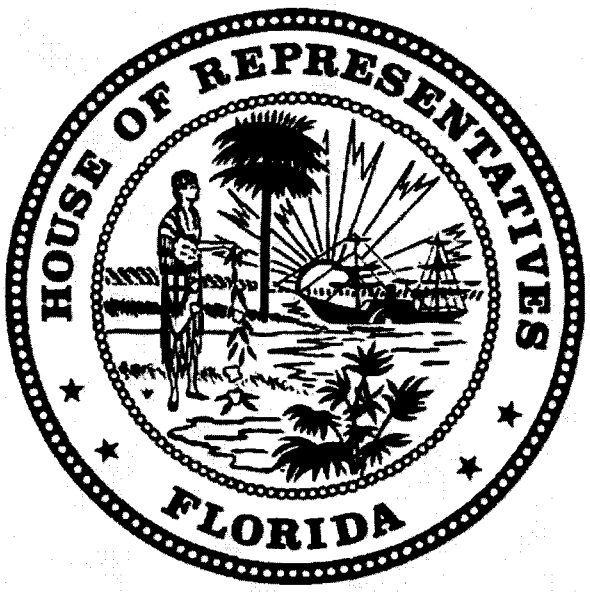

Health & Human Services Committee

Thursday, March 27, 2014
1:30 PM - 3:30 PM
Morris Hall

Will Weatherford
Speaker

Richard Corcoran
Chair

Committee Meeting Notice

HOUSE OF REPRESENTATIVES

Health & Human Services Committee

Start Date and Time:	Thursday, March 27, 2014 01:30 pm
End Date and Time:	Thursday, March 27, 2014 03:30 pm
Location:	Morris Hall (17 HOB)
Duration:	2.00 hrs

Consideration of the following bill(s):

HB 323 Pharmacy Technicians by La Rosa, Campbell
CS/HB 437 Diabetes Advisory Council by Health Quality Subcommittee, Trujillo
HB 535 Transactions in Fresh Produce Markets by Fullwood
CS/HB 709 Alzheimer's Disease by Health Quality Subcommittee, Hudson
CS/CS/HB 711 Public Meetings and Public Records/Alzheimer's Disease Research Grant Advisory Board by Government Operations Subcommittee, Health Quality Subcommittee, Hudson
HB 715 Family Care Councils by Diaz, J.
CS/HB 829 Involuntary Examinations under the Baker Act by Civil Justice Subcommittee, Campbell, Rehwinkel Vasilinda
HB 1047 Termination of Pregnancies by Adkins
CS/HB 1131 Emergency Allergy Treatment by Health Quality Subcommittee, Hudson
HB 7105 Health Care Services Rulemaking by Rulemaking Oversight & Repeal Subcommittee, Hutson

Pursuant to rule 7.12, the deadline for amendments to bills on the agenda by non-appointed members is 6:00 p.m., Wednesday, March 26, 2014.

By request of the chair, all committee members are asked to have amendments to bills on the agenda submitted to staff by 6:00 p.m., Wednesday, March 26, 2014.

NOTICE FINALIZED on 03/25/2014 16:12 by Iseminger.Bobbye

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 437 Diabetes Advisory Council
SPONSOR(S): Health Quality Subcommittee; Trujillo
TIED BILLS: **IDEN./SIM. BILLS:** SB 694

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	11 Y, 0 N, As CS	Dunn	O'Callaghan
2) Health Care Appropriations Subcommittee	12 Y, 0 N	Pridgeon	Pridgeon
3) Health & Human Services Committee		Dunn	Calamas

SUMMARY ANALYSIS

Diabetes is a group of diseases characterized by high blood glucose (blood sugar), due to the body's inability to produce insulin or inability to effectively use insulin. Diabetes is a major cause of heart disease and stroke. The economic impact of diabetes rising. Diabetes is a leading cause of death in Florida, and Florida's high diabetes rate ranks 43rd among the states. The Diabetes Advisory Council (Council) is an advisory entity to the Department of Health, government agencies, professional organizations, and the general public. The Council's purpose is to guide a statewide comprehensive approach to diabetes prevention, diagnosis, education, care, treatment, impact, and costs.

This bill amends s. 385.203, F.S., to require the Council, in conjunction with the Department of Health, the Agency for Health Care Administration, and the Department of Management Services, to submit by January 10 of each odd-numbered year a report on diabetes in Florida to the Governor, the President of the Senate, and the Speaker of the House of Representatives.

The report must provide:

- The public health consequences and financial impact on the state from all types of diabetes and resulting health complications;
- A description and an assessment of the effectiveness of state agency diabetes programs and activities, the funding of such programs and activities, and cost-savings associated with such programs and activities;
- A description of the coordination among state agencies of programs, activities, and communications designed to manage, treat, and prevent all types of diabetes; and
- A detailed action plan for reducing and controlling the number of new cases of diabetes, which must include proposed steps to reduce the impact of all types of diabetes, expected outcomes from implementing the action plan, and benchmarks for preventing and controlling diabetes.

The bill has an insignificant negative fiscal impact on the Department of Health. The bill has no fiscal impact on local governments.

The bill provides an effective date of July 1, 2014.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Diabetes is a group of diseases characterized by high blood glucose (blood sugar), due to the body's inability to produce insulin or inability to effectively use insulin. Uncontrolled glucose build up can lead to death or serious health complications, such as vision loss, kidney failure, and amputations of legs or feet. Diabetes is a major cause of heart disease and stroke, with death rates two to four times higher for adults with diabetes than those without. [1]

The three common types of diabetes are:[2]

- **Type 1:** accounts for about five percent of all diagnosed cases. Type 1 is typically diagnosed in children and young adults. Currently, there are no known ways to prevent type 1 diabetes.
- **Type 2:** accounts for about 95 percent of all diagnosed cases. Diagnosis among adults aged 65 years or older is seven times higher than those aged 20–44 years. Research shows that healthy eating, regular physical activity, and medication if prescribed can control, prevent, or delay type 2 diabetes.
- **Gestational diabetes:** develops and is diagnosed as a result of pregnancy in two to ten percent of pregnant women. Gestational diabetes increases the risk of developing type 2 diabetes in both the mother and the child.

Risk factors for diabetes include:[3]

- Being over the age of 45;
- Being overweight;
- Having a parent or sibling with diabetes;
- Having a minority family background;
- Developing diabetes while pregnant; and
- Being physically active less than three times per week.

Persons with any of the above risk factors are at risk of developing pre-diabetes. Pre-diabetes is a condition where blood sugar levels are higher than normal, but not high enough for a diagnosis of diabetes. Persons with pre-diabetes are five to fifteen times more likely to develop type 2 diabetes, heart disease, and stroke.[4] The Centers for Disease Control and Prevention (CDC) estimates that 33 percent of U.S. adults have pre-diabetes.[5]

Nationally, the CDC estimates that 25.8 million people have diabetes.[6] Of those estimated to have diabetes, only 18.8 million have been diagnosed.[7] Men are slightly more likely to have diabetes than

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[1] Centers for Disease Control and Prevention, *Diabetes Report Card 2012*, 2012, at 1, *available at* http://www.cdc.gov/diabetes/pubs/reportcard.htm (last visited Mar. 26, 2014).
[2] *Id.*
[3] Fla. Dep't of Health, *Diabetes*, http://www.floridahealth.gov/diseases-and-conditions/diabetes/ (last visited Mar. 26, 2014).
[4] *Id.*
[5] Centers for Disease Control and Prevention, *Diabetes Report Card 2012*, *supra* note 1, at 4.
[6] Centers for Disease Control and Prevention, *2011 National Diabetes Fact Sheet*, *available at* http://www.cdc.gov/Diabetes/pubs/estimates11.htm (last visited Mar. 26, 2014).
[7] *Id.*

women.[8] Minorities are at a greater risk of having diabetes than non-Hispanic white adults, with a 66 percent higher risk for Hispanics and a 77 percent higher risk for non-Hispanic blacks.[9] Based on current trends, the CDC has projected that one in three U.S. adults could have diabetes by 2050.[10]

Economic Impact of Diabetes

The American Diabetes Association estimates that the total cost of diagnosed diabetes rose 41 percent from 2007 to 2012 to $245 billion, which includes $176 billion in direct medical costs and $69 billion in reduced productivity.[11] Direct medical costs consist of hospital inpatient care, prescription medications, anti-diabetic supplies, physician visits, and nursing stays.[12] The largest factors attributing to reduced productivity costs are the absenteeism, inability to work due to disease related disability, and lost productive capacity due to early mortality.[13] The average diabetic patient spends about $7,900 per year on diabetes costs, making diabetes patient's average medical expenditures 2.3 times higher than non-diabetic persons.[14]

Diabetes in Florida

Diabetes is the sixth leading cause of death in Florida.[15] In 2010, Florida's high diabetes rate of 10.4 percent compared poorly to other states, with Florida being ranked 43rd among the states.[16]

Florida's population contains significant concentrations of groups at risk of developing diabetes. In 2010, 37.8 percent of Floridians were overweight.[17] In addition, Florida has over 8.3 million residents over the age of 45, and Florida has over 3.2 million residents over the age of 65, one of the populations most vulnerable to diabetes.[18] Florida's number of residents over the age of 65 is expected to rise to 24.4 percent by 2040 from 17.3 percent in 2011.[19] Moreover, Florida's population is comprised of 39.8 percent of Hispanics and African Americans, two groups that have a higher risk of developing diabetes.[20]

Diabetes Advisory Council

The Diabetes Advisory Council (Council) is an advisory entity to the Department of Health, government agencies, professional organizations, and the general public. The Council's purpose is to guide a statewide comprehensive approach to diabetes prevention, diagnosis, education, care, treatment, impact, and costs. The 26 members of the Council are appointed by the Governor and are comprised

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[8] *Id.* (stating that 13 million men have diabetes compared to 12.6 million women).
[9] *Id.*
[10] Centers for Disease Control and Prevention, *Diabetes Report Card 2012*, *supra* note 1, at 2.
[11] American Diabetes Association, *Economic Costs of Diabetes in the U.S. in 2012*, 36 DIABETES CARE 1033, 1033 (2013), *available at* http://care.diabetesjournals.org/content/36/4/1033.full.pdf+html (last visited Mar. 26, 2014).
[12] *Id.* (noting that the hospital care accounts for 43 percent and medications account for 18 percent).
[13] *Id.*
[14] *Id.*
[15] Fla. Dep't of Health, *Florida Mortality Atlas: 2011 Mortality Atlas*, http://www.floridacharts.com/charts/MortAtlas.aspx (last visited Mar. 26, 2014).
[16] Fla. Dep't of Health, *Florida State Health Improvement Plan 2012 – 2015*, April 2012, at B14, *available at* http://www.floridahealth.gov/public-health-in-your-life/about-the-department/_documents/state-health-improvement-plan.pdf (last visited Mar. 26, 2014) (compared to 8.7 percent national rate).
[17] *Id.*
[18] Florida Demographic Estimating Conference, February 2013 and the University of Florida, Bureau of Economic and Business Research, Florida Population Studies, Bulletin 166, June 2013, *available at* http://edr.state.fl.us/Content/population-demographics/data/ (follow "Florida Census Day Population: 1970-2040" hyperlink) (last visited Mar. 26, 2014).
[19] *Id.*
[20] U.S. Census Bureau, *State and County Quick Facts: Florida*, *available at* http://quickfacts.census.gov/qfd/states/12000.html (last modified Jan. 6, 2014) (citing population percentages of 23.2 Hispanic and 16.6 African American).

of health care professionals and members of the public, three of whom must be affected by diabetes. The Council meets once per year with the State Surgeon General to make specific recommendations regarding the public health aspects of the prevention and control of diabetes.[21]

Effect of Proposed Changes

The bill amends s. 385.203, F.S., to require the Diabetes Advisory Council (Council), in conjunction with the Department of Health, the Agency for Health Care Administration, and the Department of Management Services, to submit by January 10 of each odd-numbered year a report on diabetes in Florida to the Governor, the President of the Senate, and the Speaker of the House of Representatives.

The report must provide:

- The public health consequences and financial impact on the state from all types of diabetes and the resulting health complications;
- The number of persons with diabetes covered by Medicaid[22] or the Division of State Group Insurance;[23]
- The number of persons impacted by state agency diabetes programs and activities;
- A description and an assessment of the effectiveness of state agency diabetes programs and activities;
- The amount and source of funding for state agency diabetes programs and activities;
- The cost-savings realized by state agency diabetes programs and activities;
- A description of the coordination among state agencies of programs, activities, and communications designed to manage, treat, and prevent all types of diabetes; and
- The development of and revisions to a detailed action plan for reducing and controlling the number of new cases of diabetes and proposed steps to reduce the impact of all types of diabetes, including expected outcomes and benchmarks if the plan is implemented.

The bill provides an effective date of July 1, 2014.

B. SECTION DIRECTORY:

Section 1. Amends s. 385.203, F.S., relating to Diabetes Advisory Council; creation; function; membership.

Section 2. Provides an effective date of July 1, 2014.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

[21] Section 385.203, F.S.

[22] Medicaid is a joint federal and state funded program that pays for health care for low income Floridians and is administered by the Agency for Health Care Administration, pursuant to ch. 409, F.S. Over 3.3 million Floridians are currently enrolled in Medicaid and approximately $21 billion was spent on Florida Medicaid in FY 2012-2013. Agency for Health Care Administration, "Florida Medicaid," available at: http://ahca.myflorida.com/Medicaid/index.shtml (last visited Mar. 26, 2014).

[23] The Florida Department of Management Services administers the State Group Insurance Program created under s. 110.123, F.S. The program offers four types of health plans from which an eligible employee may choose. In FY 2012-2013, the program covered 169,804 employees at a cost of $1.8 billion. Florida Department of Management Services, Division of State Group Insurance, "State Employees' Group Health Self-Insurance Trust Fund, Report on the Financial Outlook," December 13, 2013, available at: http://edr.state.fl.us/Content/conferences/healthinsurance/HealthInsuranceOutlook.pdf (last visited Mar. 26, 2014).

2. Expenditures:

The Department of Health has reported that, although the department's workload will be increased due to the amount of information required by the bill to be provided to the Council, the increase in workload can be handled within existing department resources.[24]

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

No additional rule-making authority is necessary to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 5, 2014, the Health Quality Subcommittee adopted an amendment to HB 437 and reported the bill favorably as a committee substitute. The amendment removes the requirement that the Diabetes Advisory Council include a detailed budget request in the report submitted to the Governor and Legislature. This analysis is drafted to the committee substitute.

[24] Florida Department of Health, 2014 Agency Legislative Bill Analysis, HB 437, February 7, 2014, on file with committee staff.

A bill to be entitled

An act relating to the Diabetes Advisory Council; amending s. 385.203, F.S.; requiring the council, in conjunction with the Department of Health, the Agency for Health Care Administration, and the Department of Management Services to develop plans to manage, treat, and prevent diabetes; requiring a report to the Governor and Legislature; providing for contents of the report; providing an effective date.

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

Section 1. Paragraph (c) of subsection (1) of section 385.203, Florida Statutes, is redesignated as paragraph (d), and a new paragraph (c) is added to that subsection to read:

385.203 Diabetes Advisory Council; creation; function; membership.—

(1) To guide a statewide comprehensive approach to diabetes prevention, diagnosis, education, care, treatment, impact, and costs thereof, there is created a Diabetes Advisory Council that serves as the advisory unit to the Department of Health, other governmental agencies, professional and other organizations, and the general public. The council shall:

(c) In conjunction with the department, the Agency for Health Care Administration, and the Department of Management Services, submit by January 10 of each odd-numbered year to the

Governor, the President of the Senate, and the Speaker of the House of Representatives a report containing the following information:

1. The public health consequences and financial impact on the state from all types of diabetes and resulting health complications, including the number of persons with diabetes covered by Medicaid, the number of persons with diabetes who are insured by the Division of State Group Insurance, and the number of persons with diabetes who are impacted by state agency diabetes programs and activities.

2. A description and an assessment of the effectiveness of the diabetes programs and activities implemented by each state agency, the amount and source of funding for such programs and activities, and the cost savings realized as a result of the implementation of such programs and activities.

3. A description of the coordination among state agencies of programs, activities, and communications designed to manage, treat, and prevent all types of diabetes.

4. The development of and revisions to a detailed action plan for reducing and controlling the number of new cases of diabetes and identification of proposed action steps to reduce the impact of all types of diabetes, identification of expected outcomes if the plan is implemented, and establishment of benchmarks for preventing and controlling diabetes.

Section 2. This act shall take effect July 1, 2014.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 715 Family Care Councils
SPONSOR(S): Diaz
TIED BILLS: **IDEN./SIM. BILLS:** SB 762

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Healthy Families Subcommittee	12 Y, 0 N	Entress	Brazzell
2) Health & Human Services Committee		Entress	Calamas

SUMMARY ANALYSIS

Family Care Councils (FCCs) are local councils that advise the Agency for Persons with Disabilities on the needs of self-advocates and their families. The bill amends s. 393.502, F.S., to change membership eligibility of FCCs by allowing grandparents to be members. It also clarifies that persons waiting to receive services may be members of FCCs.

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

The bill provides an effective date of July 1, 2014.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

The Agency for Persons with Disabilities

The Agency for Persons with Disabilities (APD) was created to serve the needs of Floridians with developmental disabilities. APD works in partnership with local communities and private providers to assist people who have developmental disabilities and their families. APD serves more than 50,000 individuals with autism, cerebral palsy, spina bifida, intellectual disabilities, down syndrome, and Prader-Willi syndrome.[1]

APD is unable to provide services to all individuals with developmental disabilities. Individuals who are eligible for APD services are prioritized according to need and some individuals are placed on a waiting list for services.[2] As of February 2, 2014, 29,915 individuals were receiving services from APD and 21,290 individuals were on the waiting list to receive services.[3]

Family Care Councils

In 1993, the Florida Legislature established Family Care Councils (FCCs) to advise on policy issues relevant to the community and family support system in the local area.[4] FCCs are located within each service area of APD, of which there are 15.[5] Examples of services provided by APD include adult day training, personal care services, and specialized therapies.[6]

The primary functions of the local FCCs are to:

- Assist in providing information and outreach to families;
- Review the effectiveness of service programs and make recommendations with respect to program implementation;
- Advise the agency with respect to policy issues relevant to the community and family support system in the local area; and
- Meet and share information with other local family care councils.[7]

Membership of Family Care Councils

Each local FCC must have between 10 and 15 members. Members of each FCC must be recommended by a majority vote of the local FCC and then appointed by the Governor. Each FCC must include the following members:

- At least three of the members of the council must be consumers.[8]
    - One of these members must be a consumer who received services within the four years prior to the date of recommendation, or the legal guardian of such a consumer.

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[1] Agency for Persons with Disabilities, *About Us*, accessible at: http://apd.myflorida.com/about/ (last accessed 2/12/14).
[2] Agency for Persons with Disabilities, *Waiting List*, accessible at: http://apd.myflorida.com/customers/waitlist/ (last accessed 2/12/14).
[3] E-mail correspondence with Jared Torres, Legislative Affairs Director, Agency for Persons with Disabilities, 2/10/14.
[4] S. 393.502 (7), F.S.
[5] S. 393.502(1), F.S.
[6] S. 393.006 (3), F.S.
[7] S. 393.502 (7), F.S.
[8] The term "consumers" is not defined in ch. 393, F.S., but is used by APD to refer to individuals eligible for APD services per ch. 393, F.S. This includes both individuals receiving services and individuals on the waitlist to receive services.

- The remainder of the council members must be parents, guardians, or siblings of persons with developmental disabilities who qualify for services pursuant to Ch. 393, F.S.[9]

APD has experienced difficulty recruiting and retaining membership on the FCCs.[10]

Effect of Proposed Changes

The bill amends the membership eligibility for FCCs. The bill allows grandparents of persons with developmental disabilities who qualify for services pursuant to Ch. 393, F.S., to serve on FCCs.

The bill also clarifies that the consumer members of the FCCs members can be persons currently receiving or waiting to receive services from APD.

B. SECTION DIRECTORY:

Section 1: Amends s. 393.502, F.S., relating to family care councils.
Section 2: Provides for an effective date.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

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

[9] S. 393.502(2)(a), F.S.
[10] APD legislative proposal, November 8, 2013, on file with committee staff.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to the family care councils; amending s. 393.502, F.S.; revising membership criteria for family care councils; providing an effective date.

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

Section 1. Paragraph (b) of subsection (2) of section 393.502, Florida Statutes, is amended to read:

393.502 Family care councils.—

(2) MEMBERSHIP.—

(b) At least three ~~of the~~ members of the council must be persons currently receiving or waiting to receive services from the agency ~~consumers~~. One such member shall be a person who has been receiving ~~consumer who received~~ services within the 4 years prior to the date of recommendation~~, or the legal guardian of such a consumer~~. The remainder of the council members shall be parents, grandparents, guardians, or siblings of persons who have ~~with~~ developmental disabilities and who qualify for services pursuant to this chapter.

Section 2. This act shall take effect July 1, 2014.

COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. HB 715 (2014)

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 & Human Services Committee

Representative Diaz, J. offered the following:

Amendment

Remove line 20 and insert:

services pursuant to this chapter. For a grandparent to be a council member, the grandchild's parent or legal guardian must consent to the appointment and report the consent to the agency.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 535 Transactions in Fresh Produce Markets
SPONSOR(S): Fullwood
TIED BILLS: **IDEN./SIM. BILLS:** SB 552

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Healthy Families Subcommittee	12 Y, 0 N	Entress	Brazzell
2) Health & Human Services Committee		Entress	Calamas

SUMMARY ANALYSIS

The Supplemental Nutrition Assistance Program (SNAP) is a federal program which offers nutrition assistance to low-income individuals and families. Individuals and families who meet eligibility standards receive an Electronic Benefits Transfer (EBT) card. Money is deposited on the EBT card for families and individuals to purchase certain types of food each month. To accept SNAP benefits from an EBT card, businesses selling food must have an EBT system and be licensed by the United States Department of Agriculture (USDA). The USDA licenses farmer's markets and allows farmer's markets to operate EBT systems, but not all farmer's markets accept SNAP benefits.

The bill allows the owner or operator of a market selling fresh produce, such as a farmer's market, that does not have an Electronic Benefits Transfer (EBT) system to allow certain specified groups to implement and operate an EBT system in the market on behalf of the sellers. The bill clarifies that this applies when the market owner or operator is not an authorized Supplemental Nutrition Assistance Program (SNAP) retailer.

The bill has no fiscal impact.

The bill provides an effective date of July 1, 2014.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

History of the Food Stamp Program

The food stamp program began in 1939, providing a discount for surplus food to people on relief. From 1939-1943, those who qualified were able to purchase stamps redeemable for the purchase of food, and were given additional stamps redeemable only towards purchasing surplus food.[1] In 1961 the Pilot Food Stamp Program was created by President Kennedy. The pilot program used the original food stamp program, but did not limit the use of additional stamps toward surplus food; those stamps could be used for perishables as well.[2]

The Food Stamp Act of 1964 made the program permanent and expanded the use of food stamps to "all items eligible for consumption, with the exception of alcohol and imported foods."[3] Since then a number of changes and reforms to the program have taken place including changing the name of the program to the Supplemental Nutrition Assistance Program (SNAP), changing eligibility determinations and introducing of the use of an Electronic Benefits Transaction card (EBT).[4]

Supplemental Nutrition Assistance Program-SNAP (Federal Program)

Today, SNAP is a federal program that is administered by the individual states. SNAP aims to "provide children and low-income people access to food, a healthful diet and nutrition education in a way that supports American agriculture and inspires public confidence."[5] The Food and Nutrition Act of 2008 defines "eligible food" as "any food or food product intended for human consumption except alcoholic beverages, tobacco, hot foods and hot food products prepared for immediate consumption."[6] Eligible food also includes seeds and plants to grow foods for personal consumption, as well as some additional exceptions to allow for hot food products ready for consumption in certain circumstances.[7]

Retailers Accepting Food Stamps

Retailers accepting SNAP benefits as a form of payment must be licensed by the United States Department of Agriculture (USDA).[8] The Food and Nutrition Service (FNS) is responsible for licensing and monitoring of retail food stores participating in SNAP.[9] A separate SNAP license is required for

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[1] A Short History of SNAP, USDA Food and Nutrition Service, available at: http://www.fns.usda.gov/snap/rules/Legislation/about.htm. (last visited 3/2/14).
[2] *Id.*
[3] *Id.*
[4] *Id.*
[5] About FNS, USDA Food and Nutrition Service, available at: http://www.fns.usda.gov/about-fns (last visited 3/2/14).
[6] 7 C.F.R. s. 271.2.
[7] P.L. 110-246, provides that certain individuals because of age, disability or living arrangement may purchase hot foods with their SNAP EBT card.
[8] Supplemental Nutrition Assistance Program-Retailers, USDA Food and Nutrition Service, *accessible at:* http://www.fns.usda.gov/snap/retailers/merchants.htm. (last visited 3/2/14).
[9] Supplemental Nutrition Assistance Program-Retailers, USDA Food and Nutrition Service, *accessible at:* http://www.fns.usda.gov/snap/retailers/merchants.htm. (last visited 3/2/14).

each store location and a SNAP permit is no longer valid if a store is closed, moved, or sold.[10] Licensed stores are fully reviewed for eligibility at least once every five years.[11]

To apply as a SNAP provider, retailers must meet basic eligibility requirements. For basic eligibility, the store must sell food for home preparation and consumption and must also meet ONE of the following conditions:

- Offer at least three varieties of qualifying foods in each of the following four stable food groups on a continuous basis[12]:
  - Meat, poultry, or fish;
  - Bread or cereal;
  - Vegetables or fruits; and
  - Dairy products.
- More than 50% of the total dollar amount of all retail sales sold in the store must be from the sale of eligible staple foods.[13]

Qualified retailers can then apply to be a SNAP provider, either online or with the use of a paper application.[14]

Once a retailer is licensed, the store will receive a seven digit FNS number, which is used to identify both the store and the owner.[15]

Florida Food Assistance Program

The Florida Department of Children and Families (DCF) administers and operates the state's food assistance program (SNAP), including the eligibility process for recipients.[16] The federal government pays 100 percent of the SNAP benefits, and the federal and state governments share the administrative costs.[17] The USDA determines the amount of food assistance benefits an individual or family receives, based on the individual's or family's income and resources.[18] Food assistance benefits are a supplement to a family's food budget. Households may need to spend some of their own cash, along with their food assistance benefits, to buy enough food for a month.[19] State law provides that DCF shall establish procedures in compliance with federal law for notifying the appropriate federal and state agencies of any violation of law regarding the food assistance program and the department must also notify the Department of Financial Services.[20]

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[10] Supplemental Nutrition Assistance Program-Retailers, USDA Food and Nutrition Service, *accessible at:* http://www.fns.usda.gov/snap/retailers/merchants.htm. (last visited 3/2/14).
[11] Supplemental Nutrition Assistance Program-Retailers, USDA Food and Nutrition Service, *accessible at:* http://www.fns.usda.gov/snap/retailers/merchants.htm. (last visited 3/2/14).
[12] The store must offer perishable goods in a least two of the categories.
[13] Supplemental Nutrition Assistance Program, USDA Food and Nutrition Service, *accessible at:* http://www.fns.usda.gov/snap/retailers/store-eligibility.htm. (last visited 3/2/14).
[14] Supplemental Nutrition Assistance Program, USDA "Operating a CSA and SNAP Participation," *accessible at*: http://www.fns.usda.gov/snap/ebt/fm.htm. (last visited 3/2/14).
[15] Supplemental Nutrition Assistance Program-Retailers, USDA Food and Nutrition Service, *accessible at:* http://www.fns.usda.gov/snap/retailers/merchants.htm. (last visited 3/2/14).
[16] S. 414.31, F.S.
[17] SNAP/Food Stamps, Food Research and Action Center, accessible at: http://frac.org/federal-foodnutrition-programs/snapfood-stamps/. (last visited 3/2/14).
[18] DCF Food Assistance Program Fact Sheet, www.dcf.state.fl.us/programs/access/docs/fafactsheet.pdf . (last visited 3/2/14).
[19] DCF Food Assistance Program Fact Sheet, www.dcf.state.fl.us/programs/access/docs/fafactsheet.pdf . (last visited 3/2/14).
[20] S. 414.33, F.S.

