessary health care provided to residents of the North Lake County Hospital District who are determined to be qualified pursuant to the provisions of the Florida Health Care Responsibility Act (section 154.304(9), F.S.) and the Florida Health Care Indigency Eligibility Certification Standards (49H-1.0035(30), F.A.C.), except that the poverty rate standard shall be 200 percent of the federal poverty level.

declared to be a public purpose and necessary for the preservation of the public health of the residents of the district.

The district is governed by an elected, unpaid board of six members who reside in the district and may serve a maximum of two 4-year terms.[13]

Chapter 2012-258, Laws of Florida, required the district to expire and dissolve at the end of the 2017 fiscal year without further action by the Legislature, unless continued by a referendum approved in the 2016 general election. On November 8, 2016, a referendum[14] was held in Lake County, and the electors voted[15] to continue the district for 10 years.

The district is subject to a continuation vote every 10 years thereafter. If the district is dissolved without further action by the Legislature as provided in the act, all property owned by the district is transferred to, and all indebtedness of the district is assumed by, the Lake County Board of County Commissioners. This provision is in keeping with s. 189.076(2), F.S., which provides for financial allocations when a special district is dissolved.

Effect of Proposed Changes

The bill aligns the law with the results of the 2016 referendum. It extends the expiration date of the district to the end of its fiscal year in 2027 without further legislative action and provides for a referendum which would be held on November 3, 2026, or such other general election date as provided by general law.

B. SECTION DIRECTORY:

Section 1: Amends ch. 2012-258, Laws of Florida, providing for expiration of the district at a specified time without further legislative action and permitting continuation of the district by referendum; providing for a referendum.

Section 2: Provides the bill takes effect upon becoming law.

II. NOTICE/REFERENDUM AND OTHER REQUIREMENTS

A. NOTICE PUBLISHED? Yes [X] No []

IF YES, WHEN? February 2, 2017

WHERE? *Daily Commercial*, published in Lake County, Florida

B. REFERENDUM(S) REQUIRED? Yes [X] No []

IF YES, WHEN? November 3, 2026

C. LOCAL BILL CERTIFICATION FILED? Yes, attached [X] No []

D. ECONOMIC IMPACT STATEMENT FILED? Yes, attached [X] No []

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

None.

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[13] Ch. 2012-258, Section 4, Laws of Fla.
[14] *Supra*, at FN 9.
[15] Lake County Supervisor of Elections, *Election Results, 2016 General Election*, 2017, available at https://www.lakevotes.com/information/results (last viewed March 17, 2017).

B. RULE-MAKING AUTHORITY:

The bill neither authorizes nor requires administrative rulemaking by executive branch agencies.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to the North Lake County Hospital District, Lake County; amending ch. 2012-258, Laws of Florida; providing for expiration of the district at a specified time without further legislative action and permitting continuation of the district by referendum; providing for a referendum; providing an effective date.

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

Section 1. Sections 14 and 15 of section 3 of chapter 2012-258, Laws of Florida, are amended to read:

Section 14. DURATION AND CONTINUATION.—The district expires and shall be dissolved at the end of its fiscal year in 2027 ~~2017~~ without further action by the Legislature. However, the district may be continued at the end of that period for 10 years if in the general election in 2026 ~~2016~~ a majority of the electors voting in a referendum called for that purpose approve its continuation. The district is subject to a continuation vote in like manner every 10 years thereafter. If the district is dissolved without further action by the Legislature as provided in this act, all property owned by the district is transferred to, and all indebtedness of the district is assumed by, the Lake

County Board of County Commissioners effective upon such dissolution.

Section 15. REFERENDUM.—The Board of County Commissioners of Lake County shall call, and the Supervisor of Elections of Lake County shall conduct, in conjunction with the general election to be held on November 3 ~~8~~, 2026 ~~2016~~, or such other general election date as provided by general law, a referendum as follows:

CONTINUATION OF THE NORTH LAKE COUNTY HOSPITAL DISTRICT

Shall the independent special district known as the North Lake County Hospital District with authority to levy each year an ad valorem tax not to exceed 1 mill to fund indigent care to qualified residents of the district be continued for another 10 years?

Yes.....

No.....

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