Use of the Electronic Benefits Card

Food assistance monies are placed on an Electronic Benefits Transaction (EBT) card. Once an individual applies for cash assistance or food assistance with DCF, they will receive an EBT card in the mail.[21]

Stores must have an EBT system to accept payment from SNAP benefits.[22] Shortly after receiving approval to offer SNAP benefits, Florida's EBT contractor will contact the retailer regarding an EBT system.[23] There are three ways to accept EBT: point of sale (POS); a machine that collects EBT, credit, and debit; and a manual paper voucher process.

- The POS system is electronic and free for retailers selling over $100 in SNAP benefits monthly. Retailers using POS systems usually receive payment within two banking days.
- To use a machine that processes credit, debit, and EBT transactions, the retailer must arrange to have commercial equipment provided to you by a third-party processor. Commercial equipment is provided at a cost that the retailer negotiates with the third-party processor. Commercial equipment is often integrated, meaning that the POS terminal, cash register, and scanning device are all connected together in order to speed transactions and minimize errors.
- The manual paper voucher process is a free way for retailers to accept EBT. The retailer must fill out a voucher and have the customer sign the form. Prior to completing the transaction, the retailer must call customer service to confirm that the customer has enough money in their SNAP account to purchase the items. At that point the transaction is complete. To collect money from the transaction, the retailer must electronically clear the voucher within 15 days or send the voucher to the state by the set expiration date.[24]

Farmer's Markets

Farmer's markets are sometimes eligible to collect SNAP benefits as a form of payment for the sale of food. The USDA defines a farmer's market as "a multi-stall market at which farmer-producers sell agricultural products directly to the general public at a central or fixed location, particularly fresh fruit and vegetables (but also meat products, dairy products, and/or grains)."[25] Like traditional retailers, the USDA requires farmer's markets to obtain a license in order to accept SNAP benefits as a form of payment.[26]

Individual farmers may apply for and receive a license to accept SNAP benefits, but when individual farmers do not have a license to accept SNAP benefits, the farmer's market, rather than the individual farmers, must hold an FNS license in order to accept SNAP.[27] In these cases, the farmers market can use a scrip system for payment and use a centralized POS device to process transactions.[28]

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[21] EBT Card Issuance, Department of Children and Families Access Program. http://www.myflfamilies.com/service-programs/access-florida-food-medical-assistance-cash/ebt-card-issuance. (last visited 3/2/14).
[22] SNAP Training guide for Retailers, USDA Food and Nutrition Service, *accessible at*: http://www.fns.usda.gov/snap/retailers/store-training.htm.
[23] SNAP Training guide for Retailers, USDA Food and Nutrition Service, *accessible at*: http://www.fns.usda.gov/snap/retailers/store-training.htm. (last accessed 3/2/14).
[24] *Id.*
[25] What is a Farmer's Market, Supplemental Nutrition Assistance Program, USDA *accessible at*: http://www.fns.usda.gov/snap/ebt/fm-scrip-what_is_fm.htm. (last accessed 3/2/14).
[26] Market Responsibilities, Supplemental Nutrition Assistance Program, USDA *accessible at*: http://www.fns.usda.gov/snap/ebt/fm-scrip-market_responsibilities.htm. (last accessed 3/2/14).
[27] Scrip System, Supplemental Nutrition Assistance Program, USDA *accessible at*: http://www.fns.usda.gov/snap/ebt/fm-scrip-what_is_scrip.htm. (last accessed 3/2/14).
[28] *Id.*

There are two basic scrip systems: a paper scrip (or token system) and a receipt system.[29]

- The paper scrip system requires the farmer's market to design and purchase tokens or print paper script.[30] With the paper scrip system, customers swipe their EBT card at a centrally located POS device and the market staff give the customers paper scrip, or tokens in exchange for the amount debited from the EBT card.[31] Customers can then use the paper scrip or tokens to purchase eligible food at booths throughout the market.[32]
- With the receipt system, customers shop for eligible food and individual vendors hold this food aside for the customer.[33] The vendor makes a list of the food and the customer takes the list to a centralized POS to pay with their EBT card.[34] After paying, the customer receives a receipt, which they take to the vendor in exchange for the food which has been held aside.[35]

The farmer's market also must train farmers in scrip redemption rules and procedures, since the market's ability to accept SNAP benefits could be jeopardized if the farmer commits a SNAP violation while operating under the market's license.[36] In addition, the farmer's market must develop an accounting system and method for reimbursing vendors.[37]

Farmer's Markets Which Accept EBT

Only a small percentage of farmers' markets and produce markets participate in SNAP EBT.[38] Currently, farmers' markets choose whether or not to participate. For farmers' markets that choose to be a SNAP retailer, DCF provides them with an EBT system. The EBT POS devices are installed and the retailer receives EBT services via the vendor under contract to DCF, as required by federal regulation.

In order to encourage greater EBT participation within the markets, USDA provided grant money to expand the use of the EBT wireless POS devices within farmers' markets. The funding has been offered to markets which were not already authorized SNAP retailers on or before November 18, 2011, the date on which Public Law 112-55 was enacted.[39]

On July 27, 2012, the State of Florida announced the funding opportunity and engaged in a marketing campaign to encourage more farmers' markets to participate in EBT. Promotional letters, flyers, social media engagement, and emails have been sent out to inform farmers markets throughout the state about this opportunity. Fourteen Florida farmers markets' are currently participating in EBT with one more market in the implementation phase.[40]

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[29] Scrip System, Supplemental Nutrition Assistance Program, USDA *accessible at*: http://www.fns.usda.gov/snap/ebt/fm-scrip-what_is_scrip.htm. (last accessed 3/2/14).
[30] Market Responsibilities, Supplemental Nutrition Assistance Program, USDA *accessible at*: http://www.fns.usda.gov/snap/ebt/fm-scrip-market_responsibilities.htm. (last accessed 3/2/14).
[31] Scrip System, Supplemental Nutrition Assistance Program, USDA *accessible at*: http://www.fns.usda.gov/snap/ebt/fm-scrip-what_is_scrip.htm. (last accessed 3/2/14).
[32] *Id.*
[33] *Id.*
[34] *Id.*
[35] *Id.*
[36] Market Responsibilities, Supplemental Nutrition Assistance Program, USDA *accessible at*: http://www.fns.usda.gov/snap/ebt/fm-scrip-market_responsibilities.htm. (last accessed 3/2/14).
[37] *Id.*
[38] Feasibility of Implementing Electronic Benefit Transfer Systems in Farmer's Markets, Supplemental Nutrition Assistance Program, Report to Congress, US Department of Agriculture, Food and Nutrition Service, 2010, *accessible at*: http://www.fns.usda.gov/ebt/learn-about-snap-benefits-farmers-markets. (last accessed 3/2/14).
[39] Department of Children and Families analysis of HB 535, January 23, 2014.
[40] *Id.*

Effect of Proposed Changes

The bill authorizes the owner or operator of a fresh produce market which does not have an EBT system to allow certain groups to implement and operate an EBT system in the market on behalf of the produce sellers. The bill lists groups authorized to set up the EBT operations and specifies that these groups must also be authorized by the Food and Nutrition Service. The groups specified in the bill includes a food nutrition service group, association of produce sellers active in the market or a food nutrition service third party organization.

If an outside group establishes the EBT system, the bill requires that the market owner or operator must reasonably accommodate the group in the implementation and operation of the EBT system for accepting SNAP benefits.

This bill states that the EBT system requirement does not apply to a market selling fresh produce whose owner or operator has an EBT system for accepting SNAP benefits in the market. The requirement also does not prohibit an authorized food and nutrition service produce seller in a market selling fresh produce from operating his or her own EBT system as part of his or her customer transaction options. The bill also does not require a market owner or operator to create, operate, or maintain an EBT system on behalf of his produces sellers.

B. SECTION DIRECTORY:

Section 1: Creates an unnumbered section of law, relating to the Fresh Produce Markets
Section 2: Provides for an effective date.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The title of the bill states that the bill "requires certain owners and operators of farmers' markets, community farmers' markets, flea markets, and other open-air markets selling fresh produce to allow authorized Food and Nutrition Service groups, associations, and third-party organizations to operate electronic benefits transfer systems in such markets." This does not accurately reflect the content of the bill. The title should be amended to read "authorizing certain owners and operators of farmers' markets, community farmers' markets, flea markets, and other open-air markets selling fresh produce to allow authorized Food and Nutrition Service groups, associations, and third-party organizations to operate electronic benefits transfer systems in such markets."

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to transactions in fresh produce markets; providing definitions; requiring certain owners and operators of farmers' markets, community farmers' markets, flea markets, and other open-air markets selling fresh produce to allow authorized Food and Nutrition Service groups, associations, and third-party organizations to operate electronic benefits transfer systems in such markets; providing for applicability; providing an effective date.

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

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

(a) "Market" means a farmers' market, community farmers' market, flea market, or other open-air market.

(b) "SNAP" means the federal Supplemental Nutrition Assistance Program established under 7 U.S.C. ss. 2011 et seq.

(2)(a) The owner or operator of a market selling fresh produce who is not an authorized SNAP retailer may allow an authorized Food and Nutrition Service group or association of produce sellers that is actively participating in produce sales in the market, or an authorized Food and Nutrition Service third-party organization, to implement and operate an electronic benefits transfer system for purposes of accepting SNAP benefits in the market on behalf of the produce sellers to the extent and

manner allowed by federal law and regulation.

(b) The authorized Food and Nutrition Service group, association, or third-party organization responsible for implementation and operation of the electronic benefits transfer system may not be another market that competes with the market being served.

(c) The market owner or operator shall reasonably accommodate the authorized Food and Nutrition Service group, association, or third-party organization in the implementation and operation of an electronic benefits transfer system for purposes of accepting SNAP benefits.

(3) This section does not:

(a) Apply to a market selling fresh produce whose owner or operator has an electronic benefits transfer system for accepting SNAP benefits in the market.

(b) Prohibit an authorized Food and Nutrition Service produce seller in a market selling fresh produce from operating his or her own electronic benefits transfer system as part of his or her customer transaction options.

(c) Require a market owner or operator to create, operate, or maintain an electronic benefits transfer system on behalf of its produce sellers.

Section 2. This act shall take effect July 1, 2014.

COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. HB 535 (2014)

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 & Human Services Committee

Representative Fullwood offered the following:

Amendment (with title amendment)

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

Remove line 3 and insert:

Markets; providing definitions; authorizing certain

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 829 Involuntary Examinations under the Baker Act
SPONSOR(S): Civil Justice Subcommittee; Campbell and Rehwinkel Vasilinda
TIED BILLS: None **IDEN./SIM. BILLS:** SB 1544

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Select Committee on Health Care Workforce Innovation	16 Y, 0 N	Guzzo	Calamas
2) Civil Justice Subcommittee	11 Y, 0 N, As CS	Westcott	Bond
3) Health & Human Services Committee		Guzzo	Calamas

SUMMARY ANALYSIS

In 1971, the Legislature passed the Florida Mental Health Act (also known as "The Baker Act") to address mental health needs of individuals in the state. The Baker Act allows for voluntary and involuntary examination of an individual and establishes procedures for the court, law enforcement and the medical community that ensure the preservation of an individual's rights relating to medical services.

The Baker Act authorizes involuntary examination of an individual who appears to have a mental illness and who, because of mental illness, presents a substantial threat of harm to themselves or others. Involuntary examination may be initiated by courts, law enforcement officers, physicians, clinical psychologists, psychiatric nurses, mental health counselors, marriage and family therapists, and clinical social workers.

The bill adds advanced registered nurse practitioners and physician assistants to the list of medical professionals who may execute a certificate for involuntary examination of a person. The bill provides that a nurse practitioner or physician assistant must meet certain training or certification requirements before being able to execute a certificate for involuntary examination of a person.

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

The bill provides an effective date of July 1, 2014.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Involuntary Examination Under the Baker Act

In 1971, the Legislature passed the Florida Mental Health Act (also known as "The Baker Act") to address mental health needs in the state.[1] Part I of Chapter 394, F.S., provides authority and process for the voluntary and involuntary examination of persons with evidence of a mental illness and the subsequent inpatient or outpatient placement of individuals for treatment. The Department of Children and Families (DCF) administers this law through receiving facilities which provide for the examination of persons with evidence of a mental illness. Receiving facilities are designated by DCF and may be public or private facilities which provide the examination and short-term treatment of persons who meet criteria under The Baker Act.[2] Subsequent to examination at a receiving facility, a person who requires further treatment may be transported to a treatment facility. Treatment facilities designated by DCF are state hospitals (e.g., Florida State Hospital) which provide extended treatment and hospitalization beyond what is provided in a receiving facility.[3]

Current law provides that an involuntary examination may be initiated for a person if there is reason to believe the person has a mental illness and because of the illness:[4]

- The person has refused a voluntary examination after explanation of the purpose of the exam or is unable to determine for themselves that an examination is needed; and
- The person and is likely to suffer from self-neglect, substantial harm to themselves, or be a danger to themselves or others.

An involuntary examination may be initiated by a circuit court or a law enforcement officer.[5] A circuit court may enter an *ex parte* order stating a person meets the criteria for involuntary examination. A law enforcement officer, as defined in s. 943.10, F.S., may take a person into custody who appears to meet the criteria for involuntary examination and transport them to a receiving facility for examination.

In addition, the following professionals, when they have examined a person within the preceding 48 hours, may issue a certificate stating that the person meets the criteria for involuntary examination:[6]

- A physician licensed under ch. 458, F.S., or an osteopathic physician licensed under ch. 459, F.S., who has experience in the diagnosis and treatment of mental and nervous disorders.
- A physician employed by a facility operated by the United States Department of Veterans Affairs which qualifies as a receiving or treatment facility.
- A clinical psychologist, as defined in s. 490.003(7), F.S., with 3 years of postdoctoral experience in the practice of clinical psychology, inclusive of the experience required for licensure, or a psychologist employed by a facility operated by the United States Department of Veterans Affairs that qualifies as a receiving or treatment facility.
- A psychiatric nurse licensed under part I of ch. 464, F.S., who has a master's degree or a doctorate in psychiatric nursing and 2 years of post-master's clinical experience under the supervision of a physician.

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[1] Section 1, ch. 71-131, L.O.F.
[2] Section 394.455(26), F.S.
[3] Section 394.455(32), F.S.
[4] Section 394.463(1), F.S.
[5] Section 394.463(2)(a), F.S.
[6] *Id.*

- A mental health counselor licensed under ch. 491, F.S.
- A marriage and family therapist licensed under ch. 491, F.S.[7]
- A clinical social worker licensed under ch. 491, F.S.[8]

In 2011, there were 150,466 involuntary examinations initiated in the state. Law enforcement initiated almost half of the involuntary exams (49.21 percent) followed by mental health professionals and physicians (48.73 percent) and then *ex parte* orders by judges (2.06 percent).[9]

Physician Assistants

Sections 458.347(7) and 459.022(7), F.S., govern the licensure of physician assistants (PAs) in Florida. PAs are licensed by the Department of Health (DOH) and are regulated by the Florida Council on Physician Assistants (Council) and either the Florida Board of Medicine (Board of Medicine) for PAs licensed under ch. 458, F.S., or the Florida Board of Osteopathic Medicine (Osteopathic Board) for PAs licensed under ch. 459, F.S. Currently, there are 5,874 active licensed PAs in Florida.[10]

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

PAs are regulated through the respective physician practice acts.[13] Each of the medical practice acts has a corresponding board (i.e., the Board of Medicine and Osteopathic Board). The duty of a Board and its members is to make disciplinary decisions concerning whether a doctor or PA was practicing medicine within the confines of their practice act.[14]

To become licensed as a PA in Florida, an applicant must demonstrate to the Council:[15] passage of the National Commission on Certification of Physician Assistant exam; completion of the application; completion of a PA training program; a sworn, notarized statement of felony convictions; a sworn statement of denial or revocation of licensure in any state; letters of recommendation from physicians;[16] payment of a licensure fee; and completion of a two hour course on the prevention of medical errors, error reduction and prevention, and patient safety.[17] Licensure renewal occurs biennially.[18]

In 2008 Attorney General Bill McCollum issued an opinion stating that:

> *A physician assistant licensed pursuant to Chapter 458 or 459, F.S., may refer a patient for involuntary evaluation pursuant to section 394.463, F.S., provided that the physician assistant*

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[7] Marriage and Family Therapists use practice methods of a psychological nature to evaluate, assess, diagnose, treat and prevent emotional and mental disorders or dysfunctions. Section 491.003(8), F.S.
[8] Clinical Social Workers are required by law to have experience in providing psychotherapy and counseling. Section 491.003(3), F.S.
[9] Department of Children and Families, *Florida's Baker Act: 2013 Fact Sheet*, available at http://myflfamilies.com/service-programs/mental-health/baker-act-manual (last visited March 7, 2014).
[10] Florida Department of Health, *Medical Quality Assurance Annual Report 2012-2013*, available at http://www.floridahealth.gov/licensing-and-regulation/reports-and-publications/annual-reports.html (last visited March 7, 2014).
[11] Rule 64B8-30.012(1), F.A.C, and Rule 64B15-6.010(1), F.A.C.
[12] Section 458.347(3), F.S., and s. 459.022(3), F.S.
[13] Chapters 458 and 459, F.S.
[14] Section 458.347(12), F.S., and 459.022(12), F.S.
[15] Section 458.347(7), F.S., and s. 459.022(7), F.S.
[16] Rule 64B8-30.003(1), F.A.C., and Rule 64B15-6.003(1), F.A.C.
[17] Rule 64B8-30.003(3), F.A.C., and Rule 64B15-6.003(4), F.A.C.
[18] Section 458.347(7)(c), F.S. Rule 64B8-30.019, F.A.C., establishes the initial licensure and renewal fee schedule. Section 459.022(7)(b), F.S. Rule 64B15-6.013, F.A.C., establishes the initial licensure and renewal fee schedule.

has experience regarding the diagnosis and treatment of mental and nervous disorders and such tasks as are within the supervising physician's scope of practice.[19]

However, PAs are not required by law to have experience in the diagnosis and treatment of mental and nervous disorders.

Advanced Registered Nurse Practitioners (ARNPs)

Part I of ch. 464, F.S., governs the licensure and regulation of nurses in Florida. Nurses are licensed by DOH and are regulated by the Board of Nursing. Licensure requirements to practice advanced and specialized nursing include completion of education requirements,[20] demonstration of passage of a department approved examination, a clean criminal background screening, and payment of applicable fees.[21] Renewal is biennial and contingent upon completion of certain continuing medical education requirements.

A nurse who holds a license to practice advanced and specialized nursing may be certified as an ARNP under s. 464.012, F.S., if the nurse meets one or more of the following requirements:

- Completion of a post basic education program of at least one academic year that prepares nurses for advanced or specialized practice;
- Certification by a specialty board, such as a registered nurse anesthetist or nurse midwife; or
- Possession of a master's degree in a nursing clinical specialty area.

Current law defines three categories of ARNPs: certified registered nurse anesthetists, certified nurse midwives, and nurse practitioners.[22] All ARNPs, regardless of practice category, may only practice within the framework of an established protocol and under the supervision of an allopathic or osteopathic physician or a dentist.[23] ARNPs may carry out treatments as specified in statute, including:[24]

- Monitoring and altering drug therapies;
- Initiating appropriate therapies for certain conditions;
- Performing additional functions as may be determined by rule in accordance with s. 464.003(2), F.S.;[25] and
- Ordering diagnostic tests and physical and occupational therapy.

In addition to the above allowed acts, ARNPs may also perform other acts as authorized by statute and within his or her specialty.[26] Further, if it is within the ARNPs established protocol, the ARNP may establish behavioral problems and diagnosis and make treatment recommendations.[27]

There are 15,420 active, licensed ARNPs in Florida.[28]

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[19] *See*, 08-31 Fla. Op. Att'y Gen. (2008). Available at: http://www.dcf.state.fl.us/programs/samh/MentalHealth/laws/agopinion.pdf (last visited March 7, 2014).

[20] Rule 64B9-4.003, F.A.C., provides that an Advanced Nursing Program shall be at least one year long and shall include theory in the biological, behavioral, nursing and medical sciences relevant to the area of advanced practice in addition to clinical expertise with a qualified preceptor.

[21] Section 464.009, F.S., provides an alternative to licensure by examination for nurses through licensure by endorsement.

[22] Section 464.012(2), F.S.

[23] Section 464.012(3), F.S.

[24] *Id.*

[25] Section 464.003(2), F.S., defines "Advanced or Specialized Nursing Practice" to include additional activities that an ARNP may perform as approved by the Board of Nursing.

[26] Section 464.012(4), F.S.

[27] Section 464.012(4)(c)5, F.S.

[28] Florida Department of Health, *Medical Quality Assurance Annual Report 2012-2013*, available at http://www.floridahealth.gov/licensing-and-regulation/reports-and-publications/annual-reports.html (last visited March 7, 2014).

Effect of Proposed Changes

The bill amends s. 394.463, F.S., to add that a PA or an ARNP may execute a certificate stating that a person who the ARNP or PA has examined within the preceding 48 hours appears to meet the criteria for involuntary examination for mental illness. The PA or ARNP may only execute the certificate if he or she has:

- Completed 40 hours of training approved by the Board of Medicine or the Board of Nursing, as appropriate; or
- Has passed a national certification exam that includes testing on mental health law or the care of patients with mental illness; or
- Has subsequently completed and passed a 40-clock-hour course, approved by the relevant board, concerning the Florida Mental Health Act or mental health.

The PA or ARNP is also required to biannually complete 2 hours of approved continuing education concerning the Florida Mental Health Act. If any colleges or universities already have the Florida Mental Health Act or mental health in their curriculum, they will be grandfathered.

The bill also amends s. 394.455, F.S., to add definitions of PAs and ARNPs to the terms associated with the provision of services and care under the Florida Mental Health Act.

The bill makes several necessary conforming changes due to the statutory changes made by the bill.

B. SECTION DIRECTORY:

Section 1: Amends s. 39.407, F.S., relating to medical, psychiatric, and psychological examination and treatment of child; physical, mental, or substance abuse examination of person with or requesting child custody.
Section 2: Amends s. 394.455, F.S., relating to definitions.
Section 3: Amends s. 394.463, F.S., relating to involuntary examination.
Section 4: Amends s. 394.495, F.S., relating to child and adolescent mental health system of care; programs and services.
Section 5: Amends s. 394.496, F.S., relating to service planning.
Section 6: Amends s. 394.9085, F.S., relating to behavioral provider liability.
Section 7: Amends s. 409.972, F.S., relating to mandatory and voluntary enrollment.
Section 8: Amends s. 744.704, F.S., relating to powers and duties.
Section 9: Provides an effective date of July 1, 2014.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

No additional rule-making is necessary to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 18, 2014, the Civil Justice Subcommittee adopted one amendment and reported the bill favorably as a committee substitute. The amendment provides that a PA or ARNP must meet certain training or educational requirements before he or she may issue a certificate for involuntary examination.

This analysis is drafted to the committee substitute as passed by the Civil Justice Subcommittee.

A bill to be entitled

An act relating to involuntary examinations under the Baker Act; reordering and amending s. 394.455, F.S.; providing definitions; updating references to the Department of Children and Families; amending s. 394.463, F.S.; authorizing physician assistants and advanced registered nurse practitioners to initiate involuntary examinations under the Baker Act of persons believed to have mental illness; providing education and continuing education requirements for such physician assistants and advanced registered nurse practitioners; amending ss. 39.407, 394.495, 394.496, 394.9085, 409.972, and 744.704, F.S.; conforming cross-references; providing an effective date.

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

Section 1. Paragraph (a) of subsection (3) of section 39.407, Florida Statutes, is amended to read:

39.407 Medical, psychiatric, and psychological examination and treatment of child; physical, mental, or substance abuse examination of person with or requesting child custody.—

(3)(a)1. Except as otherwise provided in subparagraph (b)1. or paragraph (e), before the department provides psychotropic medications to a child in its custody, the

prescribing physician shall attempt to obtain express and informed consent, as defined in s. 394.455 ~~394.455(9)~~ and as described in s. 394.459(3)(a), from the child's parent or legal guardian. The department must take steps necessary to facilitate the inclusion of the parent in the child's consultation with the physician. However, if the parental rights of the parent have been terminated, the parent's location or identity is unknown or cannot reasonably be ascertained, or the parent declines to give express and informed consent, the department may, after consultation with the prescribing physician, seek court authorization to provide the psychotropic medications to the child. Unless parental rights have been terminated and if it is possible to do so, the department shall continue to involve the parent in the decisionmaking process regarding the provision of psychotropic medications. If, at any time, a parent whose parental rights have not been terminated provides express and informed consent to the provision of a psychotropic medication, the requirements of this section that the department seek court authorization do not apply to that medication until such time as the parent no longer consents.

2. Any time the department seeks a medical evaluation to determine the need to initiate or continue a psychotropic medication for a child, the department must provide to the evaluating physician all pertinent medical information known to the department concerning that child.

Section 2. Section 394.455, Florida Statutes, is reordered

and amended to read:

394.455 Definitions.—As used in this part, ~~unless the context clearly requires otherwise,~~ the term:

(1) "Administrator" means the chief administrative officer of a receiving or treatment facility or his or her designee.

(2) "Advanced registered nurse practitioner" means a practitioner licensed under part I of chapter 464 who is authorized to perform the functions listed in s. 464.012(4)(c).

(3) ~~(2)~~ "Clinical psychologist" means a psychologist as defined in s. 490.003(7) with 3 years of postdoctoral experience in the practice of clinical psychology, inclusive of the experience required for licensure, or a psychologist employed by a facility operated by the United States Department of Veterans Affairs that qualifies as a receiving or treatment facility under this part.

(4) ~~(3)~~ "Clinical record" means all parts of the record required to be maintained and includes all medical records, progress notes, charts, and admission and discharge data, and all other information recorded by a facility which pertains to the patient's hospitalization or treatment.

(5) ~~(4)~~ "Clinical social worker" means a person licensed as a clinical social worker under chapter 491.

(6) ~~(5)~~ "Community facility" means any community service provider contracting with the department to furnish substance abuse or mental health services under part IV of this chapter.

(7) ~~(6)~~ "Community mental health center or clinic" means a

publicly funded, not-for-profit center which contracts with the department for the provision of inpatient, outpatient, day treatment, or emergency services.

(8)~~(7)~~ "Court," unless otherwise specified, means the circuit court.

(9)~~(8)~~ "Department" means the Department of Children and Families ~~Family Services~~.

(10)~~(38)~~ "Electronic means" means a form of telecommunication that requires all parties to maintain visual as well as audio communication.

(11)~~(9)~~ "Express and informed consent" means consent voluntarily given in writing, by a competent person, after sufficient explanation and disclosure of the subject matter involved to enable the person to make a knowing and willful decision without any element of force, fraud, deceit, duress, or other form of constraint or coercion.

(12)~~(10)~~ "Facility" means any hospital, community facility, public or private facility, or receiving or treatment facility providing for the evaluation, diagnosis, care, treatment, training, or hospitalization of persons who appear to have a mental illness or have been diagnosed as having a mental illness. The term ~~"Facility"~~ does not include any program or entity licensed pursuant to chapter 400 or chapter 429.

(13)~~(11)~~ "Guardian" means the natural guardian of a minor, or a person appointed by a court to act on behalf of a ward's person if the ward is a minor or has been adjudicated

incapacitated.

(14) ~~(12)~~ "Guardian advocate" means a person appointed by a court to make decisions regarding mental health treatment on behalf of a patient who has been found incompetent to consent to treatment pursuant to this part. The guardian advocate may be granted specific additional powers by written order of the court, as provided in this part.

(15) ~~(13)~~ "Hospital" means a facility as defined in s. 395.002 and licensed under chapter 395 and part II of chapter 408.

(16) ~~(14)~~ "Incapacitated" means that a person has been adjudicated incapacitated pursuant to part V of chapter 744 and a guardian of the person has been appointed.

(17) ~~(15)~~ "Incompetent to consent to treatment" means that a person's judgment is so affected by his or her mental illness that the person lacks the capacity to make a well-reasoned, willful, and knowing decision concerning his or her medical or mental health treatment.

(18) ~~(34)~~ "Involuntary examination" means an examination performed under s. 394.463 to determine if an individual qualifies for involuntary inpatient treatment under s. 394.467(1) or involuntary outpatient treatment under s. 394.4655(1).

(19) ~~(35)~~ "Involuntary placement" means either involuntary outpatient treatment pursuant to s. 394.4655 or involuntary inpatient treatment pursuant to s. 394.467.

(20) ~~(16)~~ "Law enforcement officer" means a law enforcement officer as defined in s. 943.10.

(21) ~~(36)~~ "Marriage and family therapist" means a person licensed as a marriage and family therapist under chapter 491.

(22) ~~(37)~~ "Mental health counselor" means a person licensed as a mental health counselor under chapter 491.

(23) ~~(17)~~ "Mental health overlay program" means a mobile service which provides an independent examination for voluntary admissions and a range of supplemental onsite services to persons with a mental illness in a residential setting such as a nursing home, assisted living facility, adult family-care home, or nonresidential setting such as an adult day care center. Independent examinations provided pursuant to this part through a mental health overlay program must only be provided under contract with the department for this service or be attached to a public receiving facility that is also a community mental health center.

(24) ~~(18)~~ "Mental illness" means an impairment of the mental or emotional processes that exercise conscious control of one's actions or of the ability to perceive or understand reality, which impairment substantially interferes with the person's ability to meet the ordinary demands of living. For the purposes of this part, the term does not include a developmental disability as defined in chapter 393, intoxication, or conditions manifested only by antisocial behavior or substance abuse impairment.

(25)~~(19)~~ "Mobile crisis response service" means a nonresidential crisis service attached to a public receiving facility and available 24 hours a day, 7 days a week, through which immediate intensive assessments and interventions, including screening for admission into a receiving facility, take place for the purpose of identifying appropriate treatment services.

(26)~~(20)~~ "Patient" means any person who is held or accepted for mental health treatment.

(27)~~(21)~~ "Physician" means a medical practitioner licensed under chapter 458 or chapter 459 who has experience in the diagnosis and treatment of mental and nervous disorders or a physician employed by a facility operated by the United States Department of Veterans Affairs which qualifies as a receiving or treatment facility under this part.

(28) "Physician assistant" means a physician assistant licensed under chapter 458 or chapter 459 who has experience regarding the diagnosis and treatment of mental and nervous disorders and such tasks as are within the supervising physician's scope of practice.

(29)~~(22)~~ "Private facility" means any hospital or facility operated by a for-profit or not-for-profit corporation or association that provides mental health services and is not a public facility.

(30)~~(23)~~ "Psychiatric nurse" means a registered nurse licensed under part I of chapter 464 who has a master's degree

or a doctorate in psychiatric nursing and 2 years of post-master's clinical experience under the supervision of a physician.

(31) ~~(24)~~ "Psychiatrist" means a medical practitioner licensed under chapter 458 or chapter 459 who has primarily diagnosed and treated mental and nervous disorders for a period of not less than 3 years, inclusive of psychiatric residency.

(32) ~~(25)~~ "Public facility" means any facility that has contracted with the department to provide mental health services to all persons, regardless of their ability to pay, and is receiving state funds for such purpose.

(33) ~~(26)~~ "Receiving facility" means any public or private facility designated by the department to receive and hold involuntary patients under emergency conditions or for psychiatric evaluation and to provide short-term treatment. The term does not include a county jail.

(34) ~~(27)~~ "Representative" means a person selected to receive notice of proceedings during the time a patient is held in or admitted to a receiving or treatment facility.

(35) ~~(28)~~ (a) "Restraint" means a physical device, method, or drug used to control behavior. A physical restraint is any manual method or physical or mechanical device, material, or equipment attached or adjacent to the individual's body so that he or she cannot easily remove the restraint and which restricts freedom of movement or normal access to one's body.

(b) A drug used as a restraint is a medication used to

control the person's behavior or to restrict his or her freedom of movement and is not part of the standard treatment regimen of a person with a diagnosed mental illness who is a client of the department. Physically holding a person during a procedure to forcibly administer psychotropic medication is a physical restraint.

(c) Restraint does not include physical devices, such as orthopedically prescribed appliances, surgical dressings and bandages, supportive body bands, or other physical holding when necessary for routine physical examinations and tests; or for purposes of orthopedic, surgical, or other similar medical treatment; when used to provide support for the achievement of functional body position or proper balance; or when used to protect a person from falling out of bed.

(36) ~~(29)~~ "Seclusion" means the physical segregation of a person in any fashion or involuntary isolation of a person in a room or area from which the person is prevented from leaving. The prevention may be by physical barrier or by a staff member who is acting in a manner, or who is physically situated, so as to prevent the person from leaving the room or area. For purposes of this chapter, the term does not mean isolation due to a person's medical condition or symptoms.

(37) ~~(30)~~ "Secretary" means the Secretary of Children and Families ~~Family Services~~.

(38) ~~(33)~~ "Service provider" means any public or private receiving facility, an entity under contract with the Department

of Children and Families ~~Family Services~~ to provide mental health services, a clinical psychologist, a clinical social worker, a marriage and family therapist, a mental health counselor, a physician, a psychiatric nurse as defined in subsection (30) ~~(23)~~, or a community mental health center or clinic as defined in this part.

(39) ~~(31)~~ "Transfer evaluation" means the process, as approved by the appropriate district office of the department, whereby a person who is being considered for placement in a state treatment facility is first evaluated for appropriateness of admission to the facility by a community-based public receiving facility or by a community mental health center or clinic if the public receiving facility is not a community mental health center or clinic.

(40) ~~(32)~~ "Treatment facility" means any state-owned, state-operated, or state-supported hospital, center, or clinic designated by the department for extended treatment and hospitalization, beyond that provided for by a receiving facility, of persons who have a mental illness, including facilities of the United States Government, and any private facility designated by the department when rendering such services to a person pursuant to the provisions of this part. Patients treated in facilities of the United States Government shall be solely those whose care is the responsibility of the United States Department of Veterans Affairs.

Section 3. Paragraph (a) of subsection (2) of section 394.463, Florida Statutes, is amended to read:

394.463 Involuntary examination.—

(2) INVOLUNTARY EXAMINATION.—

(a) An involuntary examination may be initiated by any one of the following means:

1. A court may enter an ex parte order stating that a person appears to meet the criteria for involuntary examination, giving the findings on which that conclusion is based. The ex parte order for involuntary examination must be based on sworn testimony, written or oral. If other less restrictive means are not available, such as voluntary appearance for outpatient evaluation, a law enforcement officer, or other designated agent of the court, shall take the person into custody and deliver him or her to the nearest receiving facility for involuntary examination. The order of the court shall be made a part of the patient's clinical record. No fee shall be charged for the filing of an order under this subsection. Any receiving facility accepting the patient based on this order must send a copy of the order to the Agency for Health Care Administration on the next working day. The order shall be valid only until executed or, if not executed, for the period specified in the order itself. If no time limit is specified in the order, the order shall be valid for 7 days after the date that the order was signed.

2. A law enforcement officer shall take a person who

appears to meet the criteria for involuntary examination into custody and deliver the person or have him or her delivered to the nearest receiving facility for examination. The officer shall execute a written report detailing the circumstances under which the person was taken into custody, and the report shall be made a part of the patient's clinical record. Any receiving facility accepting the patient based on this report must send a copy of the report to the Agency for Health Care Administration on the next working day.

3.a. A physician, physician assistant, clinical psychologist, psychiatric nurse, mental health counselor, marriage and family therapist, ~~or~~ clinical social worker, or advanced registered nurse practitioner may execute a certificate stating that he or she has examined a person within the preceding 48 hours and finds that the person appears to meet the criteria for involuntary examination and stating the observations upon which that conclusion is based. If other less restrictive means are not available, such as voluntary appearance for outpatient evaluation, a law enforcement officer shall take the person named in the certificate into custody and deliver him or her to the nearest receiving facility for involuntary examination. The law enforcement officer shall execute a written report detailing the circumstances under which the person was taken into custody. The report and certificate shall be made a part of the patient's clinical record. Any receiving facility accepting the patient based on this

certificate must send a copy of the certificate to the Agency for Health Care Administration on the next working day.

b. A physician assistant or an advanced registered nurse practitioner may not execute a certificate as provided in sub-subparagraph a. unless he or she completed at least 40 clock hours of training approved by the Board of Medicine or the Board of Nursing, as appropriate, concerning the Florida Mental Health Act or mental health as part of his or her education and training program or has passed a national certification exam that includes testing on mental health law or the care of patients with mental illness or has subsequently completed and passed a 40-clock-hour course, approved by the relevant board, concerning the Florida Mental Health Act or mental health. A college or university that currently includes the Florida Mental Health Act or mental health in its curriculum shall be grandfathered. In addition, such a physician assistant or advanced registered nurse practitioner may not execute a certificate as provided in sub-subparagraph a. unless he or she biannually completes 2 hours of approved continuing education concerning the Florida Mental Health Act.

Section 4. Paragraphs (a) and (c) of subsection (3) of section 394.495, Florida Statutes, are amended to read:

394.495 Child and adolescent mental health system of care; programs and services.—

(3) Assessments must be performed by:

(a) A professional as defined in s. 394.455(3), (5), (27),

(30), or (31) ~~394.455(2), (4), (21), (23), or (24)~~;

(c) A person who is under the direct supervision of a professional as defined in s. 394.455(3), (5), (27), (30), or (31) ~~394.455(2), (4), (21), (23), or (24)~~ or a professional licensed under chapter 491.

The department shall adopt by rule statewide standards for mental health assessments, which must be based on current relevant professional and accreditation standards.

Section 5. Subsection (6) of section 394.496, Florida Statutes, is amended to read:

394.496 Service planning.—

(6) A professional as defined in s. 394.455(3), (5), (27), (30), or (31) ~~394.455(2), (4), (21), (23), or (24)~~ or a professional licensed under chapter 491 must be included among those persons developing the services plan.

Section 6. Subsection (6) of section 394.9085, Florida Statutes, is amended to read:

394.9085 Behavioral provider liability.—

(6) For purposes of this section, the terms "receiving facility," "addictions receiving facility," and "detoxification services," ~~"addictions receiving facility," and "receiving facility"~~ have the same meanings as ~~those~~ provided in ss. 394.455(33), 397.311(18)(a)1., and 397.311(18)(a)4., ~~397.311(18)(a)1., and 394.455(26),~~ respectively.

Section 7. Paragraph (b) of subsection (2) of section

409.972, Florida Statutes, is amended to read:

409.972 Mandatory and voluntary enrollment.—

(2) The following Medicaid-eligible persons are exempt from mandatory managed care enrollment required by s. 409.965, and may voluntarily choose to participate in the managed medical assistance program:

(b) Medicaid recipients residing in residential commitment facilities operated through the Department of Juvenile Justice or mental health treatment facilities as defined by s. 394.455(40) ~~394.455(32)~~.

Section 8. Subsection (7) of section 744.704, Florida Statutes, is amended to read:

744.704 Powers and duties.—

(7) A public guardian shall not commit a ward to a mental health treatment facility, as defined in s. 394.455(40) ~~394.455(32)~~, without an involuntary placement proceeding as provided by law.

Section 9. This act shall take effect July 1, 2014.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1047 Termination of Pregnancies
SPONSOR(S): Adkins
TIED BILLS: **IDEN./SIM. BILLS:** SB 918

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

SUMMARY ANALYSIS

In *Planned Parenthood v. Casey* the U.S. Supreme Court rejected the trimester framework established in *Roe v. Wade* and, instead, established viability as the point at which a state may regulate abortions. Similarly, in *In re T.W.*, the Florida Supreme Court held that the state may regulate abortion once fetal viability has been achieved.

Currently, Florida adheres to the trimester framework, as ch. 390, F.S., prohibits individuals from performing an abortion after the 24th week of pregnancy (third trimester). HB 1047 amends ch. 390 to create s. 390.01112, F.S., relating to abortions during viability. The bill prohibits an abortion if the fetus has achieved viability, which is defined in the bill as the stage of fetal development when the life of a fetus is sustainable outside the womb through standard medical measures.

Section 390.0111, F.S., currently provides exceptions to the prohibition against abortions during the third trimester when two physicians certify in writing that an abortion is medically necessary to save the life or protect the health of the pregnant woman, or one physician certifies in writing to the medical necessity for legitimate emergency medical procedures for an abortion, and another physician is not available for consultation. The bill modifies these exceptions to allow an abortion during the third trimester if:

- Two physicians certify, in writing, that the abortion is medically necessary to save the pregnant woman's life or avert a serious risk of substantial and irreversible physical impairment of a major bodily function of the pregnant woman, other than a psychological condition; or
- One physician certifies, in writing, that legitimate emergency medical procedures for an abortion are medically necessary to save the pregnant woman's life or avert a serious risk of imminent substantial and irreversible physical impairment of a major bodily function of the pregnant woman, other than a psychological condition and another physician is not available for consultation.

The bill provides identical exceptions to the prohibition against abortions during viability.

The bill requires a physician to determine if a fetus is viable before performing an abortion. The physician must document in the pregnant woman's medical record, the physician's determination and the method, equipment, fetal measurements, and any other information used to determine the viability of the fetus.

The bill provides for administrative and criminal penalties against any person who performs, or actively participates in an abortion during viability.

The bill amends s. 797.03, F.S., to prohibit any person from performing or assisting in an abortion on a person during viability other than in a hospital.

The bill includes severability and reversion clauses.

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

The bill provides an effective date of July 1, 2014.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Federal Case Law on Abortion

Right to Abortion

In 1973, the foundation of modern abortion jurisprudence, *Roe v. Wade*[1], was decided by the U.S. Supreme Court. Using strict scrutiny, the Court determined that a woman's right to an abortion is part of a fundamental right to privacy guaranteed under the Due Process Clause of the Fourteenth Amendment of the U.S. Constitution. Further, the Court reasoned that state regulation limiting the exercise of this right must be justified by a compelling state interest, and must be narrowly drawn.[2] In 1992, the fundamental holding of *Roe* was upheld by the U.S. Supreme Court in *Planned Parenthood v. Casey*.[3]

The Viability Standard

In *Roe v. Wade*, the U.S. Supreme Court established a rigid trimester framework dictating when, if ever, states can regulate abortion.[4] The Court held that states could not regulate abortions during the first trimester of pregnancy. With respect to the second trimester, the Court held that states could only enact regulations aimed at protecting the mother's health, not the fetus's life. Therefore, no ban on abortions is permitted during the second trimester. Only at the beginning of the third trimester of pregnancy does the state's interest in the life of the fetus become compelling so as to allow it to prohibit abortions. Even then, the Court requires states to permit an abortion in circumstances necessary to preserve the health or life of the mother.[5]

The current viability standard is set forth in *Planned Parenthood v. Casey*.[6] Recognizing that medical advancements in neonatal care can advance viability to a point somewhat earlier than the third trimester, the U.S. Supreme Court rejected the trimester framework and, instead, limited the states' ability to regulate abortion pre-viability.[7] Thus, while upholding the underlying holding in *Roe*, which authorizes states to "[r]egulate, and even proscribe, abortion except where it is necessary, in appropriate medical judgment, for the preservation of the life or health of the mother[,]"[8] the Court determined that the line for this authority should be drawn at "viability," because "..... there may be some medical developments that affect the precise point of viability...but this is an imprecision with tolerable limits given that the medical community and all those who must apply its discoveries will continue to explore the matter."[9] Furthermore, the Court recognized that "in some broad sense, it might be said that a woman who fails to act before viability has consented to the State's intervention on behalf of the developing child."[10]

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[1] *Roe v. Wade*, 410 U.S. 113 (1973).
[2] *Id.*
[3] *Casey*, 505 U.S. 833 (1992).
[4] *Roe*, 410 U.S. 113 (1973).
[5] *Id.* at 164-165.
[6] *Casey*, 505. U.S. 833 (1992).
[7] The standard developed in the Casey case was the "undue burden" standard, which provides that a state regulation cannot impose an undue burden on, meaning it cannot place a substantial obstacle in the path of, the woman's right to choose. *Id.* at 876-79.
[8] *See Roe*, 410 U.S. at 164-65.
[9] *See Casey, 505 U.S.* at 870.
[10] *Id.*

The Medical Emergency Exception

In *Doe v. Bolton*, the U.S. Supreme Court was faced with determining, among other things, whether a Georgia statute criminalizing abortions (pre- and post-viability), except when determined to be necessary based upon a physician's "best clinical judgment," was unconstitutionally void for vagueness for inadequately warning a physician under what circumstances an abortion could be performed.[11] In its reasoning, the Court agreed with the District Court decision that the exception was not unconstitutionally vague, by recognizing that:

> The medical judgment may be exercised in the light of all factors-physical, emotional, psychological, familial, and the woman's age-relevant to the well-being of the patient. All these factors may relate to health. This allows the attending physician the room he needs to make his best medical judgment.

This broad determination of what constituted a medical emergency was later tested in *Casey*[12], albeit in a different context. One question before the Supreme Court in *Casey* was whether the medical emergency exception to a 24-hour waiting period for an abortion was too narrow in that there were some potentially significant health risks that would not be considered "immediate."[13] The exception in question provided that a medical emergency is:

> That condition which, on the basis of the physician's good faith clinical judgment, so complicates the medical condition of a pregnant woman as to necessitate the immediate abortion of her pregnancy to avert death or for which delay will create serious risk of substantial and irreversible impairment of a major bodily function.[14]

In evaluating the more objective standard under which a physician is to determine the existence of a medical emergency, the Court in *Casey* determined that the exception would not significantly threaten the life and health of a woman and imposed no undue burden on the woman's right to choose.[15]

Florida Law on Abortion

Right to Abortion

Article I, s. 23 of the Florida Constitution provides an express right to privacy. The Florida Supreme Court has recognized the Florida's constitutional right to privacy "is clearly implicated in a woman's decision whether or not to continue her pregnancy."

In *In re T.W.,* the Florida Supreme Court ruled that:

> [P]rior to the end of the first trimester, the abortion decision must be left to the woman and may not be significantly restricted by the state. Following this point, the state may impose significant restrictions only in the least intrusive manner designed to safeguard the health of the mother. Insignificant burdens during either period must substantially further important state interests....Under our Florida Constitution, the state's interest becomes compelling upon viability....Viability under Florida law occurs at that point in

[11] *Doe*, 410 U.S. 179 (1973). Other exceptions, such as in cases of rape and when, "[t]he fetus would very likely be born with a grave, permanent, and irremediable mental or physical defect." *Id.* at 183. *See also, U.S. v. Vuitich*, 402 U.S. 62, 71-72 (1971)(determining that a medical emergency exception to a criminal statute banning abortions would include consideration of the mental health of the pregnant woman).
[12] *Casey*, 505. U.S. 833 (1992).
[13] *Id.* at 880.
[14] *Id.* at 879.
[15] *Id.* at 880.

time when the fetus becomes capable of meaningful life outside the womb through standard medical procedures.

The court recognized that after viability, the state can regulate abortion in the interest of the unborn child if the mother's health is not in jeopardy.[16]

Abortion Regulation

In Florida, abortion is defined as the termination of a human pregnancy with an intention other than to produce a live birth or to remove a dead fetus.[17] An abortion must be performed by a physician[18] licensed under ch. 458, F.S., or ch. 459, F.S., or a physician practicing medicine or osteopathic medicine in the employment of the United States.[19]

Section 390.0111, F.S., prohibits an abortion from being performed during the third trimester.[20] Exceptions to this prohibition exist when the abortion is necessary to protect the health of the pregnant woman which is established if:

- Two physicians certify in writing that, to a reasonable degree of medical probability, the abortion is necessary to save the life or preserve the health of the pregnant woman; or
- One physician certifies in writing to the medical necessity for legitimate *emergency* medical procedures for an abortion in the third trimester, and another physician is not available for consultation.[21]

The Department of Health (DOH) and its professional boards regulate healthcare practitioners under ch. 456, F.S., and various individual practice acts.[22] A board is a statutorily created entity that is authorized to exercise regulatory or rulemaking functions within the DOH.[23] Boards are responsible for approving or denying applications for licensure and making disciplinary decisions on whether a practitioner practices within the authority of their practice act. Practice acts refer to the legal authority in state statute that grants a profession the authority to provide services to the public. The range of disciplinary actions taken by a board includes citations, suspensions, reprimands, probations, and revocations.

The Agency for Health Care Administration (AHCA) licenses and regulates abortion clinics in the state, under ch. 390, F.S., and part II of ch. 408, F.S.[24] All abortion clinics and physicians performing abortions are subject to the following requirements:

- An abortion may only be performed in a validly licensed hospital, abortion clinic, or in a physician's office;[25]
- An abortion clinic must be operated by a person with a valid and current license;[26]
- A third trimester abortion may only be performed in a hospital;[27]
- Proper medical care must be given and used for a fetus when an abortion is performed during viability;[28]

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[16] *Id.*
[17] Section 390.011(1), F.S.
[18] Section 390.0111(2), F.S.
[19] Section 390.011(8), F.S.
[20] Section 390.011(9), F.S., defines the third trimester to mean the weeks of pregnancy after the 24th week of pregnancy.
[21] Section 390.0111(1)(a) and (b), F.S.
[22] Section 456.004, F.S.
[23] Section 456.001, F.S.
[24] Section 408.802(3) provides for the applicability of the Health Care Licensing Procedures Act to abortion clinics.
[25] Section 797.03 (1), F.S.
[26] Section 797.03 (2), F.S.
[27] Section 797.03(3), F.S. The violation of any of these provisions results in a second degree misdemeanor.
[28] Section 390.0111(4), F.S.

- Experimentation on a fetus is prohibited;[29]
- Except when there is a medical emergency, an abortion may only be performed after a patient has given voluntary and written informed consent;[30]
- Consent includes verification of the fetal age via ultrasound imaging;[31]
- Fetal remains are to be disposed of in a sanitary and appropriate manner;[32] and,
- Parental notice must be given 48 hours before performing an abortion on a minor,[33] unless waived by a parent or otherwise ordered by a judge.

In addition, pursuant to s. 390.012, F.S., AHCA is directed to prescribe standards for abortion clinics that include:

- Adequate private space for interviewing, counseling, and medical evaluations;
- Dressing rooms for staff and patients;
- Appropriate lavatory areas;
- Areas for pre-procedure hand-washing;
- Private procedure rooms;
- Adequate lighting and ventilation for procedures;
- Surgical or gynecological examination tables and other fixed equipment;
- Post-procedure recovery rooms that are equipped to meet the patients' needs;
- Emergency exits to accommodate a stretcher or gurney;
- Areas for cleaning and sterilizing instruments;
- Adequate areas for the secure storage of medical records and necessary equipment; and
- Conspicuous display of the clinic's license.[34]

Both DOH and AHCA have authority to take licensure action against individuals and clinics that are in violation of statutes or rules.[35]

Florida Abortion Statistics

In 2013, DOH reported that there were 214,405 live births in the state of Florida.[36] In the same year, AHCA reported that there were 71,503 abortion procedures performed in the state.[37] Of those performed:

- 65,098 were performed in the first trimester (12 weeks and under);
- 6,405 were performed in the second trimester (13 to 24 weeks); and
- None were performed in the third trimester (25 weeks and over).[38]

The majority of the procedures (65,210) were elective.[39] The remainder of the abortions were performed due to:

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[29] Section 390.0111(6), F.S.
[30] Section 390.0111(3), F.S. A physician violating this provision is subject to disciplinary action.
[31] Section 390.0111(3)(a)1.b., F.S.
[32] Section 390.0111(8), F.S. A person who improperly disposes of fetal remains commits a second degree misdemeanor.
[33] Section 390.01114(3), F.S. A physician who violates this provision is subject to disciplinary action.
[34] Section 390.012(3)(a)1., F.S. Rules related to abortion are found in ch. 59A-9, F.A.C.
[35] Section 390.018, F.S.
[36] Florida Department of Health, *Florida Vital Statistics Annual Reports- Births.* http://www.flpublichealth.com/VSBOOK/VSBOOK.aspx (last visited on March 25, 2014).
[37] Section 390.0112(1), F.S., currently requires the director of any medical facility in which any pregnancy is terminated to submit a monthly report to the AHCA that contains the number of procedures performed, the reason for same, and the period of gestation at the time such procedures were performed.
[38] *Reported Induced Terminations of Pregnancy (ITOP) by Reason, By Weeks of Gestation for Calendar Year 2013*, AHCA, on file with the Health Quality Subcommittee Staff.

- Emotional or psychological health of the mother (85);
- Physical health of the mother that was not life endangering (92);
- Life endangering physical condition (43);
- Incest (2);
- Rape (240);
- Serious fetal genetic defect, deformity, or abnormality (493); and
- Social or economic reasons (5,338).[40]

Viability

Current law defines "viability" as that stage of fetal development when the life of the unborn child may with a reasonable degree of medical probability be continued indefinitely outside the womb.[41] Twenty-one states currently place limits on abortions after the fetus is viable.[42]

The gestational age of a viable fetus has become earlier in the pregnancy over the years. In 1935, the American Academy of Pediatrics defined a premature infant as one who weighed <2,500 grams at birth regardless of gestational age.[43] Although no minimum weight for viability was established, 1,250 grams was frequently used and corresponded to an estimated gestational age of 28 weeks.[44]

As continuous positive airway pressure and neonatal total parenteral nutritional therapy became increasingly mainstream, the medical definition of viability continued to evolve as well. By the 1980s, survival of infants who were born weighing 500 to 700 grams or were of 24 to 26 weeks' gestation became an expected possibility in regional NICUs.[45] The 1980s and 1990s brought new waves of neonatal biomedical advances, led by tracheal instillation of surfactant for respiratory distress syndrome and the use of antenatal corticosteroids in women with imminent delivery of a preterm infant at 24 to 34 weeks' gestation.[46] With these changes, survival of infants born at 23 and 24 weeks' estimated gestational age became increasingly frequent.[47]

The determination of viability is not an exact science and the stage at which a fetus is viable is an individual determination based on each pregnant woman and fetus.[48] Gestational age, weight, sex, plurality or whether it is a single fetus, as well as other factors, may be considered in the determination of viability now and in the future as neonatal and medical care advances.[49]

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[39] *Id.*
[40] *Id.*
[41] Section 390.0111(4), F.S.
[42] These states include Arizona, California, Connecticut, Delaware, Georgia, Hawaii, Idaho, Illinois, Kentucky, Maine, Maryland, Michigan, Minnesota, Missouri, Montana, Ohio, Tennessee, Utah, Washington, Wisconsin, and Wyoming. *See* Guttmacher Institute State Policies in Brief *State Policies on Later Abortions*, as of February 1, 2014, found at: http://www.guttmacher.org/statecenter/spibs/spib_PLTA.pdf (Last visited March 25, 2014).
[43] *See Limits of Human Viability in the United States: A Medicolegal Review*, Bonnie Hope Arzuaga, MD and Ben Hokew Lee, MD, MPH, MSCR, Pediatrics Perspectives, published online November 1, 2011, available at: http://pediatrics.aappublications.org/content/128/6/1047.full (Last visited March 25, 2014).
[44] *Id.*
[45] *Id.*
[46]
[47] *Id.*
[48] The U.S. Department of Health and Human Services, National Institutes of Health *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, Pregnancy and Perinatology Branch-supported researchers developed a tool using data from the Neonatal Research Network (NRN) that shows outcome trends for infants born at extremely preterm gestations. Found at:http://www.nichd.nih.gov/about/org/der/branches/ppb/programs/epbo/pages/epbo_case.aspx, (Last visited March 25, 2014).
[49] Wolters Kluwer Health, UpToDate, available at: http://www.uptodate.com/contents/limit-of-viability , (Last visited March 25, 2014).

Effect of Proposed Changes

Definitions

The bill amends s. 390.011, F.S., to provide definitions for "viable" or "viability" and "standard medical measure." "Viable" or "viability" means the stage of fetal development when the life of a fetus is sustainable outside the womb through standard medical measures. "Standard medical measure" means the medical care that a physician would provide based on the particular facts of the pregnancy, the information available to the physician, and the technology reasonably available in a hospital, as defined in s. 395.002, F.S., with an obstetrical department, to preserve the life and health of the fetus, with or without temporary artificial life sustaining support, if the fetus were born at the same stage of fetal development.

Abortions After Viability

The bill creates s. 390.01112, F.S., relating to abortions during viability. The bill requires a physician to determine if a fetus is viable before performing an abortion. To satisfy this requirement, a physician must perform a medical examination of the pregnant woman and, to the maximum extent possible through reasonably available tests and the ultrasound required under s. 390.0111(3), F.S., an examination of the fetus. The physician must document in the pregnant woman's medical file the physician's determination and the method, equipment, fetal measurements, and any other information used to determine the viability of the fetus. The bill prohibits performing an abortion if a fetus has achieved viability.

Exceptions to Prohibited Abortions

Currently, s. 390.0111(1)(a), F.S., provides an exception to the prohibition against abortions during the third trimester if two physicians certify in writing to the fact that the abortion is necessary to save the life or preserve the health of the pregnant woman. The bill amends this section to allow an abortion if two physicians certify in writing that the procedure is medically necessary save the life or to avert a serious risk of substantial and irreversible physical impairment of a major bodily function of the pregnant woman. The bill expressly excludes psychological conditions from this exception. The bill creates s. 390.01112, F.S., which provides an identical exception to the ban against abortions during viability.

Currently, s. 390.0111(1)(b), F.S., provides an exception to the prohibition against abortions during the third trimester if a physician certifies in writing to the medical necessity for legitimate *emergency* medical procedures for an abortion in the third trimester, and another physician is not available for consultation. The bill requires the physician to certify in writing that legitimate emergency medical procedures for an abortion are medically necessary to save the pregnant woman's life or avert a serious risk of imminent substantial and irreversible physical impairment of a major bodily function of the pregnant woman, and another physician is not available for consultation. The bill expressly excludes psychological conditions from this exception. The bill creates s. 390.01112, F.S., which provides an identical exception to the ban against abortions during viability.

Standard of Care

Section 390.0111(4), F.S., currently establishes the standard of medical care to be applied when an abortion is performed during viability. It requires the physician performing the abortions exercise the same skill, care, and diligence to preserve the life and health of the fetus that would be required had it been intended to be born and not aborted. It also requires a physician to treat the preservation of the pregnant woman's life and health as the overriding and superior concern when performing an abortion. The bill amends this section so that this standard of care applies

only to an abortion performed during the third trimester. However, the bill creates s. 390.01112, F.S., which establishes that this standard of care is applicable to an abortion performed during viability.

Administrative and Criminal Penalties

Currently, under s. 390.0111(10), F.S., any person who performs, or actively participates in, an abortion in violation of s. 390.0111, F.S., commits a third degree felony. The bill expands the applicability of this penalty to include any person who performs, or actively participates in, an abortion in violation of s. 390.01112, F.S. Thus, anyone who violates the requirements for an abortion during viability commits a third degree felony.

Currently, under s. 390.0111(14), F.S., failure to comply with the requirements of s. 390.0111, F.S., constitutes grounds for disciplinary action under each practice act and under s. 456.072, F.S. The bill expands the applicability of this penalty to include any person who fails to comply with the requirements of s. 390.01112, F.S. Thus, failure to comply with the requirements for an abortion during viability constitutes grounds for disciplinary action under each practice act and under s. 456.072, F.S.

Section 797.03, F.S., currently prohibits any person from performing or assisting in an abortion in the third trimester other than in a hospital. The bill extends this prohibition to include any person performing or assisting in an abortion on a person during viability other than in a hospital.

Severability and Reversion

The bill includes a severability clause which requires the provisions of the abortion act to be severed if any provision or its application to any person or circumstance is held invalid.

The bill also includes a reversion clause. Under this clause, the amendments made by this act to s. 390.011, F.S., and subsections (4), (10), and (13) of s. 390.0111, F.S., will be repealed and will revert to the law as it existed on January 1, 2014, if s. 390.01112, F.S., is found unconstitutional and severed by a court.

B. SECTION DIRECTORY:

Section 1: Amends s. 390.011, F.S., relating to definitions.
Section 2: Amends s. 390.0111, F.S., relating to termination of pregnancies.
Section 3: Creates s. 390.01112, F.S., relating to termination of pregnancies during viability.
Section 4: Amends s. 797.03, F.S., relating to prohibited acts; penalties.
Section 5: Provides severability and reversion clauses.
Section 6: Provides for an effective date of July 1, 2014.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   Not applicable. This bill does not appear to 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 termination of pregnancies; amending s. 390.011, F.S.; defining the term "standard medical measure" and redefining the term "viability"; amending s. 390.0111, F.S.; revising the circumstances under which a pregnancy in the third trimester may be terminated; providing the standard of medical care for the termination of a pregnancy during the third trimester; providing criminal penalties for a violation of s. 390.01112, F.S.; authorizing administrative discipline for a violation of s. 390.01112, F.S., by certain licensed professionals; creating s. 390.01112, F.S.; prohibiting the termination of a viable fetus; providing exceptions; requiring a physician to perform certain examinations to determine the viability of a fetus; providing the standard of care for the termination of a viable fetus; amending s. 797.03, F.S.; prohibiting an abortion of a viable fetus outside of a hospital; providing for severability; providing for a contingent future repeal and reversion of law; providing an effective date.

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

Section 1. Present subsection (9) of section 390.011,

Florida Statutes, is redesignated as subsection (10), and new subsections (9) and (11) are added to that section, to read:

390.011 Definitions.—As used in this chapter, the term:

(9) "Standard medical measure" means the medical care that a physician would provide based on the particular facts of the pregnancy, the information available to the physician, and the technology reasonably available in a hospital, as defined in s. 395.002, with an obstetrical department, to preserve the life and health of the fetus, with or without temporary artificial life sustaining support, if the fetus were born at the same stage of fetal development.

(11) "Viable" or "viability" means the stage of fetal development when the life of a fetus is sustainable outside the womb through standard medical measures.

Section 2. Subsections (1), (4), (10), and (13) of section 390.0111, Florida Statutes, are amended to read:

390.0111 Termination of pregnancies.—

(1) TERMINATION IN THIRD TRIMESTER; WHEN ALLOWED.—No termination of pregnancy shall be performed on any human being in the third trimester of pregnancy unless one of the following conditions is met:

(a) Two physicians certify in writing ~~to the fact~~ that, to a reasonable degree of medical probability, the termination of the pregnancy is necessary to save the pregnant woman's life or avert a serious risk of substantial and irreversible physical impairment of a major bodily function of the pregnant woman

other than a psychological condition. ~~or preserve the health of the pregnant woman; or~~

(b) The physician certifies in writing to the medical necessity for legitimate emergency medical procedures for termination of the pregnancy to save the pregnant woman's life or avert a serious risk of imminent substantial and irreversible physical impairment of a major bodily function of the pregnant woman other than a psychological condition ~~in the third trimester~~, and another physician is not available for consultation.

(4) STANDARD OF MEDICAL CARE TO BE USED IN THIRD TRIMESTER ~~DURING VIABILITY~~.—If a termination of pregnancy is performed in the third trimester, the physician performing ~~during viability, no person who performs or induces~~ the termination of pregnancy must exercise the same ~~shall fail to use that~~ degree of professional skill, care, and diligence to preserve the life and health of the fetus which the physician ~~such person~~ would be required to exercise in order to preserve the life and health of a ~~any~~ fetus intended to be born and not aborted. However, if preserving the life and health of the fetus conflicts with preserving the life and health of the pregnant woman, the physician must consider preserving the woman's life and health the overriding and superior concern ~~"Viability" means that stage of fetal development when the life of the unborn child may with a reasonable degree of medical probability be continued indefinitely outside the womb~~. ~~Notwithstanding the provisions of~~

~~this subsection, the woman's life and health shall constitute an overriding and superior consideration to the concern for the life and health of the fetus when such concerns are in conflict.~~

(10) PENALTIES FOR VIOLATION.—Except as provided in subsections (3), (7), and (12):

(a) Any person who willfully performs, or actively participates in, a termination of pregnancy ~~procedure~~ in violation of the requirements of this section or s. 390.01112 commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(b) Any person who performs, or actively participates in, a termination of pregnancy ~~procedure~~ in violation of ~~the provisions of~~ this section or s. 390.01112 which results in the death of the woman commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(13) FAILURE TO COMPLY.—Failure to comply with the requirements of this section or s. 390.01112 constitutes grounds for disciplinary action under each respective practice act and under s. 456.072.

Section 3. Section 390.01112, Florida Statutes, is created to read:

390.01112 Termination of pregnancies during viability.—

(1) No termination of pregnancy shall be performed on any human being if the physician reasonably determines that, in the physician's good faith medical judgment, the fetus has achieved viability, unless:

(a) Two physicians certify in writing that, to a reasonable degree of medical probability, the termination of the pregnancy is necessary to save the pregnant woman's life or avert a serious risk of substantial and irreversible physical impairment of a major bodily function of the pregnant woman other than a psychological condition; or

(b) The physician certifies in writing to the medical necessity for legitimate emergency medical procedures for termination of the pregnancy to save the pregnant woman's life or avert a serious risk of imminent substantial and irreversible physical impairment of a major bodily function of the pregnant woman other than a psychological condition, and another physician is not available for consultation.

(2) Before performing a termination of pregnancy, a physician must determine if the fetus is viable by, at a minimum, performing a medical examination of the pregnant woman and, to the maximum extent possible through reasonably available tests and the ultrasound required under s. 390.0111(3), an examination of the fetus. The physician must document in the pregnant woman's medical file the physician's determination and the method, equipment, fetal measurements, and any other information used to determine the viability of the fetus.

(3) If a termination of pregnancy is performed during viability, the physician performing the termination of pregnancy must exercise the same degree of professional skill, care, and diligence to preserve the life and health of the fetus that the

physician would be required to exercise in order to preserve the life and health of a fetus intended to be born and not aborted. However, if preserving the life and health of the fetus conflicts with preserving the life and health of the woman, the physician must consider preserving the woman's life and health the overriding and superior concern.

Section 4. Subsection (3) of section 797.03, Florida Statutes, is amended to read:

797.03 Prohibited acts; penalties.—

(3) It is unlawful for any person to perform or assist in performing an abortion on a person during viability or in the third trimester other than in a hospital.

Section 5. Severability and reversion.—

(1) If any provision of this act or its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of this act which can be given effect without the invalid provision or application, and to this end the provisions of this act are severable.

(2) Notwithstanding subsection (1), if s. 390.01112, Florida Statutes, is held unconstitutional and severed by a court having jurisdiction, the amendments made by this act to s. 390.011, Florida Statutes, and subsections (4), (10), and (13) of s. 390.0111, Florida Statutes, will be repealed and will revert to the law as it existed on January 1, 2014.

Section 6. This act shall take effect July 1, 2014.

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 & Human Services Committee

Representative Adkins offered the following:

Amendment (with title amendment)

Remove lines 26-38 and insert:

Section 1. Present subsection (9) of section 390.011, Florida Statutes, is redesignated as subsection (11), and new subsections (9), (10), and (12) are added to that section, to read:

390.011 Definitions.—As used in this chapter, the term:

(9) "Reasonable medical judgment" means a medical judgment that would be made by a reasonably prudent physician, knowledgeable about the case and the treatment possibilities with respect to the medical conditions involved.

(10) "Standard medical measure" means the medical care that a physician would provide based on the particular facts of the

pregnancy, the information available to the physician, and the technology reasonably available in a hospital, as defined in s. 395.002, with an obstetrical department, to preserve the life and health of the fetus, with or without temporary artificial life sustaining support, if the fetus were born at the same stage of fetal development.

(12) "Viable" or "viability" means the stage of fetal

Remove lines 48-49 and insert:

(a) Two physicians certify in writing ~~to the fact~~ that, ~~to a~~ in reasonable ~~degree of~~ medical ~~probability~~ judgment, the termination of

Remove lines 55-56 and insert:

(b) The physician certifies in writing that, in reasonable ~~to the~~ medical judgment, there is a medical necessity for legitimate emergency medical procedures for

Remove lines 102-103 and insert:

human being if the physician determines that, in reasonable medical judgment, the fetus has achieved

Remove lines 105-106 and insert:

(a) Two physicians certify in writing that, in reasonable medical judgment, the termination of the

Amendment No.

Remove lines 111-112 and insert:

(b) The physician certifies in writing that, in reasonable medical judgment, there is a medical necessity for legitimate emergency medical procedures for

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

Remove lines 3-4 and insert:

amending s. 390.011, F.S.; defining the terms "reasonable medical judgment" and "standard medical measure" and redefining the term "viability";

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 7105 PCB RORS 14-03 Health Care Services Rulemaking
SPONSOR(S): Rulemaking Oversight & Repeal Subcommittee, Hutson
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
Orig. Comm.: Rulemaking Oversight & Repeal Subcommittee	11 Y, 0 N	Rubottom	Rubottom
1) Health & Human Services Committee		Guzzo	Calamas

SUMMARY ANALYSIS

The bill repeals or revises a number of statutes containing unnecessary or confusing rulemaking directives and references relating to the Agency for Health Care Administration (AHCA) and the Department of Elderly Affairs (DOEA), respecting various licensed or registered health care and related services.

The Administrative Procedure Act (APA) provides clear guidance on when rules are necessary to implement laws. Provisions in the substantive laws that add directives to make rules in addition to any needed rulemaking authority and substantive policy guiding rulemaking are either unnecessary, redundant to the requirements of the APA, or provide for rules that are unnecessary. The bill provides WHEREAS language to clarify the intent not to substantively change rulemaking authority by deleting unnecessary rulemaking mandates and references.

The bill strikes unnecessary rulemaking provisions, or revises statutes providing guidelines for rulemaking to ensure that the APA will be the consistent guide to when rules are needed to implement the particular substantive laws.

The bill only affects rulemaking authority and responsibility of AHCA and DOEA in their health care licensure or registration responsibilities.

The bill does not make substantive changes to law.

The bill provides an effective date of July 1, 2014.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

The Agency for Health Care Administration (AHCA) has a number of regulatory responsibilities, among these being the licensure of health care facilities including abortion clinics, nursing homes and clinical laboratories. The Department of Elder Affairs (DOEA) has licensure and rulemaking responsibilities for hospices, adult family day care centers and assisted living facilities.

In recent years, many of the facilities licensed by AHCA have come under increasing regulatory control of federal law relating to Medicaid and Medicare, and state laws providing greater specificity than previously provided. At the same time, frequent changes to many of these overlapping programs have made it difficult for AHCA to maintain rules consistent with current law. Some of this difficulty has related to unnecessary rulemaking mandates, particularly relating to statutes that provide sufficient specificity to enforce without resort to rulemaking.

Rulemaking is required by the Administrative Procedures Act (APA) whenever an agency has express authority to make rules, and must resort to rulemaking in order to implement, interpret or prescribe law, policy or requirements including mandatory forms.[1] Rulemaking is not discretionary under the APA.[2]

In 2009 and again in 2013, the Joint Administrative Procedures Committee held hearings focusing on 2007 legislation that, on its face, requires AHCA to make rules that have yet to be finally adopted. In some cases, that legislation and similar legislation contemplated rulemaking that was either unnecessary under the APA or already promulgated under previously enacted law.

Subsections 400.23(3) and 400.23(5), F.S., now set very specific staffing ratios for licensed nursing homes. AHCA has been unable to update its rules to incorporate these standards but enforces the staffing standards pursuant to other statutory authority. Rulemaking mandates in these two provisions are unnecessary and inconsistent with the APA and the substantive law that requires enforcement with or without rules.[3] Technically, AHCA is out of compliance with these nominal rulemaking mandates, but no practical effect flows from that status.

Section 390.012, F.S., provides for rulemaking by AHCA to implement the provisions of chapter 390, F.S. The statute specifically provides that rules must require abortion clinics to be in compliance with s. 390.0111, F.S. In essence, AHCA has authority and direction to adopt rules to implement chapter 390, including a requirement to require clinics to comply with a particular provision of chapter 390, F.S. This is unnecessary verbiage in statute law and adds nothing to the agency's duties or authority. Moreover, it is inconsistent with the clear intent of the APA that statutes speak for themselves and rules should not reiterate them.[4]

A number of other current provisions include unnecessary rulemaking language that is either redundant as to authority, or provide an express mandate for rulemaking when general APA principles oblige agency rulemaking only as necessary.

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[1] Section 120.52(16), F.S., defines "rule" to mean "each agency statement of general applicability that implements, interprets, or prescribes law or policy or describes the procedure or practice requirements of an agency and includes any form which imposes any requirement or solicits any information not specifically required by statute...".

[2] Section 120.54(1)(a), F.S.

[3] Section 120.54(1)(c), F.S., requires "No statutory provision shall be delayed in its implementation pending an agency's adoption of implementing rules unless there is an express statutory provision prohibiting its application until the adoption of implementing rules."

[4] Section 120.545(1)(c), F.S., directing JAPC to make a determination whether a proposed rules reiterates or paraphrases statutory material.

Effect of Proposed Changes

The bill repeals or revises a number of statutory provisions to eliminate redundant, unnecessary, confusing and unused mandates and references relating to AHCA's rulemaking authority. The bill does not reduce any rulemaking authority possessed by AHCA nor alter any substantive law. The bill provides WHEREAS language to clarify that no change in substantive law or rulemaking authority is intended by the statutory amendments.

An explanation of the particular changes follows:

Section 1 amends s. 390.012(3)(d), F.S., the abortion clinic licensure law, to repeal a provision requiring AHCA to adopt a rule requiring that abortion clinics obey s. 390.0111, F.S., the termination of pregnancy statute. Section 390.012(1), F.S., already provides full rulemaking authority to AHCA to implement ss. 390.011-390.018, F.S., including s. 390.0111, F.S. In addition, s. 390.0111, F.S., has its own rule authorizing provision directed to the Department of Health and the licensing boards. Abortion clinics must obey s. 390.0111, F.S. Thus, a specific rule directing them to obey that law would not add to the force of law. AHCA will retain the power to enforce the relevant standards by rules as necessary. AHCA requested this mandate to be deleted from the statute.

Section 2 amends s. 400.021(11), F.S., to remove an unnecessary rulemaking reference. The generally applicable specifications authorized by provision can only be established by rule.[5] Therefore, deleting the words "rule of" does not change the law.

Section 3 repeals s. 400.0712(3), F.S., which mandates "necessary" rules. AHCA has the authority and responsibility to adopt rules necessary to the implementation of the laws it enforces. Therefore, the provision being repealed is redundant.

Section 4 amends s. 400.23, F.S., to:

- Clarify the rulemaking authority of AHCA for the regulation of nursing homes.
- Remove the rulemaking requirement to establish minimum staffing ratios, as the staffing ratios are already statutorily established in s. 400.23(3)(a), F.S.
- Clarify various provisions that set standards to remove unnecessary rulemaking references.

Section 5 amends s. 400.487(7), F.S., to remove unneeded rulemaking in a self-executing provision exempting nursing home licensees and staff from civil and criminal liability for following "Do Not Resuscitate" orders. Rules cannot supply civil and criminal immunity. That power is reserved to the Legislature. AHCA requested this change.

Section 6 amends s. 400.497, F.S., to revise a number of provisions to clarify the rulemaking authority of AHCA for the regulation of home health agencies.

Sections 7 and 8 amend s. 400.506, F.S., and s. 400.509, F.S., to remove rulemaking authority that is duplicative of the clear and express provisions of s. 400.497, F.S., as revised in Section 6.

Section 9 amends s. 400.6095(8), F.S. to remove unneeded rulemaking by DOEA in a self-executing provision exempting hospice licensees and staff from civil and criminal liability for following "Do Not Resuscitate" orders. Rules cannot supply civil and criminal immunity. That power is reserved to the Legislature. This conforms to the changes to AHCA rulemaking in s. 400.487(7), F.S., a parallel provision of law, in Section 5 of the bill.

Section 10, amending s. 400.914, F.S., and Section 11, creating s. 400.9141, F.S., to:

[5] *See* s. 120.51(16), F.S.

- Clarify the rulemaking authority of AHCA for the regulation of prescribed pediatric extended care facilities.
- Clarify various provisions that set standards, removing unnecessary rulemaking references.
- Transfer standards limiting PPEC services deleted from s. 400.914(2), F.S., to new s. 400.9141, F.S.

Sections 12 and 13 amend ss. 400.934, F.S., and 400.935, F.S., to remove unnecessary rulemaking directives and redundant language and to relocate emergency plan criteria from s. 400.935(9), F.S., to s. 400.934(20), F.S. The provisions deleted from s. 400.935(1)-(8), F.S., are all duplicative.[6]

Section 14 amends s. 400.962(5), F.S., to remove an unnecessary rulemaking mandate. AHCA has sufficient rulemaking authority under s. 400.967(2), F.S., to adopt the standards contemplated by the provision deleted.

Section 15 amends s. 400.967(2)-(3), F.S., to remove unnecessary language including unnecessary rulemaking mandates. AHCA has sufficient rulemaking authority to adopt any rules necessary to implement the relevant laws.

Section 16 amends s. 400.980(2), F.S., to remove unnecessary rulemaking language. The APA requires that requirements and forms be adopted by rulemaking and s. 400.980(8), F.S., provides sufficient authority for AHCA to make any rules necessary to implement subsection (2) as amended by this bill.

Section 17 amends s. 409.912(43), F.S., to remove redundant rulemaking authority. AHCA has sufficient rulemaking authority under s. 409.919, F.S., to implement s. 409.912(43), F.S., as amended by this bill.

Sections 18 and 19 amend ss. 429.255(4), F.S., and 429.73, F.S., to remove unneeded rulemaking by DOEA in a self-executing provision exempting assisted living facility licensees, adult family day care licensees and staff of each from civil and criminal liability for following "Do Not Resuscitate" orders. Rules cannot supply civil and criminal immunity. That power is reserved to the Legislature. This conforms to the changes to AHCA rulemaking in s. 400.487(7), F.S., a parallel provision of law, in Section 5 of the bill. DOEA retains rulemaking authority to implement the substantive provisions of law.[7]

Section 20 amends s. 440.102(10), F.S., to remove unnecessary rulemaking language. AHCA has sufficient rulemaking authority under s. 112.0455(13), F.S., related to drug testing laboratories, to implement s. 440.102(10), F.S.

Section 21 amends s. 483.245, F.S., to remove an unnecessary rulemaking mandate to clarify AHCA's responsibility to enforce the law prohibiting rebates, kickbacks and fee splitting by licensed clinical laboratories. AHCA requested this change. AHCA has full rulemaking authority to enforce the section under s. 483.051, F.S.

Section 22 amends s. 765.541(2), F.S., to clarify rulemaking language with respect to certification of organ and tissue procurement organizations, eliminate an unnecessary rulemaking mandate, and to remove unnecessary language. The APA obliges agency rulemaking only as necessary.

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[6] *See,* provisions of: pt. II, ch. 408, F.S. (duplicative of particular provisions in 400.935(1)-(8)); s. 400.933, F.S. (s. 400.935(1)); ss. 400.931, .934, .94 (s. 400.935(3)); ss. 400.934, .94 (s. 400.935(4)-(5)); ss. 400.931(1), .934 (s. 400.935(6), (8)). A more detailed cross-reference chart is available from Rulemaking Oversight & Repeal Subcommittee staff upon request.

[7] Section 429.41, F.S., provides rulemaking authority to implement ss. 429.01-429.54; s. 429.73, F.S., provides rulemaking authority to implement ss. 429.60-429.87, F.S.

Section 23 repeals s. 765.544(2), F.S., related to administrative fines. The provision is duplicative of provisions in s. 408.813, F.S.

None of the provisions remove authority of AHCA or DOEA to make rules necessary to the enforcement of laws assigned to their agencies. None of the provisions alter the substantive law governing the various areas of health care services governed by the statutes amended.

B. SECTION DIRECTORY:

Section 1: Amends s. 390.012(3)(d), F.S., by deleting a sentence requiring rules to require clinics to comply with s. 390.0111. The sentence is unnecessary to the enforcement of the provisions of the chapter.

Section 2: Amends s. 400.021, F.S., to remove an unnecessary rulemaking reference.

Section 3: Repeals s. 400.0712, F.S., which mandates "necessary" rules.

Section 4: Amends s. 400.23, F.S., by removing unnecessary rulemaking requirements and references.

Section 5: Amends s. 400.487, F.S., by deleting an unnecessary rulemaking mandate.

Section 6: Amends s. 400.497, F.S., by removing unnecessary rulemaking mandates.

Section 7: Amends s. 400.506, F.S., by eliminating unnecessary rulemaking mandates.

Section 8: Repeals s. 400.509, F.S., an unnecessary rulemaking mandate.

Section 9: Amends s. 400.6095, F.S., relating to patient admission; assessment; plan of care; discharge; death.

Section 10: Amends s. 400.914, F.S., to remove an unnecessary rulemaking mandate and remove a provision recodified elsewhere.

Section 11: Creates s. 400.9141, F.S., to recodify standards moved from s. 400.914, F.S.

Section 12: Amends s. 400.934, F.S., to remove unnecessary rulemaking directives and redundant language and to recodify language moved from s. 400.935, F.S.

Section 13: Amends s. 400.935, F.S., to remove unnecessary redundant language and delete language moved to s. 400.934(20), F.S.

Section 14: Amends s. 400.962, F.S., to remove an unnecessary rulemaking mandate.

Section 15: Amends s. 400.967, F.S., to remove unnecessary language including unnecessary rulemaking mandates.

Section 16: Amends s. 400.980, F.S., to remove unnecessary rulemaking language.

Section 17: Amends s. 409.912, F.S., to remove unnecessary rulemaking language.

Section 18: Amends s. 429.255, F.S., to remove unnecessary rulemaking language.

Section 19: Amends s. 429.73, F.S., to remove unnecessary rulemaking language.

Section 20: Amends s. 440.102, F.S., to remove unnecessary rulemaking language.

Section 21: Amends s. 483.245, F.S., to remove an unnecessary rulemaking mandate.

Section 22: Amends s. 765.541, F.S., to clarify rulemaking language and remove unnecessary language.

Section 23: Repeals s. 765.544(2), deleting a redundant provision of law.

Section 24: Provides an effective date of July 1, 2014.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None anticipated.

2. Expenditures:

   None anticipated.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None anticipated.

2. Expenditures:

   None anticipated

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None anticipated

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

The purpose of the bill is to clarify the administrative authority of AHCA and DOEA to adopt rules as required by the provisions of the APA consistent with the needs of implementation of the relevant substantive laws. Accordingly the bill removes unnecessary, redundant and confusing rulemaking requirements and references.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

One amendment was adopted by the Rulemaking Oversight & Repeal Subcommittee before approving the PCB. Section 18 was amended to include an amendment to s. 429.255(5), F.S., to clarify that the Department of Elder Affairs retains full rulemaking authority for implementing that entire section of law including the use of Do Not Resuscitate Orders in assisted living facilities. The DOEA expressed concern that repeal of the rulemaking mandate in subsection (4) could be misconstrued, notwithstanding the DOEA's broad rulemaking authority in s. 429.41, F.S., to enforce all ALF statutory responsibilities to their residents.

A bill to be entitled

An act relating to health care services rulemaking; amending s. 390.012, F.S.; revising rulemaking authority relating to the operation of certain abortion clinics; amending s. 400.021, F.S.; revising the definition of the term "nursing home bed" to remove rulemaking authority for determining minimum space requirements for nursing home beds; amending s. 400.0712, F.S.; removing rulemaking authority relating to inactive nursing home facility licenses; amending s. 400.23, F.S.; revising general rulemaking authority relating to nursing homes and certain health care providers; amending s. 400.487, F.S.; removing rulemaking authority relating to orders not to resuscitate presented to home health agency personnel; amending s. 400.497, F.S.; revising rulemaking authority relating to the Home Health Services Act; amending s. 400.506, F.S.; removing rulemaking authority relating to the licensure of nurse registries and the establishment of certain emergency management plans; amending s. 400.509, F.S.; removing rulemaking authority relating to registration of certain companion services and homemaker services; amending s. 400.6095, F.S.; removing rulemaking authority relating to orders not to resuscitate presented to a hospice care team; amending s. 400.914,

F.S.; revising rulemaking authority relating to standards for prescribed pediatric extended care (PPEC) centers; removing rulemaking authority relating to certain limitations on PPEC centers; creating s. 400.9141, F.S.; providing limitations on PPEC centers; amending s. 400.934, F.S.; revising rulemaking authority relating to the preparation of emergency managements plans by home medical equipment providers; amending s. 400.935, F.S.; revising rulemaking authority relating to minimum standards for home medical equipment providers; amending s. 400.962, F.S.; removing rulemaking authority relating to certain standards for active treatment by intermediate care facilities for the developmentally disabled; amending s. 400.967, F.S.; revising rulemaking authority relating to the construction of, the preparation of emergency management plans by, and the classification of deficiencies of intermediate care facilities for the developmentally disabled; amending s. 400.980, F.S.; removing rulemaking authority relating to the registration of health care services pools; amending s. 409.912, F.S.; removing rulemaking authority relating to Medicaid provider lock-in programs; amending s. 429.255, F.S.; removing rulemaking authority relating to orders not to resuscitate presented to assisted living facility

staff and the use of automated external defibrillators; amending s. 429.73, F.S.; removing rulemaking authority relating to orders not to resuscitate presented to adult family-care home providers; amending s. 440.102, F.S.; removing rulemaking authority relating to certain guidelines for drug-free workplace laboratories; amending s. 483.245, F.S.; revising rulemaking authority relating to the imposition of certain administrative penalties against clinical laboratories; amending s. 765.541, F.S.; revising rulemaking authority relating to standards and guidelines for certain organ donation programs; amending s. 765.544, F.S., removing rulemaking authority relating to administrative penalties for violations with respect to organ and tissue donations; providing an effective date.

WHEREAS, rulemaking is not a matter of agency discretion; rulemaking authority is delegated by the Legislature for agencies to adopt statements of general applicability that interpret or implement law; the valid adoption of a rule requires both a grant of express rulemaking authority and a specific law to be implemented or interpreted, and

WHEREAS, the repeal or deletion of a redundant or unnecessary provision authorizing agency rulemaking does not repeal rulemaking authority otherwise provided that clearly

applies to the same subject, and

WHEREAS, statutory provisions mandating rules, when the substantive law otherwise would be implemented either without need for administrative rules or by rulemaking under a broader grant of authority, may be repealed without altering the substantive law or rulemaking authority on which existing rules rely, NOW THEREFORE

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

Section 1. Paragraph (d) of subsection (3) of section 390.012, Florida Statutes, is amended to read:

390.012 Powers of agency; rules; disposal of fetal remains.—

(3) For clinics that perform or claim to perform abortions after the first trimester of pregnancy, the agency shall adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this chapter, including the following:

(d) Rules relating to the medical screening and evaluation of each abortion clinic patient. At a minimum, these rules shall require:

1. A medical history, including reported allergies to medications, antiseptic solutions, or latex; past surgeries; and an obstetric and gynecological history.

2. A physical examination, including a bimanual examination estimating uterine size and palpation of the adnexa.

3. The appropriate laboratory tests, including:

a. Urine or blood tests for pregnancy performed before the abortion procedure.

b. A test for anemia.

c. Rh typing, unless reliable written documentation of blood type is available.

d. Other tests as indicated from the physical examination.

4. An ultrasound evaluation for all patients. The rules shall require that if a person who is not a physician performs an ultrasound examination, that person shall have documented evidence that he or she has completed a course in the operation of ultrasound equipment as prescribed in rule. ~~The rules shall require clinics to be in compliance with s. 390.0111.~~

5. That the physician is responsible for estimating the gestational age of the fetus based on the ultrasound examination and obstetric standards in keeping with established standards of care regarding the estimation of fetal age as defined in rule and shall write the estimate in the patient's medical history. The physician shall keep original prints of each ultrasound examination of a patient in the patient's medical history file.

Section 2. Subsection (11) of section 400.021, Florida Statutes, is amended to read:

400.021 Definitions.—When used in this part, unless the context otherwise requires, the term:

(11) "Nursing home bed" means an accommodation <u>that</u> ~~which~~ is ready for immediate occupancy, or is capable of being made

ready for occupancy within 48 hours, excluding provision of staffing; and that ~~which~~ conforms to minimum space requirements, including the availability of appropriate equipment and furnishings within the 48 hours, as specified by ~~rule of~~ the agency, for the provision of services specified in this part to a single resident.

Section 3. Subsection (3) of section 400.0712, Florida Statutes, is amended to read:

400.0712 Application for inactive license.—

~~(3) The agency shall adopt rules pursuant to ss. 120.536(1) and 120.54 necessary to implement this section.~~

Section 4. Subsection (2), paragraph (a) of subsection (3), subsections (4) and (5), paragraph (e) of subsection (7), and subsection (8) of section 400.23, Florida Statutes, are amended to read:

400.23 Rules; evaluation and deficiencies; licensure status.—

(2) Pursuant to the intention of the Legislature, the agency, in consultation with the Department of Health and the Department of Elderly Affairs, may ~~shall~~ adopt ~~and enforce~~ rules to implement this part and part II of chapter 408. The rules~~,~~ ~~which~~ shall include, but need not be limited to, reasonable and fair criteria in relation to:

(a) The location of the facility and housing conditions that will ensure the health, safety, and comfort of residents, including an adequate call system. In making such rules, the

agency shall be guided by criteria recommended by nationally recognized reputable professional groups and associations with knowledge of such subject matters. The agency shall update or revise such criteria as the need arises. The agency may require alterations to a building if it determines that an existing condition constitutes a distinct hazard to life, health, or safety. In performing any inspections of facilities authorized by this part or part II of chapter 408, the agency may enforce the special-occupancy provisions of the Florida Building Code and the Florida Fire Prevention Code which apply to nursing homes. Residents or their representatives shall be able to request a change in the placement of the bed in their room, provided that at admission they are presented with a room that meets requirements of the Florida Building Code. The location of a bed may be changed if the requested placement does not infringe on the resident's roommate or interfere with the resident's care or safety as determined by the care planning team in accordance with facility policies and procedures. In addition, the bed placement may not be used as a restraint. Each facility shall maintain a log of resident rooms with beds that are not in strict compliance with the Florida Building Code in order for such log to be used by surveyors and nurse monitors during inspections and visits. A resident or resident representative who requests that a bed be moved shall sign a statement indicating that he or she understands the room will not be in compliance with the Florida Building Code, but they

would prefer to exercise their right to self-determination. The statement must be retained as part of the resident's care plan. Any facility that offers this option must submit a letter signed by the nursing home administrator of record to the agency notifying it of this practice with a copy of the policies and procedures of the facility. The agency is directed to provide assistance to the Florida Building Commission in updating the construction standards of the code relative to nursing homes.

(b) The number and qualifications of all personnel, including management, medical, nursing, and other professional personnel, and nursing assistants, orderlies, and support personnel, having responsibility for any part of the care given residents.

(c) All sanitary conditions within the facility and its surroundings, including water supply, sewage disposal, food handling, and general hygiene which will ensure the health and comfort of residents.

(d) The equipment essential to the health and welfare of the residents.

(e) A uniform accounting system.

(f) The care, treatment, and maintenance of residents and measurement of the quality and adequacy thereof, based on rules developed under this chapter and the Omnibus Budget Reconciliation Act of 1987 (Pub. L. No. 100-203) (December 22, 1987), Title IV (Medicare, Medicaid, and Other Health-Related Programs), Subtitle C (Nursing Home Reform), as amended.

(g) The preparation and annual update of a comprehensive emergency management plan. The agency shall establish ~~adopt rules establishing~~ minimum criteria for the plan after consultation with the Division of Emergency Management. At a minimum, ~~the rules must provide for~~ plan components shall provide for ~~that address~~ emergency evacuation transportation; adequate sheltering arrangements; postdisaster activities, including emergency power, food, and water; postdisaster transportation; supplies; staffing; emergency equipment; individual identification of residents and transfer of records; and responding to family inquiries. The comprehensive emergency management plan is subject to review and approval by the local emergency management agency. During its review, the local emergency management agency shall ensure that the following agencies, at a minimum, are given the opportunity to review the plan: the Department of Elderly Affairs, the Department of Health, the Agency for Health Care Administration, and the Division of Emergency Management. Also, appropriate volunteer organizations must be given the opportunity to review the plan. The local emergency management agency shall complete its review within 60 days and either approve the plan or advise the facility of necessary revisions.

(h) The availability, distribution, and posting of reports and records pursuant to s. 400.191 and the Gold Seal Program pursuant to s. 400.235.

(3)(a)1. The agency shall enforce ~~adopt rules providing~~

minimum staffing requirements for nursing home facilities that. ~~These requirements~~ must include, for each facility:

a. A minimum weekly average of certified nursing assistant and licensed nursing staffing combined of 3.6 hours of direct care per resident per day. As used in this sub-subparagraph, a week is defined as Sunday through Saturday.

b. A minimum certified nursing assistant staffing of 2.5 hours of direct care per resident per day. A facility may not staff below one certified nursing assistant per 20 residents.

c. A minimum licensed nursing staffing of 1.0 hour of direct care per resident per day. A facility may not staff below one licensed nurse per 40 residents.

2. Nursing assistants employed under s. 400.211(2) may be included in computing the staffing ratio for certified nursing assistants if their job responsibilities include only nursing-assistant-related duties.

3. Each nursing home facility must document compliance with staffing standards as required under this paragraph and post daily the names of staff on duty for the benefit of facility residents and the public.

4. The agency shall recognize the use of licensed nurses for compliance with minimum staffing requirements for certified nursing assistants if the nursing home facility otherwise meets the minimum staffing requirements for licensed nurses and the licensed nurses are performing the duties of a certified nursing assistant. Unless otherwise approved by the agency, licensed

nurses counted toward the minimum staffing requirements for certified nursing assistants must exclusively perform the duties of a certified nursing assistant for the entire shift and not also be counted toward the minimum staffing requirements for licensed nurses. If the agency approved a facility's request to use a licensed nurse to perform both licensed nursing and certified nursing assistant duties, the facility must allocate the amount of staff time specifically spent on certified nursing assistant duties for the purpose of documenting compliance with minimum staffing requirements for certified and licensed nursing staff. The hours of a licensed nurse with dual job responsibilities may not be counted twice.

(4) ~~Rules developed pursuant to~~ This section does ~~shall~~ not restrict the use of shared staffing and shared programming in facilities that ~~which~~ are part of retirement communities that provide multiple levels of care and otherwise meet the requirement of law or rule.

(5)(a) The agency, in collaboration with the Division of Children's Medical Services of the Department of Health, may establish ~~must adopt rules for:~~

~~(a)~~ minimum standards of care for persons under 21 years of age who reside in nursing home facilities. A facility may be exempted from these standards and the requirements of paragraph (b) for specific persons between 18 and 21 years of age, if the person's physician agrees that minimum standards of care based on age are not necessary.

(b) The following ~~Minimum~~ staffing requirements for persons under 21 years of age who reside in nursing home facilities~~, which~~ apply in lieu of the requirements contained in subsection (3):~~.~~

1. For persons under 21 years of age who require skilled care:

a. A minimum combined average of 3.9 hours of direct care per resident per day must be provided by licensed nurses, respiratory therapists, respiratory care practitioners, and certified nursing assistants.

b. A minimum licensed nursing staffing of 1.0 hour of direct care per resident per day must be provided.

c. No more than 1.5 hours of certified nursing assistant care per resident per day may be counted in determining the minimum direct care hours required.

d. One registered nurse must be on duty on the site 24 hours per day on the unit where children reside.

2. For persons under 21 years of age who are medically fragile:

a. A minimum combined average of 5.0 hours of direct care per resident per day must be provided by licensed nurses, respiratory therapists, respiratory care practitioners, and certified nursing assistants.

b. A minimum licensed nursing staffing of 1.7 hours of direct care per resident per day must be provided.

c. No more than 1.5 hours of certified nursing assistant

care per resident per day may be counted in determining the minimum direct care hours required.

d. One registered nurse must be on duty on the site 24 hours per day on the unit where children reside.

(7) The agency shall, at least every 15 months, evaluate all nursing home facilities and make a determination as to the degree of compliance by each licensee with the established rules adopted under this part as a basis for assigning a licensure status to that facility. The agency shall base its evaluation on the most recent inspection report, taking into consideration findings from other official reports, surveys, interviews, investigations, and inspections. In addition to license categories authorized under part II of chapter 408, the agency shall assign a licensure status of standard or conditional to each nursing home.

(e) The agency shall ~~adopt rules that~~:

1. Establish uniform procedures for the evaluation of facilities.

2. Provide criteria in the areas referenced in paragraph (c).

3. Address other areas necessary for carrying out the intent of this section.

(8) The agency shall ensure that ~~adopt rules pursuant to this part and part II of chapter 408 to provide that~~, when the criteria established under subsection (2) are not met, such deficiencies shall be classified according to the nature and the

scope of the deficiency. The scope shall be cited as isolated, patterned, or widespread. An isolated deficiency is a deficiency affecting one or a very limited number of residents, or involving one or a very limited number of staff, or a situation that occurred only occasionally or in a very limited number of locations. A patterned deficiency is a deficiency where more than a very limited number of residents are affected, or more than a very limited number of staff are involved, or the situation has occurred in several locations, or the same resident or residents have been affected by repeated occurrences of the same deficient practice but the effect of the deficient practice is not found to be pervasive throughout the facility. A widespread deficiency is a deficiency in which the problems causing the deficiency are pervasive in the facility or represent systemic failure that has affected or has the potential to affect a large portion of the facility's residents. The agency shall indicate the classification on the face of the notice of deficiencies as follows:

(a) A class I deficiency is a deficiency that the agency determines presents a situation in which immediate corrective action is necessary because the facility's noncompliance has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident receiving care in a facility. The condition or practice constituting a class I violation shall be abated or eliminated immediately, unless a fixed period of time, as determined by the agency, is required for correction. A class

I deficiency is subject to a civil penalty of $10,000 for an isolated deficiency, $12,500 for a patterned deficiency, and $15,000 for a widespread deficiency. The fine amount shall be doubled for each deficiency if the facility was previously cited for one or more class I or class II deficiencies during the last licensure inspection or any inspection or complaint investigation since the last licensure inspection. A fine must be levied notwithstanding the correction of the deficiency.

(b) A class II deficiency is a deficiency that the agency determines has compromised the resident's ability to maintain or reach his or her highest practicable physical, mental, and psychosocial well-being, as defined by an accurate and comprehensive resident assessment, plan of care, and provision of services. A class II deficiency is subject to a civil penalty of $2,500 for an isolated deficiency, $5,000 for a patterned deficiency, and $7,500 for a widespread deficiency. The fine amount shall be doubled for each deficiency if the facility was previously cited for one or more class I or class II deficiencies during the last licensure inspection or any inspection or complaint investigation since the last licensure inspection. A fine shall be levied notwithstanding the correction of the deficiency.

(c) A class III deficiency is a deficiency that the agency determines will result in no more than minimal physical, mental, or psychosocial discomfort to the resident or has the potential to compromise the resident's ability to maintain or reach his or

her highest practical physical, mental, or psychosocial well-being, as defined by an accurate and comprehensive resident assessment, plan of care, and provision of services. A class III deficiency is subject to a civil penalty of $1,000 for an isolated deficiency, $2,000 for a patterned deficiency, and $3,000 for a widespread deficiency. The fine amount shall be doubled for each deficiency if the facility was previously cited for one or more class I or class II deficiencies during the last licensure inspection or any inspection or complaint investigation since the last licensure inspection. A citation for a class III deficiency must specify the time within which the deficiency is required to be corrected. If a class III deficiency is corrected within the time specified, a civil penalty may not be imposed.

(d) A class IV deficiency is a deficiency that the agency determines has the potential for causing no more than a minor negative impact on the resident. If the class IV deficiency is isolated, no plan of correction is required.

Section 5. Subsection (7) of section 400.487, Florida Statutes, is amended to read:

400.487 Home health service agreements; physician's, physician assistant's, and advanced registered nurse practitioner's treatment orders; patient assessment; establishment and review of plan of care; provision of services; orders not to resuscitate.—

(7) Home health agency personnel may withhold or withdraw

cardiopulmonary resuscitation if presented with an order not to resuscitate executed pursuant to s. 401.45. ~~The agency shall adopt rules providing for the implementation of such orders.~~ Home health personnel and agencies shall not be subject to criminal prosecution or civil liability, nor be considered to have engaged in negligent or unprofessional conduct, for withholding or withdrawing cardiopulmonary resuscitation pursuant to such an order ~~and rules adopted by the agency~~.

Section 6. Section 400.497, Florida Statutes, is amended to read:

400.497 Rules establishing minimum standards.—The agency may ~~shall~~ adopt~~, publish, and enforce~~ rules to implement part II of chapter 408 and this part, including the agency's duties and responsibilities under~~, as applicable,~~ ss. 400.506 and 400.509. The rules shall include, but need not be limited to, ~~which must provide~~ reasonable and fair minimum standards relating to:

(1) The home health aide competency test and home health aide training. The agency shall create the home health aide competency test and establish the curriculum and instructor qualifications for home health aide training. Licensed home health agencies may provide this training and shall furnish documentation of such training to other licensed home health agencies upon request. Successful passage of the competency test by home health aides may be substituted for the training required under this section and any rule adopted pursuant thereto.

(2) Shared staffing. ~~The agency shall allow~~ Shared staffing is permitted if the home health agency is part of a retirement community that provides multiple levels of care, is located on one campus, is licensed under this chapter or chapter 429, and otherwise meets the requirements of law and rule.

(3) The criteria for the frequency of onsite licensure surveys.

(4) Licensure application and renewal.

(5) Oversight by the director of nursing, including~~. The agency shall develop rules related to~~:

(a) Standards that address oversight responsibilities by the director of nursing of skilled nursing and personal care services provided by the home health agency's staff;

(b) Requirements for a director of nursing to provide to the agency, upon request, a certified daily report of the home health services provided by a specified direct employee or contracted staff member on behalf of the home health agency. The agency may request a certified daily report only for a period not to exceed 2 years before ~~prior to~~ the date of the request; and

(c) A quality assurance program for home health services provided by the home health agency.

(6) Conditions for using a recent unannounced licensure inspection for the inspection required in s. 408.806 related to a licensure application associated with a change in ownership of a licensed home health agency.

(7) The requirements for onsite and electronic accessibility of supervisory personnel of home health agencies.

(8) Information to be included in patients' records.

(9) Geographic service areas.

(10) Preparation of a comprehensive emergency management plan pursuant to s. 400.492.

~~(a) The Agency for Health Care Administration shall adopt rules establishing minimum criteria for the plan and plan updates, with the concurrence of the Department of Health and in consultation with the Division of Emergency Management.~~

(a) ~~(b)~~ An emergency plan ~~The rules must address the requirements in s. 400.492. In addition, the rules~~ shall provide for the maintenance of patient-specific medication lists that can accompany patients who are transported from their homes.

(b) ~~(c)~~ The plan is subject to review and approval by the county health department. During its review, the county health department shall contact state and local health and medical stakeholders when necessary. The county health department shall complete its review to ensure that the plan complies ~~is in accordance~~ with the requirements of law ~~criteria in the Agency for Health Care Administration rules~~ within 90 days after receipt of the plan and shall approve the plan or advise the home health agency of necessary revisions. If the home health agency fails to submit a plan or fails to submit the requested information or revisions to the county health department within 30 days after written notification from the county health

department, the county health department shall notify the Agency for Health Care Administration. The agency shall notify the home health agency that its failure constitutes a deficiency, subject to a fine of $5,000 per occurrence. If the plan is not submitted, information is not provided, or revisions are not made as requested, the agency may impose the fine.

(c) ~~(d)~~ For any home health agency that operates in more than one county, the Department of Health shall review the plan, after consulting with state and local health and medical stakeholders when necessary. The department shall complete its review within 90 days after receipt of the plan and shall approve the plan or advise the home health agency of necessary revisions. The department shall make every effort to avoid imposing differing requirements on a home health agency that operates in more than one county as a result of differing or conflicting comprehensive plan requirements of the counties in which the home health agency operates.

(d) ~~(e)~~ The requirements in this subsection do not apply to:

1. A facility that is certified under chapter 651 and has a licensed home health agency used exclusively by residents of the facility; or

2. A retirement community that consists of residential units for independent living and either a licensed nursing home or an assisted living facility, and has a licensed home health agency used exclusively by the residents of the retirement

community, provided the comprehensive emergency management plan for the facility or retirement community provides for continuous care of all residents with special needs during an emergency.

Section 7. Paragraph (f) of subsection (12) and subsection (17) of section 400.506, Florida Statutes, are amended to read:

400.506 Licensure of nurse registries; requirements; penalties.—

(12) Each nurse registry shall prepare and maintain a comprehensive emergency management plan that is consistent with the criteria in this subsection and with the local special needs plan. The plan shall be updated annually. The plan shall include the means by which the nurse registry will continue to provide the same type and quantity of services to its patients who evacuate to special needs shelters which were being provided to those patients prior to evacuation. The plan shall specify how the nurse registry shall facilitate the provision of continuous care by persons referred for contract to persons who are registered pursuant to s. 252.355 during an emergency that interrupts the provision of care or services in private residences. Nurse registries may establish links to local emergency operations centers to determine a mechanism by which to approach specific areas within a disaster area in order for a provider to reach its clients. Nurse registries shall demonstrate a good faith effort to comply with the requirements of this subsection by documenting attempts of staff to follow procedures outlined in the nurse registry's comprehensive

emergency management plan which support a finding that the provision of continuing care has been attempted for patients identified as needing care by the nurse registry and registered under s. 252.355 in the event of an emergency under this subsection.

~~(f) The Agency for Health Care Administration shall adopt rules establishing minimum criteria for the comprehensive emergency management plan and plan updates required by this subsection, with the concurrence of the Department of Health and in consultation with the Division of Emergency Management.~~

~~(17) The Agency for Health Care Administration shall adopt rules to implement this section and part II of chapter 408.~~

Section 8. Subsection (7) of section 400.509, Florida Statutes, is amended to read:

400.509 Registration of particular service providers exempt from licensure; certificate of registration; regulation of registrants.—

~~(7) The Agency for Health Care Administration shall adopt rules to administer this section and part II of chapter 408.~~

Section 9. Subsection (8) of section 400.6095, Florida Statutes, is amended to read:

400.6095 Patient admission; assessment; plan of care; discharge; death.—

(8) The hospice care team may withhold or withdraw cardiopulmonary resuscitation if presented with an order not to resuscitate executed pursuant to s. 401.45. ~~The department shall~~

~~adopt rules providing for the implementation of such orders.~~ Hospice staff shall not be subject to criminal prosecution or civil liability, nor be considered to have engaged in negligent or unprofessional conduct, for withholding or withdrawing cardiopulmonary resuscitation pursuant to such an order and applicable rules. The absence of an order to resuscitate executed pursuant to s. 401.45 does not preclude a physician from withholding or withdrawing cardiopulmonary resuscitation as otherwise permitted by law.

Section 10. Section 400.914, Florida Statutes, is amended to read:

400.914 Rulemaking; ~~Rules establishing~~ standards.—

~~(1)~~ Pursuant to the intention of the Legislature to provide safe and sanitary facilities and healthful programs, the agency in conjunction with the Division of Children's Medical Services of the Department of Health may ~~shall~~ adopt ~~and publish~~ rules to implement the provisions of this part and part II of chapter 408~~, which shall include reasonable and fair standards~~. Any conflict between these rules ~~standards~~ and those standards that may be set forth in local, county, or city ordinances shall be resolved in favor of those having statewide effect. The rules shall include, but need not be limited to, reasonable and fair standards relating ~~Such standards shall relate~~ to:

(1)~~(a)~~ The assurance that PPEC services are family centered and provide individualized medical, developmental, and family training services.

(2) ~~(b)~~ The maintenance of PPEC centers, not in conflict with the provisions of chapter 553 and based upon the size of the structure and number of children, relating to plumbing, heating, lighting, ventilation, and other building conditions, including adequate space, which will ensure the health, safety, comfort, and protection from fire of the children served.

(c) The appropriate provisions of the most recent edition of the "Life Safety Code" (NFPA-101) shall be applied.

(d) The number and qualifications of all personnel who have responsibility for the care of the children served.

(e) All sanitary conditions within the PPEC center and its surroundings, including water supply, sewage disposal, food handling, and general hygiene, and maintenance thereof, which will ensure the health and comfort of children served.

(f) Programs and basic services promoting and maintaining the health and development of the children served and meeting the training needs of the children's legal guardians.

(g) Supportive, contracted, other operational, and transportation services.

(h) Maintenance of appropriate medical records, data, and information relative to the children and programs. Such records shall be maintained in the facility for inspection by the agency.

~~(2) The agency shall adopt rules to ensure that:~~

~~(a) No child attends a PPEC center for more than 12 hours within a 24-hour period.~~

~~(b) No PPEC center provides services other than those provided to medically or technologically dependent children.~~

Section 11. Section 400.9141, Florida Statutes, is created to read:

400.9141 Limitations.—

(1) A child may not attend a PPEC center for more than 12 hours within a 24-hour period.

(2) A PPEC center may only provide those services that are provided to medically or technologically dependent children.

Section 12. Paragraph (a) of subsection (20) of section 400.934, Florida Statutes, is amended to read:

400.934 Minimum standards.—As a requirement of licensure, home medical equipment providers shall:

(20)(a) Prepare and maintain a comprehensive emergency management plan that meets minimum criteria established by agency rule, including the maintenance of patient equipment and supply lists that can accompany patients who are transported from their homes. Such rules shall be formulated in consultation with the Department of Health and the Division of Emergency Management ~~under s. 400.935~~. The plan shall be updated annually and shall provide for continuing home medical equipment services for life-supporting or life-sustaining equipment, as defined in s. 400.925, during an emergency that interrupts home medical equipment services in a patient's home. The plan shall include:

1. The means by which the home medical equipment provider will continue to provide equipment to perform the same type and

quantity of services to its patients who evacuate to special needs shelters which were being provided to those patients prior to evacuation.

2. The means by which the home medical equipment provider establishes and maintains an effective response to emergencies and disasters, including plans for:

a. Notification of staff when emergency response measures are initiated.

b. Communication between staff members, county health departments, and local emergency management agencies, which includes provisions for a backup communications system.

c. Identification of resources necessary to continue essential care or services or referrals to other organizations subject to written agreement.

d. Contacting and prioritizing patients in need of continued medical equipment services and supplies.

Section 13. Section 400.935, Florida Statutes, is amended to read:

400.935 Rulemaking authority ~~Rules establishing minimum standards~~.~~—~~The agency shall adopt~~, publish, and enforce~~ rules necessary to implement this part and part II of chapter 408.~~,~~ ~~which must provide reasonable and fair minimum standards relating to:~~

~~(1) The qualifications and minimum training requirements of all home medical equipment provider personnel.~~

~~(2) Financial ability to operate.~~

~~(3) The administration of the home medical equipment provider.~~

~~(4) Procedures for maintaining patient records.~~

~~(5) Ensuring that the home medical equipment and services provided by a home medical equipment provider are in accordance with the plan of treatment established for each patient, when provided as a part of a plan of treatment.~~

~~(6) Contractual arrangements for the provision of home medical equipment and services by providers not employed by the home medical equipment provider providing for the consumer's needs.~~

~~(7) Physical location and zoning requirements.~~

~~(8) Home medical equipment requiring home medical equipment services.~~

~~(9) Preparation of the comprehensive emergency management plan under s. 400.934 and the establishment of minimum criteria for the plan, including the maintenance of patient equipment and supply lists that can accompany patients who are transported from their homes. Such rules shall be formulated in consultation with the Department of Health and the Division of Emergency Management.~~

Section 14. Subsection (5) of section 400.962, Florida Statutes, is amended to read:

400.962 License required; license application.—

(5) The applicant must agree to provide or arrange for active treatment services by an interdisciplinary team to

maximize individual independence or prevent regression or loss of functional status. ~~Standards for active treatment shall be adopted by the Agency for Health Care Administration by rule pursuant to ss. 120.536(1) and 120.54.~~ Active treatment services shall be provided in accordance with the individual support plan and shall be reimbursed as part of the per diem rate as paid under the Medicaid program.

Section 15. Subsections (2) and (3) of section 400.967, Florida Statutes, are amended to read:

400.967 Rules and classification of deficiencies.—

(2) ~~Pursuant to the intention of the Legislature,~~ The agency, in consultation with the Agency for Persons with Disabilities and the Department of Elderly Affairs, may ~~shall~~ adopt ~~and enforce~~ rules necessary to administer this part and part II of chapter 408, which may ~~shall~~ include ~~reasonable and fair~~ criteria governing:

(a) The location and construction of the facility; including fire and life safety, plumbing, heating, cooling, lighting, ventilation, and other housing conditions that ensure the health, safety, and comfort of residents. The agency shall establish standards for facilities and equipment to increase the extent to which new facilities and a new wing or floor added to an existing facility after July 1, 2000, are structurally capable of serving as shelters only for residents, staff, and families of residents and staff, and equipped to be self-supporting during and immediately following disasters. The

agency shall update or revise the criteria as the need arises. All facilities must comply with those lifesafety code requirements and building code standards applicable at the time of approval of their construction plans. The agency may require alterations to a building if it determines that an existing condition constitutes a distinct hazard to life, health, or safety. The agency may prescribe the ~~shall adopt fair and reasonable rules setting forth~~ conditions under which existing facilities undergoing additions, alterations, conversions, renovations, or repairs are required to comply with the most recent updated or revised standards.

(b) The number and qualifications of all personnel, including management, medical nursing, and other personnel, having responsibility for any part of the care given to residents.

(c) All sanitary conditions within the facility and its surroundings, including water supply, sewage disposal, food handling, and general hygiene, which will ensure the health and comfort of residents.

(d) The equipment essential to the health and welfare of the residents.

(e) A uniform accounting system.

(f) The care, treatment, and maintenance of residents and measurement of the quality and adequacy thereof.

(g) The preparation and annual update of a comprehensive emergency management plan. After consultation with the Division

of Emergency Management, the agency may establish ~~shall adopt rules establishing~~ minimum criteria for ~~the plan after consultation with the Division of Emergency Management. At a minimum, the rules must provide for~~ plan components that address emergency evacuation transportation; adequate sheltering arrangements; postdisaster activities, including emergency power, food, and water; postdisaster transportation; supplies; staffing; emergency equipment; individual identification of residents and transfer of records; and responding to family inquiries. The comprehensive emergency management plan is subject to review and approval by the local emergency management agency. During its review, the local emergency management agency shall ensure that the following agencies, at a minimum, are given the opportunity to review the plan: the Department of Elderly Affairs, the Agency for Persons with Disabilities, the Agency for Health Care Administration, and the Division of Emergency Management. Also, appropriate volunteer organizations must be given the opportunity to review the plan. The local emergency management agency shall complete its review within 60 days and either approve the plan or advise the facility of necessary revisions.

(h) The use of restraint and seclusion. Such rules must be consistent with recognized best practices; prohibit inherently dangerous restraint or seclusion procedures; establish limitations on the use and duration of restraint and seclusion; establish measures to ensure the safety of clients and staff

during an incident of restraint or seclusion; establish procedures for staff to follow before, during, and after incidents of restraint or seclusion, including individualized plans for the use of restraints or seclusion in emergency situations; establish professional qualifications of and training for staff who may order or be engaged in the use of restraint or seclusion; establish requirements for facility data collection and reporting relating to the use of restraint and seclusion; and establish procedures relating to the documentation of the use of restraint or seclusion in the client's facility or program record.

(3) ~~The agency shall adopt rules to provide that,~~ When the criteria established under this part and part II of chapter 408 are not met, such deficiencies shall be classified according to the nature of the deficiency. The agency shall indicate the classification on the face of the notice of deficiencies as follows:

(a) Class I deficiencies are those which the agency determines present an imminent danger to the residents or guests of the facility or a substantial probability that death or serious physical harm would result therefrom. The condition or practice constituting a class I violation must be abated or eliminated immediately, unless a fixed period of time, as determined by the agency, is required for correction. A class I deficiency is subject to a civil penalty in an amount not less than $5,000 and not exceeding $10,000 for each deficiency. A

fine may be levied notwithstanding the correction of the deficiency.

(b) Class II deficiencies are those which the agency determines have a direct or immediate relationship to the health, safety, or security of the facility residents, other than class I deficiencies. A class II deficiency is subject to a civil penalty in an amount not less than $1,000 and not exceeding $5,000 for each deficiency. A citation for a class II deficiency shall specify the time within which the deficiency must be corrected. If a class II deficiency is corrected within the time specified, no civil penalty shall be imposed, unless it is a repeated offense.

(c) Class III deficiencies are those which the agency determines to have an indirect or potential relationship to the health, safety, or security of the facility residents, other than class I or class II deficiencies. A class III deficiency is subject to a civil penalty of not less than $500 and not exceeding $1,000 for each deficiency. A citation for a class III deficiency shall specify the time within which the deficiency must be corrected. If a class III deficiency is corrected within the time specified, no civil penalty shall be imposed, unless it is a repeated offense.

Section 16. Subsection (2) of section 400.980, Florida Statutes, is amended to read:

400.980 Health care services pools.—

(2) The requirements of part II of chapter 408 apply to

the provision of services that require licensure or registration pursuant to this part and part II of chapter 408 and to entities registered by or applying for such registration from the agency pursuant to this part. Registration or a license issued by the agency is required for the operation of a health care services pool in this state. In accordance with s. 408.805, an applicant or licensee shall pay a fee for each license application submitted using this part, part II of chapter 408, and applicable rules. The agency shall ~~adopt rules and~~ provide forms required for such registration and shall impose a registration fee in an amount sufficient to cover the cost of administering this part and part II of chapter 408. In addition to the requirements in part II of chapter 408, the registrant must provide the agency with any change of information contained on the original registration application within 14 days prior to the change.

Section 17. Subsection (43) of section 409.912, Florida Statutes, is amended to read:

409.912 Cost-effective purchasing of health care.—The agency shall purchase goods and services for Medicaid recipients in the most cost-effective manner consistent with the delivery of quality medical care. To ensure that medical services are effectively utilized, the agency may, in any case, require a confirmation or second physician's opinion of the correct diagnosis for purposes of authorizing future services under the Medicaid program. This section does not restrict access to

emergency services or poststabilization care services as defined in 42 C.F.R. part 438.114. Such confirmation or second opinion shall be rendered in a manner approved by the agency. The agency shall maximize the use of prepaid per capita and prepaid aggregate fixed-sum basis services when appropriate and other alternative service delivery and reimbursement methodologies, including competitive bidding pursuant to s. 287.057, designed to facilitate the cost-effective purchase of a case-managed continuum of care. The agency shall also require providers to minimize the exposure of recipients to the need for acute inpatient, custodial, and other institutional care and the inappropriate or unnecessary use of high-cost services. The agency shall contract with a vendor to monitor and evaluate the clinical practice patterns of providers in order to identify trends that are outside the normal practice patterns of a provider's professional peers or the national guidelines of a provider's professional association. The vendor must be able to provide information and counseling to a provider whose practice patterns are outside the norms, in consultation with the agency, to improve patient care and reduce inappropriate utilization. The agency may mandate prior authorization, drug therapy management, or disease management participation for certain populations of Medicaid beneficiaries, certain drug classes, or particular drugs to prevent fraud, abuse, overuse, and possible dangerous drug interactions. The Pharmaceutical and Therapeutics Committee shall make recommendations to the agency on drugs for

which prior authorization is required. The agency shall inform the Pharmaceutical and Therapeutics Committee of its decisions regarding drugs subject to prior authorization. The agency is authorized to limit the entities it contracts with or enrolls as Medicaid providers by developing a provider network through provider credentialing. The agency may competitively bid single-source-provider contracts if procurement of goods or services results in demonstrated cost savings to the state without limiting access to care. The agency may limit its network based on the assessment of beneficiary access to care, provider availability, provider quality standards, time and distance standards for access to care, the cultural competence of the provider network, demographic characteristics of Medicaid beneficiaries, practice and provider-to-beneficiary standards, appointment wait times, beneficiary use of services, provider turnover, provider profiling, provider licensure history, previous program integrity investigations and findings, peer review, provider Medicaid policy and billing compliance records, clinical and medical record audits, and other factors. Providers are not entitled to enrollment in the Medicaid provider network. The agency shall determine instances in which allowing Medicaid beneficiaries to purchase durable medical equipment and other goods is less expensive to the Medicaid program than long-term rental of the equipment or goods. The agency may establish rules to facilitate purchases in lieu of long-term rentals in order to protect against fraud and abuse in the Medicaid program as

defined in s. 409.913. The agency may seek federal waivers necessary to administer these policies.

(43) Subject to the availability of funds, the agency shall mandate a recipient's participation in a provider lock-in program, when appropriate, if a recipient is found by the agency to have used Medicaid goods or services at a frequency or amount not medically necessary, limiting the receipt of goods or services to medically necessary providers after the 21-day appeal process has ended, for a period of not less than 1 year. The lock-in programs shall include, but are not limited to, pharmacies, medical doctors, and infusion clinics. The limitation does not apply to emergency services and care provided to the recipient in a hospital emergency department. The agency shall seek any federal waivers necessary to implement this subsection. ~~The agency shall adopt any rules necessary to comply with or administer this subsection.~~ This subsection expires October 1, 2014.

Section 18. Subsections (4) and (5) of section 429.255, Florida Statutes, are amended to read:

429.255 Use of personnel; emergency care.—

(4) Facility staff may withhold or withdraw cardiopulmonary resuscitation or the use of an automated external defibrillator if presented with an order not to resuscitate executed pursuant to s. 401.45. ~~The department shall adopt rules providing for the implementation of such orders.~~ Facility staff and facilities shall not be subject to criminal

prosecution or civil liability, nor be considered to have engaged in negligent or unprofessional conduct, for withholding or withdrawing cardiopulmonary resuscitation or use of an automated external defibrillator pursuant to such an order and rules adopted by the department. The absence of an order to resuscitate executed pursuant to s. 401.45 does not preclude a physician from withholding or withdrawing cardiopulmonary resuscitation or use of an automated external defibrillator as otherwise permitted by law.

(5) The Department of Elderly Affairs may adopt rules to implement the provisions of this section ~~relating to use of an automated external defibrillator~~.

Section 19. Subsection (3) of section 429.73, Florida Statutes, is amended to read:

429.73 Rules and standards relating to adult family-care homes.—

(3) ~~The department shall adopt rules providing for the implementation of orders not to resuscitate.~~ The provider may withhold or withdraw cardiopulmonary resuscitation if presented with an order not to resuscitate executed pursuant to s. 401.45. The provider shall not be subject to criminal prosecution or civil liability, nor be considered to have engaged in negligent or unprofessional conduct, for withholding or withdrawing cardiopulmonary resuscitation pursuant to such an order and applicable rules.

Section 20. Subsection (10) of section 440.102, Florida

Statutes, is amended to read:

440.102 Drug-free workplace program requirements.—The following provisions apply to a drug-free workplace program implemented pursuant to law or to rules adopted by the Agency for Health Care Administration:

(10) RULES.—~~The Agency for Health Care Administration shall adopt rules~~ Pursuant to s. 112.0455, part II of chapter 408, and criteria established by the United States Department of Health and Human Services, the agency shall adopt ~~as~~ general guidelines for modeling drug-free workplace laboratories, concerning, but not limited to:

(a) Standards for licensing drug-testing laboratories and suspension and revocation of such licenses.

(b) Urine, hair, blood, and other body specimens and minimum specimen amounts that are appropriate for drug testing.

(c) Methods of analysis and procedures to ensure reliable drug-testing results, including standards for initial tests and confirmation tests.

(d) Minimum cutoff detection levels for each drug or metabolites of such drug for the purposes of determining a positive test result.

(e) Chain-of-custody procedures to ensure proper identification, labeling, and handling of specimens tested.

(f) Retention, storage, and transportation procedures to ensure reliable results on confirmation tests and retests.

Section 21. Subsection (2) of section 483.245, Florida

Statutes, is amended to read:

483.245 Rebates prohibited; penalties.—

(2) The agency may establish and ~~shall adopt rules that~~ assess administrative penalties for acts prohibited by subsection (1). In the case of an entity licensed by the agency, such penalties may include any disciplinary action available to the agency under the appropriate licensing laws. In the case of an entity not licensed by the agency, such penalties may include:

(a) A fine not to exceed $1,000;

(b) If applicable, a recommendation by the agency to the appropriate licensing board that disciplinary action be taken.

Section 22. Subsection (2) of section 765.541, Florida Statutes, is amended to read:

765.541 Certification of procurement organizations; agency responsibilities.—The agency shall:

(2) Adopt rules necessary to implement ~~that set forth appropriate standards and guidelines for the program in accordance with~~ ss. 765.541-765.546 and part II of chapter 408.

(a) ~~These~~ Standards and guidelines for the program adopted by the agency must be substantially based on the ~~existing~~ laws of the Federal Government and this state and the ~~existing~~ standards and guidelines of the United Network for Organ Sharing (UNOS), the American Association of Tissue Banks (AATB), the South-Eastern Organ Procurement Foundation (SEOPF), the North American Transplant Coordinators Organization (NATCO), and the

Eye Bank Association of America (EBAA), existing as of January 1, 2014.

(b) ~~In addition, the agency shall,~~ Before adopting ~~these~~ standards and guidelines for the program, the agency shall~~,~~ seek input from all procurement organizations based in this state.

Section 23. Subsection (2) of section 765.544, Florida Statutes, is amended to read:

765.544 Fees; organ and tissue donor education and procurement.—

~~(2) The agency shall specify by rule the administrative penalties for the purpose of ensuring adherence to the standards of quality and practice required by this chapter, part II of chapter 408, and applicable rules of the agency for continued certification.~~

Section 24. This act shall take effect July 1, 2014.

COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. HB 7105 (2014)

Amendment No. 1

COMMITTEE/SUBCOMMITTEE ACTION

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

Committee/Subcommittee hearing bill: Health & Human Services Committee

Representative Hutson offered the following:

Amendment

Remove lines 429-432 and insert:

of chapter 408 and this part including, as applicable, ss. 400.506 and 400.509, which must provide reasonable and fair minimum standards relating to:

COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. HB 7105 (2014)

Amendment No. 2

COMMITTEE/SUBCOMMITTEE ACTION

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

Committee/Subcommittee hearing bill: Health & Human Services Committee

Representative Hutson offered the following:

Amendment

Remove lines 970-971 and insert:

408, and using criteria established by the United States Department of Health and Human Services, the agency shall adopt rules as necessary to establish ~~as~~ general

Amendment No. 3

COMMITTEE/SUBCOMMITTEE ACTION

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

Committee/Subcommittee hearing bill: Health & Human Services Committee

Representative Wood offered the following:

Amendment (with title amendment)

Between lines 848 and 849, insert:

Section 17. Subsection (17) of section 408.032, Florida Statutes, is amended to read:

408.032 Definitions relating to Health Facility and Services Development Act.—As used in ss. 408.031-408.045, the term:

(17) "Tertiary health service" means a health service which, due to its high level of intensity, complexity, specialized or limited applicability, and cost, should be limited to, and concentrated in, a limited number of hospitals to ensure the quality, availability, and cost-effectiveness of such service. Examples of such service include, but are not

limited to, pediatric cardiac catheterization, pediatric open-heart surgery, organ transplantation, neonatal intensive care units, ~~comprehensive rehabilitation,~~ and medical or surgical services which are experimental or developmental in nature to the extent that the provision of such services is not yet contemplated within the commonly accepted course of diagnosis or treatment for the condition addressed by a given service. The agency shall establish by rule a list of all tertiary health services.

Section 18. Paragraph (f) of subsection (1) of section 408.036, Florida Statutes, is amended to read:

408.036 Projects subject to review; exemptions.—

(1) APPLICABILITY.—Unless exempt under subsection (3), all health-care-related projects, as described in paragraphs (a)-(g), are subject to review and must file an application for a certificate of need with the agency. The agency is exclusively responsible for determining whether a health-care-related project is subject to review under ss. 408.031-408.045.

(f) The establishment of tertiary health services~~, including inpatient comprehensive rehabilitation services~~.

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

Remove line 48 and insert:

services pools; amending s. 408.032, F.S.; revising the definition of "tertiary health service" to remove comprehensive rehabilitation from the examples of such services; amending s. 408.036, F.S.; removing inpatient comprehensive rehabilitation services, associated with the establishment of tertiary health services, from health-care related projects subject to certificate of need review; amending s. 409.912, F.S.; removing

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 323 Pharmacy Technicians
SPONSOR(S): La Rosa
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	8 Y, 4 N	Guzzo	O'Callaghan
2) Health & Human Services Committee		Guzzo	Calamas

SUMMARY ANALYSIS

Currently, Florida's laws prohibit a licensed pharmacist from supervising more than one registered pharmacy technician, unless the Department of Health's (DOH) Board of Pharmacy (Board) determines the pharmacy meets certain guidelines and authorizes the licensed pharmacist to supervise more than one, but not more than three, pharmacy technicians.

The bill increases the number of registered pharmacy technicians a licensed pharmacist may supervise to six. Additional registered pharmacy technicians may be supervised if permitted by guidelines adopted by the Board.

The bill requires, for a written prescription for a controlled substance, the date on the prescription to be written legibly and in a certain numeric format.

The bill has an indeterminate, insignificant fiscal impact on DOH.

The bill provides an effective date of July 1, 2014.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Pharmacist and Pharmacy Technician Workforce Demand

Pharmacy technicians assist, and work under the supervision of, licensed pharmacists. Their duties may include dispensing, measuring, or compounding medications; taking information needed to fill a prescription; packaging and labeling prescriptions; accepting payment for prescriptions; answering phones; or referring patients with questions to the pharmacist. Ultimately, the pharmacist reviews all prescriptions. Some reports suggest that the utilization of educated and certified pharmacy technicians allows pharmacists to focus more on direct patient care.[1]

Factors that contribute to a high demand for pharmacists and pharmacy technicians include:

- Increased use of prescription medications and the number of prescription medications available;
- Market growth and competition among retail pharmacies resulting in increased job openings and expanded store hours;
- The aging of the U.S. population; and
- An increase in time spent on non-patient care activities, such as office administration.[2]

Employment of pharmacy technicians in the U.S. has been projected by the U.S. Department of Labor, Bureau of Labor Statistics to increase by 20% between 2012 and 2022.[3]

As of 2009, Florida was among 18 states allowing a maximum 1:3 pharmacist-to-pharmacist technician ratio.[4] Seventeen states and the District of Columbia had no ratio limits; 8 states allowed a maximum 1:2 pharmacist-to-pharmacist technician ratio; 7 states allowed a 1:4 ratio; and 1 state allowed a 1:1 ratio. More recently, Indiana and Idaho have allowed a 1:6 ratio.[5] Some states require that higher

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[1] *See* "ASHP Long-Range Vision for the Pharmacy Work Force in Hospitals and Health Systems: Ensuring the Best Use of Medicines in Hospitals and Health Systems," *American Journal of Health-System Pharmacy*, 64(12):1320-1330, June 15, 2007, available at: www.ashp.org/DocLibrary/BestPractices/HRRptWorkForceVision.aspx (visited January 30, 2014); "White Paper on Pharmacy Technicians 2002: Needed changes can no longer wait," American Journal of Health-System Pharmacy, 60(1): 37-51, January 1, 2003, available at: www.acpe-accredit.org/pdf/whitePaper.pdf (last visited January 30, 2014); and "The Adequacy of Pharmacist Supply: 2004 to 2030," Department of Health and Human Services, Health Resources and Services Administration, Bureau of Health Professions, December 2008, available at: bhpr.hrsa.gov/healthworkforce/reports/pharmsupply20042030.pdf (last visited January 30, 2014).

[2] "The Pharmacist Workforce, A Study of the Supply and Demand for Pharmacists," Department of Health and Human Services, Health Resources and Services Administration, Bureau of Health Professions, December 2000, available at: bhpr.hrsa.gov/healthworkforce/reports/pharmacistsstudy.pdf (last visited January 30, 2014).

[3] Occupational Outlook Handbook: Pharmacy Technicians, Bureau of Labor Statistics, U.S. Department of Labor, available at: http://www.bls.gov/ooh/healthcare/pharmacy-technicians.htm (last visited January 30, 2014).

[4] Presentation by Kevin N. Nicholson, RPh, JD; National Association of Chain Drug Stores, "Standardized Pharmacy Technician Education and Training," May 2009, available at http://www.nabp.net/events/assets/AnnualMtgTechTrainStd(Nicholson).pdf (last visited February 3, 2014).

[5] Indiana changed its ratio July 2, 2012. *See* Indiana Code, 25-26-13-18. *See also*, Idaho Board of Pharmacy Rule 251, Pharmacy Technicians.

ratios are contingent on certification or licensure of technicians, or other quality assurance measures.[6]

According to the October 2013 Aggregate Demand Index compiled by the Pharmacy Manpower Project, Inc., Florida has a ranking of 2.86, meaning Florida does not have a shortage of pharmacists. Specifically, this ranking falls between "demand is less than the pharmacist supply available" and "demand is in balance with supply."[7]

In January 2014, there were approximately 2,149 unemployed pharmacy technicians, and approximately 1,135 publicly advertised job openings for pharmacy technicians in Florida, meaning Florida had an oversupply of pharmacy technicians by approximately 1,083 in the month of January.[8]

Pharmacy Technicians in Florida

In 2008, the Florida Legislature passed CS/CS 1360, which amended s. 465.014, F.S., to require pharmacy technician applicants to complete a pharmacy technician training program to become a registered pharmacy technician. The new law also required the direct supervision of a registered pharmacy technician by a licensed pharmacist.[9] Prior to this time, pharmacies and pharmacists trained pharmacy technicians, and there were no statutory limits on the number of pharmacy technicians a pharmacist may supervise.

Section 465.014, F.S., authorizes a licensed pharmacist to delegate to registered pharmacy technicians those duties, tasks, and functions that do not fall within the definition of the practice of the profession of pharmacy. Registered pharmacy technicians' responsibilities include: [10]

- Retrieval of prescription files;
- Data entry;
- Label preparation;
- Counting, weighing, measuring, pouring, and mixing prescription medication;
- Initiation of communication with a prescribing practitioner or medical staff regarding requests for prescription refill authorization, clarification of missing information on prescriptions, and confirmation of information such as names, medication, and strength; and
- Acceptance of authorization for prescription renewals.

The Board[11] specifies by rule[12] certain acts that pharmacy technicians are prohibited from performing. Those acts include:

- Receiving new verbal prescriptions or any change in the medication, strength, or directions;

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[6] *See* National Association of Boards of Pharmacy: Kansas News: Pharmacy Technician Ratio (2006), Minnesota Board of Pharmacy (2000), Idaho State Board of Pharmacy News (2009), available at: http://www.nabp.net/ (last visited January 30, 2014).

[7] Aggregate Demand Index, Supported by Pharmacy Manpower Project Inc., available at: http://www.pharmacymanpower.com/about.jsp (last visited January 30, 2014).

[8] Presentation by Rebecca Rust, Director of the Bureau of Labor Market Statistics of the Florida Department of Economic Opportunity, January 15, 2014, available at: http://myfloridahouse.gov/Sections/Documents/loaddoc.aspx?PublicationType=Committees&CommitteeId=2786&Session=2014&DocumentType=Meeting Packets&FileName=schcwi 1-15-14.pdf (last visited February 3, 2014).

[9] 2008-216, L.O.F.

[10] Rule, 64B16-27.420, F.A.C.

[11] The Board of Pharmacy is created under s. 465.004, F.S., and consists of nine members appointed by the Governor and confirmed by the Senate. Seven members are licensed pharmacists, who are Florida residents and who have practiced pharmacy for at least 4 years. The remaining two members are Florida residents who have no connection to the profession of pharmacy.

[12] *Supra* fn. 10.

- Interpreting a prescription or medication order for therapeutic acceptability and appropriateness;
- Conducting a final verification of dosage and directions;
- Engaging in prospective drug review;
- Providing patient counseling;
- Monitoring prescription drug usage; and
- Overriding clinical alerts without first notifying the pharmacist.

All registered pharmacy technicians must identify themselves as registered pharmacy technicians by wearing an identification badge with a designation as a "registered pharmacy technician" and verbally identifying themselves as a registered pharmacy technician over the telephone.[13]

The licensed pharmacist is responsible for acts performed by persons under his or her supervision.[14] Licensed pharmacists may not supervise more than one registered pharmacy technician unless authorized by the Board under guidelines it has established to determine circumstances when a licensed pharmacist may supervise more than one, but not more than three, registered pharmacy technicians.[15] A prescription department manager or consultant pharmacist of record who seeks to have more than one registered pharmacy technician must submit a written request to the Board for approval and demonstrate workflow needs to justify the increased ratio.[16]

At the end of the first quarter of Fiscal Year 2013-2014, there were 44,492 registered pharmacy technicians, 31,445 licensed pharmacists, and 9,179 licensed pharmacies in Florida.[17] As of February 2014, 4,436 Florida licensed pharmacies had a ratio of three pharmacy technicians to one pharmacist, and 580 pharmacies had a ratio of two pharmacy technicians to one pharmacist.[18]

Prescriptions

Section 893.04, F.S., authorizes a pharmacist, in good faith and in the course of professional practice, to dispense a controlled substance upon written or oral prescription. An oral prescription must be promptly reduced to writing by the pharmacist. The written prescription must be dated and signed by the prescribing practitioner on the date issued. The face of the prescription or written record for the controlled substance must include:[19]

- The full name and address of the person for whom the controlled substance is dispensed;
- The full name and address of the prescribing practitioner and the prescriber's federal controlled substance registry number;
- The name of the controlled substance prescribed and the strength, quantity, and directions for the use thereof;
- The number of the prescription, as recorded in the prescription files of the pharmacy in which it is filled; and
- The initials of the pharmacist filling the prescription and the date filled.

[13] *Id.*
[14] Rule 64B16-27.1001(7), F.A.C.
[15] Section 465.014, F.S.
[16] The brief description of workflow needs must include the operating hours of the pharmacy and the number of pharmacists, registered interns, and registered pharmacy technicians employed by the pharmacy. Rule 64B16-27.410, F.A.C.
[17] Department of Health, Bill Analysis of HB 323, January 31, 2014, on file with committee staff.
[18] *Id.*
[19] Section 893.04(1), F.S.

Further, each written prescription for a controlled substance listed in Schedules II, III, or IV, must include both a written and a numerical notation of the quantity of the controlled substance prescribed and a notation of the date with the abbreviated month written out.[20]

Effect of Proposed Changes

Section 465.014, F.S., prohibits a licensed pharmacist from supervising more than one registered pharmacy technician, unless the Board determines the pharmacy meets certain guidelines and authorizes the licensed pharmacist to supervise more than one, but not more than three, pharmacy technicians.

The bill increases the number of registered pharmacy technicians a licensed pharmacist may supervise to six. Additional registered pharmacy technicians may be supervised if permitted by guidelines adopted by the Board.

The bill amends s. 893.04(2)(d), F.S., to require, for a written prescription for a controlled substance, the date on the prescription to be written legibly and in a numeric month/day/year format.

B. SECTION DIRECTORY:

Section 1: Amends s. 465.014, F.S., relating to pharmacy technicians.
Section 2: Amends s. 456.42, F.S., relating to written prescriptions for medicinal drugs.
Section 3: Amends s. 893.04, F.S., relating to pharmacist and practitioner.
Section 4: Provides an effective date of July 1, 2014.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The bill will have an indeterminate, insignificant impact on DOH, associated with the cost of rule-making.[21]

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

[20] Section 893.04(2)(d), F.S.
[21] *Supra* fn. 17.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

No additional rule-making authority is necessary to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to pharmacy technicians; amending s. 465.014, F.S.; revising the number of registered pharmacy technicians that a pharmacist may supervise; amending ss. 456.42 and 893.04, F.S.; requiring written prescriptions for specified controlled substances to be legibly dated in a specified format; providing an effective date.

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

Section 1. Subsection (1) of section 465.014, Florida Statutes, is amended to read:

465.014 Pharmacy technician.—

(1) A person other than a licensed pharmacist or pharmacy intern may not engage in the practice of the profession of pharmacy, except that a licensed pharmacist may delegate to pharmacy technicians who are registered pursuant to this section those duties, tasks, and functions that do not fall within the purview of s. 465.003(13). All such delegated acts shall be performed under the direct supervision of a licensed pharmacist who shall be responsible for all such acts performed by persons under his or her supervision. A <u>registered</u> pharmacy ~~registered~~ technician, under the supervision of a pharmacist, may initiate or receive communications with a practitioner or his or her agent, on behalf of a patient, regarding refill authorization

requests. A licensed pharmacist may not supervise more than six ~~one~~ registered pharmacy technicians ~~technician~~ unless otherwise permitted by the guidelines adopted by the board. ~~The board shall establish guidelines to be followed by licensees or permittees in determining the circumstances under which a licensed pharmacist may supervise more than one but not more than three pharmacy technicians.~~

Section 2. Subsection (2) of section 456.42, Florida Statutes, is amended to read:

456.42 Written prescriptions for medicinal drugs.—

(2) A written prescription for a controlled substance listed in chapter 893 must have the quantity of the drug prescribed in both textual and numerical formats, must be legibly dated on the face of the prescription in numeric month/day/year format or with the abbreviated month written out ~~on the face of the prescription~~, and must be either written on a standardized counterfeit-proof prescription pad produced by a vendor approved by the department or electronically prescribed as that term is used in s. 408.0611. As a condition of being an approved vendor, a prescription pad vendor must submit a monthly report to the department that ~~which~~, at a minimum, documents the number of prescription pads sold and identifies the purchasers. The department may, by rule, require the reporting of additional information.

Section 3. Paragraph (d) of subsection (2) of section 893.04, Florida Statutes, is amended to read:

893.04 Pharmacist and practitioner.—

(2)

(d) Each written prescription prescribed by a practitioner in this state for a controlled substance listed in Schedule II, Schedule III, or Schedule IV must include on the face of the prescription both a written and a numerical notation of the quantity of the controlled substance prescribed ~~on the face of the prescription~~ and a legible notation of the date in numeric month/day/year format or~~,~~ with the abbreviated month written out ~~on the face of the prescription~~. A pharmacist may, upon verification by the prescriber, document any information required by this paragraph. If the prescriber is not available to verify a prescription, the pharmacist may dispense the controlled substance but may insist that the person to whom the controlled substance is dispensed provide valid photographic identification. If a prescription includes a numerical notation of the quantity of the controlled substance or date, but does not include the quantity or date written out in textual format, the pharmacist may dispense the controlled substance without verification by the prescriber of the quantity or date if the pharmacy previously dispensed another prescription for the person to whom the prescription was written.

Section 4. This act shall take effect July 1, 2014.

COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. HB 323 (2014)

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 & Human Services Committee

Representative La Rosa offered the following:

Amendment (with title amendment)

Remove lines 20-74 and insert:

purview of s. 465.003(13). All such delegated acts must ~~shall~~ be performed under the direct supervision of a licensed pharmacist who is ~~shall be~~ responsible for all such acts performed by persons under his or her supervision. A ~~pharmacy~~ registered pharmacy technician, under the supervision of a pharmacist, may initiate or receive communications with a practitioner or his or her agent, on behalf of a patient, regarding refill authorization requests. A licensed pharmacist may ~~not~~ supervise more than one registered pharmacy technician as ~~unless otherwise~~ permitted by the guidelines to be followed by licensees or permittees in determining the circumstances under which a

licensed pharmacist may supervise more than one ~~but not more than three~~ pharmacy technician ~~technicians~~. Guidelines adopted by the board must include a provision for automatic board approval of licensed pharmacists supervising more than one pharmacy technician in the operation of an automated pharmacy system or within a pharmacy performing or contracting for the performance of centralized prescription filling.

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

Remove lines 4-7 and insert:

pharmacy technicians that a pharmacist may supervise as permitted by the guidelines adopted by the Board of Pharmacy; requiring the guidelines adopted by the Board of Pharmacy to include a provision for automatic board approval under certain circumstances;

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 709 Alzheimer's Disease
SPONSOR(S): Health Quality Subcommittee; Hudson and others
TIED BILLS: CS/CS/HB 711 **IDEN./SIM. BILLS:** CS/SB 872

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	11 Y, 0 N, As CS	Guzzo	O'Callaghan
2) Appropriations Committee	23 Y, 0 N	Pridgeon	Leznoff
3) Health & Human Services Committee		Guzzo	Calamas

SUMMARY ANALYSIS

In 2012, the Legislature created the Purple Ribbon Task Force (task force) within the Department of Elder Affairs (DOEA) to develop a comprehensive state plan to address the needs of individuals with Alzheimer's disease and their caregivers. The task force submitted its final report and recommendations for an Alzheimer's disease state strategy to the Governor and the Legislature on August 1, 2013.

CS/HB 709 implements several of the recommendations identified by the task force.

Special needs shelters (SNSs) provide shelter and services to persons with special needs, including individuals with Alzheimer's disease, who have no other option for sheltering in an emergency situation. Each local emergency management agency in the state is required to maintain a registry of persons with special needs. Currently, local emergency management agencies are required to register individuals with special needs with SNSs, but they are not required to provide SNS registration online.

The bill requires the Division of Emergency Management (DEM) to develop and implement a SNS registration program by specified dates. The registration program must include a uniform registration form and a database for uploading and storing registration forms. The bill also requires SNSs to have a staff member who is familiar with the needs of persons with Alzheimer's disease and to establish a designated area in the shelter for individuals with Alzheimer's disease to enable them to maintain their normal habits and routines.

The bill creates the Ed and Ethel Moore Alzheimer's Disease Research Program within the Department of Health to fund research leading to prevention of, or a cure for, Alzheimer's disease. The bill creates the Alzheimer's Disease Research Grant Advisory Board to consist of 11 members, including a required number of licensed professionals in specific fields generally associated with the provision of care for the elderly and individuals with Alzheimer's disease. The board is tasked with recommending to the State Surgeon General which research proposals should be funded.

DOEA is responsible for oversight and management of Memory Disorder Clinics (MDCs) in Florida. MDCs provide comprehensive assessments, diagnostic services, and treatment to individuals who exhibit symptoms of Alzheimer's disease. There are 13 MDCs in Florida, which are funded by the state. Currently, these MDCs receive equal funding and are not required to meet any performance measures.

The bill requires DOEA to develop a performance-based funding mechanism to allocate funds based on minimum performance standards, and reward those MDCs who exceed the minimum performance standards with funding above the base level.

The bill has a significant fiscal impact on DEM related to the SNS registration program; however, this impact will be funded through a federal fund source. The House proposed General Appropriations Act for Fiscal Year 2014-2015 includes $3 million from the General Revenue Fund to implement the provisions related to the Ed and Ethel Moore Alzheimer's Research Program within the Department of Health.

The bill provides an effective date of July 1, 2014.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Alzheimer's Disease Statistics

United States

There are an estimated 5.4 million people in the United States with Alzheimer's disease, including 5.2 million people aged 65 and older and 200,000 individuals under age 65 who have younger-onset Alzheimer's disease.[1]

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.[2] By 2050, the number of people aged 65 and older with Alzheimer's disease is expected to triple to a projected 16 million people.[3]

Between 2000 and 2008, deaths attributed to Alzheimer's disease increased 66 percent nationally, while deaths attributed to heart disease, the number one cause of death, decreased by 13 percent. 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.[4]

Florida

In 2000, there were an estimated 360,000 Floridians with Alzheimer's disease. The estimated number in 2010 was 450,000, and the estimated number for 2025 is 590,000.[5]

Alzheimer's Disease Research[6]

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. 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. The 13 state funded MDCs provide valuable ADRD research, and the majority of academic institutions in Florida have active ADRD research programs.

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.[7] NIH ADRCs serve a similar role to nationally designated cancer centers. They create infrastructure that supports clinical care for patients with ADRD.

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[1] Alzheimer's Association, 2013 Alzheimer's Disease Fact and Figures, available at http://www.alz.org/alzheimers_disease_facts_and_figures.asp (last visited February 26, 2014).
[2] *Id.*
[3] *Id.*
[4] *Id.*
[5] *Id.*
[6] 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 February 26, 2014).
[7] 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).

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.[8]

Currently, the Mayo Clinic Alzheimer's Disease Research Center is the only active NIH ADRC in Florida. Other states have multiple ADRCs, including California, which has six active NIH ADRCs and a similar population of individuals with ADRD compared to Florida. NIH ADRCs receive $1.5 million in federal funding, annually, for five years.

The Mayo Clinic ADRC has more than 20 physicians and scientists involved in researching neurodegenerative diseases, and they receive more than $10 million each year from the NIH and other agencies to study ADRD. The Mayo Clinic ADRC focuses their research on patient-oriented research and basic science research. 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[9] and the three most common dominantly inherited gene mutations that cause frontotemporal dementia were discovered at the Mayo Clinic ADRC.[10]

Alzheimer's Disease – State Plans

In 2009, the Alzheimer's Study Group (ASG), an eleven member blue ribbon panel, released a report outlining recommendations to deal with Alzheimer's disease-related issues and policy. In response to the ASG report, Congress passed the National Alzheimer's Project Act (NAPA). NAPA requires the federal Department of Health and Human Services to create a national strategic plan to coordinate Alzheimer's disease efforts across the federal government.[11] Currently, 35 states have developed state plans to deal with the Alzheimer's disease epidemic.

Purple Ribbon Task Force

In 2012, the Legislature adopted HB 473, which created the Purple Ribbon Task Force (task force) within the Department of Elder Affairs (DOEA) to develop a comprehensive state plan to address the needs of individuals with Alzheimer's disease and their caregivers.

The task force conducted an inventory of resources available to assist and support individuals with ADRD, and their caregivers and families. DOEA conducted five surveys developed in collaboration with the task force. The surveys addressed the experiences of five groups of stakeholders, including:

- Persons with ADRD;
- Family caregivers of persons with ADRD;
- Concerned family members and friends of persons with ADRD;
- Health care providers and paid caregivers of persons with ADRD; and

[8] 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 3, 2014).

[9] 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 7, 2015).

[10] Mayo Clinic Alzheimer's Disease Research Center, *Focus Areas,* available at http://www.mayo.edu/research/centers-programs/alzheimers-disease-research-center/focus-areas (last visited March 7, 2015).

[11] Alzheimer's Association, *Issue Kit: State Government Alzheimer's Disease Plans*

- Policy, legal, education, and other professionals.

A total of 840 people responded to the surveys. The inventory of resources and the surveys together highlighted needs of persons with ADRD and their caregivers, the impact of ADRD, and the existing services and resources, and also provided an identification of gaps and limitations.[12]

The task force submitted its final report and recommendations for an Alzheimer's disease state strategy to the Governor and the Legislature on August 1, 2013.

Alzheimer's Disease Initiative

The Alzheimer's Disease Initiative (ADI) was created in law to provide a continuum of services to meet the changing needs of individuals with Alzheimer's disease and their families.[13] DOEA coordinates and develops policy to carry out the statutory requirements for the ADI. In conjunction with a ten-member advisory committee appointed by the Governor, the program includes the following four components:[14]

- Respite and supportive services;
- Model day care programs to test new care alternatives;
- A research database and brain bank to support research; and
- Memory disorder clinics to provide diagnosis, research, treatment, and referral.

Section 430.501, F.S., authorizes DOEA to adopt rules necessary to carry out the duties of the advisory committee. Each Area Agency on Aging (AAA), under contract with DOEA, is responsible for the planning and administration of respite and model day care services funded under the ADI and must contract with local service providers for the provision of these services.[15]

The ADI is funded by General Revenue and Tobacco Settlement funds. DOEA allocates General Revenue funding appropriated by the Legislature to each of the 11 AAAs, which in turn fund providers of model day care and respite care programs in designated counties. Provider agencies are responsible for the collection of fees for ADI services. To help pay for services received pursuant to the ADI, a functionally impaired elderly person is assessed a fee based on an overall ability to pay in accordance with Rule 58C-1.007, F.A.C.

Respite Services

Alzheimer's Respite Care programs are established in all of Florida's 67 counties. ADI respite includes in-home, facility-based, emergency and extended care (up to 30 days) respite for caregivers who serve individuals with memory disorders. Funds are contracted according to an allocation formula, which is based on the number and proportion of the county population of individuals who are 75 years of age and older.[16] The AAAs contract with more than 60 providers for the provision of respite care, caregiver training and support, education, counseling, specialized medical equipment, services and supplies, and case management.[17] Services are authorized by a case manager based on a comprehensive assessment.

[12] 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 February 26, 2014).
[13] Chapter 95-418, L.O.F., *see also* ss. 430.501-430.504, F.S.
[14] Florida Department of Elder Affairs, see http://elderaffairs.state.fl.us/english/alz.php (last visited February 26, 2014).
[15] Rule 58D-1.005, F.A.C.
[16] Section 430.502(5), F.S.
[17] *Supra* note 10.

Model Day Care

Specialized model day care programs provide services to persons suffering from ADRD and training for health care and social service personnel caring for persons having ADRD. Currently, model day care services are funded in three planning and service areas (PSAs 3 - Gainesville, 6 - Tampa, and 11 - Miami-Dade). Examples of activities implemented at model day care centers may include:[18]

- Exercise programs;
- Active and passive range of motion exercises;
- Daily walks;
- Music Therapy; and
- Therapeutic Art.

Brain Bank

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

Memory Disorder Clinics (MDCs) provide diagnostic and referral services, conduct basic and service-related multidisciplinary research, and develop training materials and educational opportunities for lay and professional caregivers of individuals with Alzheimer's disease. Currently, there are 13 state funded MDCs in Florida.[19] MDCs are established at medical schools, teaching hospitals, and public and private not-for-profit hospitals throughout the state in accordance with s. 430.502, F.S.

Currently MDCs receive equal funding regardless of performance. Each of the 13 MDCs received $222,801 during fiscal year 2013-2014.

Pursuant to an annual contract agreement with DOEA, MDCs are required to provide and conduct certain services, training, and research.[20] Specifically, the contract requires MDCs to:[21]

- Evaluate at least 80 new unduplicated patients with symptoms of memory loss or other cognitive impairment;
- Follow-up with at least 40 patients or reevaluate patients to document rate of progression of the disease, its symptoms and its reaction to treatment;
- Identify and evaluate the needs of patients, including underserved minority populations, undergoing medical evaluation and their caregivers to provide appropriate referrals for services;
- Address driving issues with all patients, such as whether the patient is driving and if the patient or caregiver have concerns about driving;
- Follow-up on all Silver Alerts in the service area;
- Refer all appropriate patients to the State of Florida Brain Bank for enrollment;
- Identify and disseminate information on community resources for assistance with Alzheimer's disease, including information on Silver Alert;
- Determine satisfaction with the services provided; and

[18] *Id.*
[19] Section 430.502(1), F.S.
[20] Department of Elder Affairs, *Standard Contract-Alzheimer's Disease Initiative-Memory Disorder Clinic*, June 2013-July 2014.
[21] *Id.*

- Monitor the performance of subcontractors.

MDCs are required to provide at least 4 hours of in-service training annually to model day care and respite care providers in the designated service areas, and they must annually contact each model day care and respite care provider in the designated service areas to plan and develop service-related research projects. Further, MDCs must develop and disseminate training modules to respite and model day care providers and DOEA.[22]

According to the final report of the task force, the MDCs at the University of Florida and Mayo Clinic Jacksonville play a crucial role in the training of behavioral neurology fellows who are subspecialists able to care expertly for dementia patients. To date, the University of Florida has trained 81 fellows, and Mayo Clinic Jacksonville has trained 9 fellows.

The annual contract also requires MDCs to identify major research projects to be undertaken, which must include an innovative service-related research project designed, conducted, and evaluated in association with model day care, respite, and Brain Bank projects. MDCs are required to describe the scope, research methodology, and timeframe of the project.[23]

Included in the contract, is the MDC annual plan, which describes how the MDC will accomplish the services, training, and research initiatives to be undertaken during the contract period.

MDCs are required to submit quarterly reports to DOEA with details on the services and training provided, and the research conducted. The quarterly report must include specific information on the services provided, including the total number of:[24]

- Unduplicated persons seen;
- New patients;
- Evaluations completed;
- Community screenings conducted;
- Office visits;
- Referrals;
- Persons involved in research; and
- Persons referred to the Brain Bank.

The quarterly report also provides DOEA with demographic information for the individuals served, including age, sex, race, and ethnicity information.

In fiscal year 2011-2012, the MDCs:[25]

- Provided 3,942 total training hours to a total of 34,784 trainees, including 14,000 medical health professionals, 3,000 students, and 6,975 volunteers;
- Conducted 10,105 office visits and served 6,723 unduplicated persons;
- Provided telephone counseling, information, and support 12,570 times;
- Conducted 1,573 memory screenings;
- Made 13,678 referrals on the behalf of clients and caregivers for respite care, support groups, long-term care placement, counseling, medical care, and other social services.

The final report of the task force made a recommendation to remove the equal funding mechanism for MDCs. The task force recommends authorizing DOEA to develop minimum standards that must be

[22] *Id.*
[23] *Id.*
[24] *Id.*
[25] Department of Elder Affairs, *Memory Disorder Clinic Statewide Report*, 2011-2012.

achieved to be eligible for base level annual funding, and creating an incentive-based funding mechanism to reward MDCs who achieve greater levels of performance.

Special Needs Shelters (SNS)

Part I of chapter 252, F.S., is the "State Emergency Management Act" (Act). Under s. 252.35, F.S., the Division of Emergency Management (DEM) is responsible for maintaining a comprehensive statewide program of emergency management and for coordinating with efforts of the Federal Government, other departments and agencies of state government, county and municipal governments and school boards, and private agencies that have a role in emergency management. Included in the Act, is a provision to set forth policy guidance for public shelters, including sheltering people with special needs.[26]

Section 252.355, F.S., requires each local emergency management agency to maintain a registry of persons with special needs located within the jurisdiction of the local agency. This section also requires all appropriate agencies and community-based service providers, including, home health care providers, hospices, nurse registries, and home medical equipment providers to assist local emergency management agencies by:

- Collecting registration information for persons with special needs;
- Establishing programs to increase the awareness of the registration process; and
- Educating clients about the procedures that may be necessary for their safety during disasters.

Section 381.0303, F.S., designates the Department of Health (DOH), through its county health departments, as the lead agency for coordination of the recruitment of health care practitioners to staff special needs shelters in times of emergency or disaster. This section requires DOH to reimburse, subject to the availability of funds for this purpose, health care practitioners for medical care provided at the request of DOH in special needs shelters.

Currently, local emergency management agencies are not required to post SNS registration information online. The DEM's website does provide links to each county's local emergency management website. However, the registration information is often very difficult to find and many local emergency management agencies do not include any special needs information at all.

A review was performed of all 67 counties in Florida to assess the availability of special needs information provided on their websites.[27] The results indicated the websites of 17 counties did not include a SNS page, a SNS registration form, or SNS information.[28]

Effect of Proposed Changes

Alzheimer's Disease Research

As recommended by the task force, the bill creates the Ed and Ethel Moore Alzheimer's Disease Research Program (program), and authorizes the program to be administered by DOH. The purpose of the program is to fund research leading to prevention of, or a cure for, Alzheimer's disease.

The bill provides that applications for research funding under the program may be submitted by any university or established research institute in the state, and all qualified investigators in the state must have equal access and opportunity to compete for research funding. The bill authorizes certain types of applications to be considered for funding, including:

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[26] Section 252.35(2)(a), F.S.
[27] Review based on data report generated by Florida CHARTS.
[28] The Counties include Bay, Calhoun, Escambia, Gilchrest, Gulf, Highlands, Jackson, Jefferson, Lafayette, Leon, Liberty, Madison, Okaloosa, Okeechobee, Putnam, Suwanee, and Wakulla.

- Investigatory-initiated research grants;
- Institutional research grants;
- Pre-doctoral and post-doctoral research fellowships; and
- Collaborative research grants, including those that advance the finding of cures through basic or applied research.

The bill creates the Alzheimer's Disease Research Grant Advisory Board (board). The board must consist of 11 members appointed by the State Surgeon General. The board members must include two gerontologists, two geriatric psychiatrists, two geriatricians, two neuroscientists, and three neurologists. In addition, the bill:

- Requires staggered 4-year terms for board members;
- Requires the board to elect a chairperson from the membership of the board to serve a term of two years;
- Requires the board to establish operating procedures and follow rigorous guidelines for ethical conduct and adhere to a strict policy with regard to conflict of interest;
- Requires DOH to provide staff to assist the board in carrying out its duties, and prohibits members of the board from receiving compensation, or reimbursement for per diem or travel;
- Requires the board to advise the State Surgeon General as to the scope of the research program;
- Requires the board to submit their recommendations to the State Surgeon General by December 15 of each year; and
- Requires the board to submit a fiscal-year progress report to the Governor, President of the Senate, and Speaker of the House by a specified date.

The bill provides that implementation of the program is subject to legislative appropriation.

Memory Disorder Clinics

Currently, each of the 13 statutorily designated memory disorder clinics receives equal funding in the amount of $222,801. As recommended by the task force, the bill allows for the creation of a performance-based funding mechanism to allocate funds based on minimum performance standards and benchmark goals.

Specifically, the bill:

- Requires DOEA to develop minimum performance standards that memory disorder clinics must achieve in order to receive base level annual funding;
- Requires DOEA to develop performance goals that exceed the minimum performance standards, which must be achieved in order for a memory disorder clinic to be eligible for incentive funding, which is above base level funding, and subject to appropriations;
- Provides guidance relating to criteria to be considered by DOEA in creating the minimum performance standards and performance goals; and
- Requires DOEA to measure and score memory disorder clinics based on the minimum performance standards and incentive performance goals.

DOEA has already created a performance check list to score MDCs in accordance with the provisions of the bill.[29]

[29] Department of Elder Affairs, *(Draft) Memory Disorder Clinic Performance Check List,* on file with subcommittee staff.

Special Needs Shelters

The bill amends s. 252.355, F.S., to require DEM to develop and maintain a SNS registration program. The registration program is required to be developed by January 1, 2015 and fully implemented by March 1, 2015 and must include a uniform electronic registration form and a database for uploading and storing the registration forms. The link to the registration form must be easily accessible on each local emergency management agency's website. The registration information must be accessible to the local emergency management agency responsible for providing shelter for that individual.

Currently, certain agencies and entities are required to provide registration information to all of their clients. These agencies and entities include:

- Home health agencies;
- Hospices;
- Nurse registries;
- Home medical equipment providers;
- The Department of Children and Families;
- DOH;
- The Agency for Health Care Administration;
- The Department of Education;
- The Agency for Persons with Disabilities; and
- DOEA.

The bill adds memory disorder clinics to the list of entities and agencies that will provide registration information and assistance to their special needs clients or caregivers. Physicians licensed under chapters 458 or 459, F.S., and any pharmacy licensed under chapter 465, F.S., may provide the registration information assistance. Further, the bill requires DEM to develop a brochure that provides information regarding SNS registration procedures. The brochure must be easily accessible on DEM's website. The informational brochure is intended to assist the specified agencies and entities in providing registration information to their clients.

Currently, all appropriate agencies and community-based service providers, including, home health care providers, hospices, nurse registries, and home medical equipment providers are required to assist emergency management agencies by collecting registration information for persons with special needs as a part of program intake processes, establishing programs to increase the awareness of the registration process, and educating clients about the procedures that may be necessary for their safety during disasters. Since these entities and agencies are currently only required to "assist emergency management agencies by collecting registration information" it is unclear what they are required to do with the registration information upon collection.

The bill requires the appropriate agencies and community-based service providers to assist emergency management agencies by annually registering persons with special needs for special needs shelters. Since these agencies and entities are currently required to collect registration information, this provides guidance by requiring them to submit any registration forms collected at least annually. Submitting the registration forms may be accomplished by means of the newly created registration program and database. The bill adds memory disorder clinics to the list of entities required to submit registration forms and makes it discretionary for physicians licensed under chapters 458 or 459, F.S.

B. SECTION DIRECTORY:

Section 1: Amends s. 120.80, F.S., relating to exceptions and special requirements.
Section 2: Amends s. 252.355, F.S., relating to registry of persons with special needs; notice.
Section 3: Amends s. 381.0303, F.S., relating to special needs shelters.
Section 4: Creates s. 381.82, F.S., relating to the Ed and Ethel Moore Alzheimer's Disease Research Program.

Section 5: Amends s. 430.502, F.S., relating to Alzheimer's disease; memory disorder clinics and day care and respite care programs.

Section 6: Provides an effective date of July1, 2014.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   According to DEM, the costs for developing and maintaining a statewide electronic registration form and database system is estimated to be $400,000 annually. The DEM has identified funding through a federal grant to cover the expense of procuring and maintaining a statewide special needs shelter registration program.[30] The department has also indicated this can be implemented through existing budget authority.

   In addition, the bill creates the Ed and Ethel Moore Alzheimer's Disease Research Program and provides that implementation is subject to legislative appropriation. The Department of Health will utilize their existing infrastructure to implement the research program. The House proposed General Appropriations Act for Fiscal Year 2014-2015 includes $3 million from the General Revenue Fund to implement the provisions related to Alzheimer's research.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

   None.

[30] HB 709 Agency Legislative Bill Analysis, Division of Emergency Management, March 4, 2014 (on file with the Appropriations Committee Staff).

B. RULE-MAKING AUTHORITY:

No additional rule-making is necessary to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 5, 2014, the Health Quality Subcommittee adopted two amendments to HB 709 and reported the bill favorably as a committee substitute. The amendments made the following changes to the bill:

- Required the Division of Emergency Management to have the special needs shelter registration program developed by January 1, 2015, and fully implemented by March 1, 2015; and
- Changed the composition of the Alzheimer's Disease Research Grant Advisory Board from 12 members to 11 members to provide recourse in the event of a tie vote and added two neuroscientists to the professionals to be included on the board.

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

A bill to be entitled

An act relating to Alzheimer's disease; amending s. 120.80, F.S.; exempting grant programs administered by the Alzheimer's Disease Research Grant Advisory Board from the Administrative Procedure Act; amending s. 252.355, F.S.; requiring the Division of Emergency Management, in coordination with local emergency management agencies, to maintain a registry of persons with special needs; requiring the division to develop and maintain a special needs shelter registration program by a specified date; requiring specified agencies and authorizing specified health care providers to provide registration information to special needs clients or their caregivers and to assist emergency management agencies in registering persons for special needs shelters; amending s. 381.0303, F.S.; providing additional staffing requirements for special needs shelters; requiring special needs shelters to establish designated shelter areas for persons with Alzheimer's disease or related forms of dementia; authorizing the Department of Health, in coordination with the division, to adopt rules relating to standards for the special needs registration program; creating s. 381.82, F.S.; establishing the Ed and Ethel Moore Alzheimer's Disease Research Program within the department;

requiring the program to provide grants and fellowships for research relating to Alzheimer's disease; creating the Alzheimer's Disease Research Grant Advisory Board; providing for appointment and terms of members; providing for organization, duties, and operating procedures of the board; requiring the department to provide staff to assist the board in carrying out its duties; requiring the board to annually submit recommendations for proposals to be funded; requiring a report to the Governor, Legislature, and State Surgeon General; providing that implementation of the program is subject to appropriation; amending s. 430.502, F.S.; requiring the Department of Elderly Affairs to develop minimum performance standards for memory disorder clinics to receive base-level annual funding; requiring the department to provide incentive-based funding, subject to appropriation, for certain memory disorder clinics; providing an effective date.

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

Section 1. Subsection (15) of section 120.80, Florida Statutes, is amended to read:

120.80 Exceptions and special requirements; agencies.—

(15) DEPARTMENT OF HEALTH.—

(a) Notwithstanding s. 120.57(1)(a), formal hearings may not be conducted by the State Surgeon General, the Secretary of Health Care Administration, or a board or member of a board within the Department of Health or the Agency for Health Care Administration for matters relating to the regulation of professions, as defined by chapter 456. Notwithstanding s. 120.57(1)(a), hearings conducted within the Department of Health in execution of the Special Supplemental Nutrition Program for Women, Infants, and Children; Child Care Food Program; Children's Medical Services Program; the Brain and Spinal Cord Injury Program; and the exemption from disqualification reviews for certified nurse assistants program need not be conducted by an administrative law judge assigned by the division. The Department of Health may contract with the Department of Children and Family Services for a hearing officer in these matters.

(b) This chapter does not apply to grant programs administered by the Alzheimer's Disease Research Grant Advisory Board pursuant to s. 381.82.

Section 2. Section 252.355, Florida Statutes, is amended to read:

252.355 Registry of persons with special needs; notice; registration program.—

(1) In order to meet the special needs of persons who would need assistance during evacuations and sheltering because of physical, mental, cognitive impairment, or sensory

disabilities, the division, in coordination with each local emergency management agency in the state, shall maintain a registry of persons with special needs located within the jurisdiction of the local agency. The registration shall identify those persons in need of assistance and plan for resource allocation to meet those identified needs.

(2) In order to ensure that all persons with special needs may register, the division shall develop and maintain a special needs shelter registration program. The registration program must be developed by January 1, 2015, and fully implemented by March 1, 2015.

(a) The registration program shall include, at a minimum, a uniform electronic registration form and a database for uploading and storing submitted registration forms that may be accessed by the appropriate local emergency management agency. The link to the registration form shall be easily accessible on each local emergency management agency's website. Upon receipt of a paper registration form, the local emergency management agency shall enter the person's registration information into the database.

(b) To assist ~~the local emergency management agency~~ in identifying ~~such~~ persons with special needs, home health agencies, hospices, nurse registries, home medical equipment providers, the Department of Children and Families ~~Family Services~~, the Department of Health, the Agency for Health Care Administration, the Department of Education, the Agency for

Persons with Disabilities, the ~~and~~ Department of Elderly Affairs, and memory disorder clinics shall, and any physician licensed under chapter 458 or chapter 459 and any pharmacy licensed under chapter 465 may, annually ~~shall~~ provide registration information to all of their special needs clients or their caregivers ~~and to all persons with special needs who receive services~~. The division shall develop a brochure that provides information regarding special needs shelter registration procedures. The brochure must be easily accessible on the division's website. All appropriate agencies and community-based service providers, including memory disorder clinics, home health care providers, hospices, nurse registries, and home medical equipment providers shall, and any physician licensed under chapter 458 or chapter 459 may, assist emergency management agencies by annually registering persons with special needs for special needs shelters, collecting registration information for persons with special needs as part of the program intake process, and establishing programs to educate clients about the registration process and disaster preparedness safety procedures. A client of a state-funded or federally funded service program who has a physical, mental, or cognitive impairment or sensory disability and who needs assistance in evacuating, or when in a shelter, must register as a person with special needs. ~~The registry shall be updated annually.~~ The registration program shall give persons with special needs the option of preauthorizing emergency response personnel to enter

their homes during search and rescue operations if necessary to ensure ~~assure~~ their safety and welfare following disasters.

(c) ~~(2)~~ The division shall be the designated lead agency responsible for community education and outreach to the public, including special needs clients, regarding registration and special needs shelters and general information regarding shelter stays.

(d) ~~(4)(a)~~ On or before May 31 of each year, each electric utility in the state shall annually notify residential customers in its service area of the availability of the registration program available through their local emergency management agency by:

1. An initial notification upon the activation of new residential service with the electric utility, followed by one annual notification between January 1 and May 31; or

2. Two separate annual notifications between January 1 and May 31.

~~(b)~~ The notification may be made by any available means, including, but not limited to, written, electronic, or verbal notification, and may be made concurrently with any other notification to residential customers required by law or rule.

(3) A person with special needs must be allowed to bring his or her service animal into a special needs shelter in accordance with s. 413.08.

(4) ~~(5)~~ All records, data, information, correspondence, and

communications relating to the registration of persons with special needs as provided in subsection (1) are confidential and exempt from ~~the provisions of~~ s. 119.07(1), except that such information shall be available to other emergency response agencies, as determined by the local emergency management director. Local law enforcement agencies shall be given complete shelter roster information upon request.

~~(6) All appropriate agencies and community-based service providers, including home health care providers, hospices, nurse registries, and home medical equipment providers, shall assist emergency management agencies by collecting registration information for persons with special needs as part of program intake processes, establishing programs to increase the awareness of the registration process, and educating clients about the procedures that may be necessary for their safety during disasters. Clients of state or federally funded service programs with physical, mental, cognitive impairment, or sensory disabilities who need assistance in evacuating, or when in shelters, must register as persons with special needs.~~

Section 3. Subsections (3) through (7) of section 381.0303, Florida Statutes, are renumbered as subsections (4) through (8), respectively, paragraph (b) of subsection (2) and present subsection (6) are amended, and a new subsection (3) is added to that section, to read:

381.0303 Special needs shelters.—

(2) SPECIAL NEEDS SHELTER PLAN; STAFFING; STATE AGENCY

ASSISTANCE.—If funds have been appropriated to support disaster coordinator positions in county health departments:

(b) County health departments shall, in conjunction with the local emergency management agencies, have the lead responsibility for coordination of the recruitment of health care practitioners to staff local special needs shelters. County health departments shall assign their employees to work in special needs shelters when those employees are needed to protect the health and safety of persons with special needs. County governments shall assist the department with nonmedical staffing and the operation of special needs shelters. The local health department and emergency management agency shall coordinate these efforts to ensure appropriate staffing in special needs shelters, including a staff member who is familiar with the needs of persons with Alzheimer's disease.

(3) SPECIAL CARE FOR PERSONS WITH ALZHEIMER'S DISEASE OR RELATED FORMS OF DEMENTIA.—All special needs shelters must establish designated shelter areas for persons with Alzheimer's disease or related forms of dementia to enable those persons to maintain their normal habits and routines to the greatest extent possible.

(7) ~~(6)~~ RULES.—The department, in coordination with the Division of Emergency Management, has the authority to adopt rules necessary to implement this section. Rules shall include:

(a) The definition of a "person with special needs," including eligibility criteria for individuals with physical,

mental, cognitive impairment, or sensory disabilities and the services a person with special needs can expect to receive in a special needs shelter.

(b) The process for special needs shelter health care practitioners and facility reimbursement for services provided in a disaster.

(c) Guidelines for special needs shelter staffing levels to provide services.

(d) The definition of and standards for special needs shelter supplies and equipment, including durable medical equipment.

(e) Standards for the special needs shelter registration program ~~process~~, including all necessary forms and guidelines for addressing the needs of unregistered persons in need of a special needs shelter.

(f) Standards for addressing the needs of families where only one dependent is eligible for admission to a special needs shelter and the needs of adults with special needs who are caregivers for individuals without special needs.

(g) The requirement of the county health departments to seek the participation of hospitals, nursing homes, assisted living facilities, home health agencies, hospice providers, nurse registries, home medical equipment providers, dialysis centers, and other health and medical emergency preparedness stakeholders in pre-event planning activities.

Section 4. Section 381.82, Florida Statutes, is created to

read:

381.82 Ed and Ethel Moore Alzheimer's Disease Research Program.—

(1) The Ed and Ethel Moore Alzheimer's Disease Research Program is created within the Department of Health. The purpose of the program is to fund research leading to prevention of or a cure for Alzheimer's disease. The long-term goals of the program are to:

(a) Improve the health of Floridians by researching better prevention and diagnoses of and treatments and cures for Alzheimer's disease.

(b) Expand the foundation of knowledge relating to the prevention, diagnosis, treatment, and cure of Alzheimer's disease.

(c) Stimulate economic activity in the state in areas related to Alzheimer's disease research.

(2)(a) Funds appropriated for the Ed and Ethel Moore Alzheimer's Disease Research Program shall be used exclusively for the award of grants and fellowships through a competitive, peer-reviewed process for research relating to the prevention, diagnosis, treatment, and cure of Alzheimer's disease and for expenses incurred in the administration of this section. Priority shall be granted to research designed to prevent or cure Alzheimer's disease.

(b) Applications for Alzheimer's disease research funding under the program may be submitted from any university or

established research institute in the state. All qualified investigators in the state, regardless of institution affiliation, shall have equal access and opportunity to compete for research funding. The following types of applications may be considered for funding:

1. Investigator-initiated research grants.

2. Institutional research grants.

3. Predoctoral and postdoctoral research fellowships.

4. Collaborative research grants, including those that advance the finding of cures through basic or applied research.

(3) There is created within the Department of Health the Alzheimer's Disease Research Grant Advisory Board.

(a) The board shall consist of 11 members appointed by the State Surgeon General. The board shall be composed of two gerontologists, two geriatric psychiatrists, two geriatricians, two neuroscientists, and three neurologists. Initial appointments to the board shall be made by October 1, 2014. The board members shall serve 4-year terms, except that, to provide for staggered terms, five of the initial appointees shall serve 2-year terms and six shall serve 4-year terms. All subsequent appointments shall be for 4-year terms. The chair of the board shall be elected from the membership of the board and shall serve as chair for 2 years. An appointed member may not serve more than two consecutive terms. Appointed members must have experience in Alzheimer's disease or related biomedical research. The board shall adopt internal organizational

procedures as necessary for its efficient organization. The board shall establish and follow rigorous guidelines for ethical conduct and adhere to a strict policy with regard to conflicts of interest. A member of the board may not participate in any discussion or decision of the board or a panel with respect to a research proposal by any firm, entity, or agency with which the member is associated as a member of the governing body or as an employee or with which the member has entered into a contractual arrangement.

(b) The department shall provide such staff, information, and other assistance as is reasonably necessary to assist the board in carrying out its responsibilities. Members of the board shall serve without compensation and may not receive reimbursement for per diem or travel expenses.

(c) The board shall advise the State Surgeon General as to the scope of the research program and shall submit its recommendations for proposals to be funded to the State Surgeon General by December 15 of each year. Grants and fellowships shall be awarded by the State Surgeon General, after consultation with the board, on the basis of scientific merit. Other responsibilities of the board may include, but are not limited to, providing advice on program priorities and emphases; assisting in the development of appropriate linkages to nonacademic entities, such as voluntary organizations, health care delivery institutions, industry, government agencies, and public officials; and developing and providing oversight

regarding mechanisms for the dissemination of research results.

(4) The board shall submit a fiscal-year progress report on the programs under its purview annually to the Governor, the President of the Senate, the Speaker of the House of Representatives, and the State Surgeon General by February 15. The report must include:

(a) A list of research projects supported by grants or fellowships awarded under the program.

(b) A list of recipients of program grants or fellowships.

(c) A list of publications in peer-reviewed journals involving research supported by grants or fellowships awarded under the program.

(d) The state ranking and total amount of Alzheimer's disease research funding currently flowing into the state from the National Institutes of Health.

(e) New grants for Alzheimer's disease research which were funded based on research supported by grants or fellowships awarded under the program.

(f) Progress toward programmatic goals, particularly in the prevention, diagnosis, treatment, and cure of Alzheimer's disease.

(g) Recommendations to further the mission of the program.

(5) Implementation of the Ed and Ethel Moore Alzheimer's Disease Research Program is subject to legislative appropriation.

Section 5. Subsections (3) through (9) of section 430.502,

Florida Statutes, are renumbered as subsections (6) through (12), respectively, new subsections (3), (4), and (5) are added to that section, and present subsections (4), (5), (8), and (9) of that section are amended, to read:

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

(3) The department shall develop minimum performance standards for memory disorder clinics and include those standards in each memory disorder clinic contract as a condition for receiving base-level funding. The performance standards must address, at a minimum, quality of care, comprehensiveness of services, and access to services.

(4) The department shall develop performance goals that exceed the minimum performance standards developed under subsection (3), which goals must be achieved in order for a memory disorder clinic to be eligible for incentive funding above the base level, subject to legislative appropriation. Incentive funding shall be based on criteria including, but not limited to:

(a) Significant increase in the volume of clinical services.

(b) Significant increase in public outreach to low-income and minority populations.

(c) Significant increase in acceptance of Medicaid and commercial insurance policies.

(d) Significant institutional financial commitments.

(5) The department shall measure and score each memory disorder clinic based on minimum performance standards and incentive performance goals.

(7)~~(4)~~ Pursuant to ~~the provisions of~~ s. 287.057, the department ~~of Elderly Affairs~~ may contract for the provision of specialized model day care programs in conjunction with the memory disorder clinics. The purpose of each model day care program must be to provide service delivery to persons suffering from Alzheimer's disease or a related memory disorder and training for health care and social service personnel in the care of persons having Alzheimer's disease or related memory disorders.

(8)~~(5)~~ Pursuant to s. 287.057, the department ~~of Elderly Affairs~~ shall contract for the provision of respite care. All funds appropriated for the provision of respite care shall be distributed annually by the department to each funded county according to an allocation formula. In developing the formula, the department shall consider the number and proportion of the county population of individuals who are 75 years of age and older. Each respite care program shall be used as a resource for research and statistical data by the memory disorder clinics established in this part. In consultation with the memory disorder clinics, the department shall specify the information to be provided by the respite care programs for research purposes.

(11)~~(8)~~ The department shall implement the waiver program

specified in subsection (10) ~~(7)~~. The agency and the department shall ensure that providers who have a history of successfully serving persons with Alzheimer's disease are selected. The department and the agency shall develop specialized standards for providers and services tailored to persons in the early, middle, and late stages of Alzheimer's disease and designate a level of care determination process and standard that is most appropriate to this population. The department and the agency shall include in the waiver services designed to assist the caregiver in continuing to provide in-home care. The department shall implement this waiver program subject to a specific appropriation or as provided in the General Appropriations Act.

(12) ~~(9)~~ Authority to continue the waiver program specified in subsection (10) ~~(7)~~ shall be automatically eliminated at the close of the 2010 Regular Session of the Legislature unless further legislative action is taken to continue it before ~~prior to~~ such time.

Section 6. This act shall take effect July 1, 2014.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/CS/HB 711 Public Meetings and Public Records/Alzheimer's Disease Research Grant Advisory Board
SPONSOR(S): Government Operations Subcommittee; Health Quality Subcommittee; Hudson and others
TIED BILLS: CS/HB 709 **IDEN./SIM. BILLS:** SB 840

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	12 Y, 0 N, As CS	Guzzo	O'Callaghan
2) Government Operations Subcommittee	10 Y, 0 N, As CS	Williamson	Williamson
3) Health & Human Services Committee		Guzzo TG	Calamas CEC

SUMMARY ANALYSIS

House Bill 709 (2014) creates the Ed and Ethel Moore Alzheimer's Disease Research Program and the Alzheimer's Disease Research Grant Advisory Board (board) in order to make recommendations to the State Surgeon General regarding funding for certain research proposals.

This bill, which is linked to the passage of House Bill 709, creates public record and public meeting exemptions for the board.

The bill provides that applications provided to the board for Alzheimer's disease research grants are confidential and exempt from public record requirements. In addition any records generated by the board relating to the review of research grant applications, except final recommendations, are confidential and exempt.

The bill also creates a public meeting exemption for those portions of a board meeting during which such applications are discussed. The closed portion of the meeting must be recorded, and the recording must be maintained by the board.

The bill provides that the confidential and exempt records, including the recording of the meeting, may be disclosed with the written consent of the individual to whom the information pertains, or the individual's legally authorized representative, or by a court order upon a showing of good cause.

The bill provides that the public record and public meeting exemptions are subject to the Open Government Sunset Review Act and will stand repealed on October, 2, 2019, unless saved from repeal by reenactment by the Legislature. It also provides a public necessity statement as required by the State Constitution.

Article I, s. 24(c) of the State Constitution requires a two-thirds vote of the members present and voting for final passage of a newly created public record or public meeting exemption. The bill creates public record and public meeting exemptions; thus, it appears to require a two-thirds vote for final passage.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Public Records Law
Article I, s. 24(a) of the State Constitution sets forth the state's public policy regarding access to government records. The section guarantees every person a right to inspect or copy any public record of the legislative, executive, and judicial branches of government.

Public policy regarding access to government records is addressed further in the Florida Statutes. Section 119.07(1), F.S., guarantees every person a right to inspect and copy any state, county, or municipal record.

Public Meetings Law
Article I, s. 24(b) of the State Constitution sets forth the state's public policy regarding access to government meetings. The section requires that all meetings of any collegial public body of the executive branch of state government or of any collegial public body of a county, municipality, school district, or special district, at which official acts are to be taken or at which public business of such body is to be transacted or discussed, be open and noticed to the public.

Public policy regarding access to government meetings also is addressed in the Florida Statutes. Section 286.011, F.S., known as the "Government in the Sunshine Law" or "Sunshine Law," further requires that all meetings of any board or commission of any state agency or authority or of any agency or authority of any county, municipal corporation, or political subdivision, at which official acts are to be taken be open to the public at all times.[1] The board or commission must provide reasonable notice of all public meetings.[2] Public meetings may not be held at any location that discriminates on the basis of sex, age, race, creed, color, origin or economic status or which operates in a manner that unreasonably restricts the public's access to the facility.[3] Minutes of a public meeting must be promptly recorded and open to public inspection.[4]

Public Record and Public Meeting Exemptions
The Legislature, however, may provide by general law for the exemption of records and meetings from the requirements of Article I, s. 24(a) and (b) of the State Constitution. The general law must state with specificity the public necessity justifying the exemption (public necessity statement) and must be no broader than necessary to accomplish its purpose.[5]

Furthermore, the Open Government Sunset Review Act[6] provides that a public record or public meeting exemption may be created or maintained only if it serves an identifiable public purpose. In addition, it may be no broader than is necessary to meet one of the following purposes:

- Allows the state or its political subdivisions to effectively and efficiently administer a governmental program, which administration would be significantly impaired without the exemption;
- Protects sensitive personal information that, if released, would be defamatory or would jeopardize an individual's safety; however, only the identity of an individual may be exempted under this provision; or

[1] Section 286.011(1), F.S.
[2] *Ibid.*
[3] Section 286.011(6), F.S.
[4] Section 286.011(2), F.S.
[5] Art. I, s. 24(c), Fla. Const.
[6] Section 119.15, F.S.

- Protects trade or business secrets.

The Open Government Sunset Review Act requires the automatic repeal of a newly created exemption on October 2nd of the fifth year after creation or substantial amendment, unless the Legislature reenacts the exemption.

House Bill 709 (2014), Ed and Ethel Moore Alzheimer's Disease Research Program

House Bill 709 creates the Ed and Ethel Moore Alzheimer's Disease Research Program (program), and authorizes the program to be administered by the Department of Health (DOH). The purpose of the program is to fund research leading to prevention of or a cure for Alzheimer's disease.

The bill authorizes applications for research funding under the program to be submitted by any university or established research institute in the state, and requires that all qualified investigators in the state have equal access and opportunity to compete for research funding. The bill authorizes certain types of applications to be considered for funding, including:

- Investigatory-initiated research grants;
- Institutional research grants;
- Pre-doctoral and post-doctoral research fellowships; and
- Collaborative research grants, including those that advance the finding of cures through basic or applied research.

House Bill 709 also creates the Alzheimer's Disease Research Grant Advisory Board (board). The board must consist of 11 members appointed by the State Surgeon General, and must include two gerontologists, two geriatric psychiatrists, two geriatricians, two neuroscientists, and three neurologists. The bill provides requirements for the board, including requiring the board to advise the State Surgeon General as to the scope of the research program.

Effect of Proposed Changes

The bill creates a public record and public meeting exemption for the board.

The bill provides that applications provided to the board for Alzheimer's disease research grants are confidential and exempt[7] from public record requirements. In addition any records generated by the board relating to the review of research grant applications, except final recommendations, are confidential and exempt.

The bill also creates a public meeting exemption for those portions of a board meeting during which such applications are discussed. The closed portion of the meeting must be recorded, and the recording must be maintained by the board.

The bill provides that the confidential and exempt records, including the recording of the meeting, may be disclosed with the written consent of the individual to whom the information pertains, or the individual's legally authorized representative, or by a court order upon a showing of good cause.

[7] There is a difference between records the Legislature designates as exempt from public record requirements and those the Legislature deems confidential and exempt. A record classified as exempt from public disclosure may be disclosed under certain circumstances. *See WFTV, Inc. v. The School Board of Seminole*, 874 So.2d 48, 53 (Fla. 5th DCA 2004), review denied 892 So.2d 1015 (Fla. 2004); *City of Riviera Beach v. Barfield*, 642 So.2d 1135 (Fla. 4th DCA 1994); *Williams v. City of Minneola*, 575 So.2d 687 (Fla. 5th DCA 1991) If the Legislature designates a record as confidential and exempt from public disclosure, such record may not be released, by the custodian of public records, to anyone other than the persons or entities specifically designated in the statutory exemption. *See* Attorney General Opinion 85-62 (August 1, 1985).

The bill provides that the public record and public meeting exemptions are subject to the Open Government Sunset Review Act and will stand repealed on October, 2, 2019, unless saved from repeal by reenactment by the Legislature.

The bill provides a public necessity statement as required by the State Constitution, which states the exemptions are a public necessity because the research grant applications and the records generated by the board related to review of the applications contain information of a confidential nature, including ideas and processes, the disclosure of which could injure the affected researchers. Further, closing the access to those portions of meetings of the board during which research grant applications are discussed serves a public good by ensuring that decisions are based upon merit without bias or undue influence.

B. SECTION DIRECTORY:

Section 1: Amends s. 381.82, F.S., as created by House Bill 709, 2014 Regular Session, relating to the Ed and Ethel Moore Alzheimer's Disease Research Program.

Section 2: Provides a public necessity statement.

Section 3: Provides a contingent effective date.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

The bill may create a minimal fiscal impact on the board because staff responsible for complying with public records requests could require training related to the public record exemption. In addition, the board could incur costs associated with redacting the confidential and exempt information prior to releasing a record. The costs, however, would be absorbed, as they are part of the day-to-day responsibilities of the board.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

   Vote Requirement
   Article I, s. 24(c) of the State Constitution requires a two-thirds vote of the members present and voting for final passage of a newly created public record or public meeting exemption. The bill creates new exemptions; thus, it requires a two-thirds vote for final passage.

   Public Necessity Statement
   Article I, s. 24(c) of the State Constitution requires a public necessity statement for a newly created or expanded public record or public meeting exemption. The bill creates new exemptions; thus, it includes a public necessity statement.

   Exemption Bills
   Article I, s. 24(c) of the State Constitution provides that an exemption must be created by general law and the law must contain only exemptions from public record or public meeting requirements. The exemption does not appear to be in conflict with the constitutional requirement.

B. RULE-MAKING AUTHORITY:

   The bill does not appear to create a need for rule-making or rule-making authority.

C. DRAFTING ISSUES OR OTHER COMMENTS:

   None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

Healthy Quality Subcommittee
On March 5, 2014, the Health Quality Subcommittee adopted an amendment to HB 711 and reported the bill favorably as a committee substitute. The amendment made the following changes to the bill:

- Required the closed portion of a meeting to be recorded;
- Required the recording to be maintained by the board; and
- Authorized the recording to be disclosed with the written consent of either the individual affected or the individual's legally authorized representative, by a court order, or in the event of the exemption being repealed as a result of the Open Government Sunset Review Act.

Government Operations Subcommittee
On March 18, 2014, the Government Operations Subcommittee adopted an amendment and reported the bill favorably as a committee substitute. The amendment corrected drafting errors and removed an incorrect cross-reference.

This analysis is drafted to the committee substitute as passed by the Government Operations Subcommittee.

A bill to be entitled

An act relating to public meetings and public records; amending s. 381.82, F.S.; providing an exemption from public records requirements for research grant applications provided to the Alzheimer's Disease Research Grant Advisory Board under the Ed and Ethel Moore Alzheimer's Disease Research Program and records generated by the board relating to review of the applications; providing an exemption from public meetings requirements for those portions of meetings of the board during which the research grant applications are discussed; requiring the recording of closed portions of meetings; authorizing disclosure of such confidential information under certain circumstances; providing for legislative review and repeal of the exemptions; providing a statement of public necessity; providing a contingent effective date.

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

Section 1. Paragraph (d) is added to subsection (3) of section 381.82, Florida Statutes, as created by HB 709, 2014 Regular Session, to read:

381.82 Ed and Ethel Moore Alzheimer's Disease Research Program.—

(3) There is created within the Department of Health the Alzheimer's Disease Research Grant Advisory Board.

(d)1. Applications provided to the board for Alzheimer's disease research grants under this section, and any records generated by the board relating to review of such applications, except final recommendations, are confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

2. Those portions of a meeting of the board during which applications for Alzheimer's disease research grants under this section are discussed are exempt from s. 286.011 and s. 24(b), Art. I of the State Constitution. The closed portion of a meeting must be recorded. The recording shall be maintained by the board and shall be subject to disclosure in accordance with subparagraph 3.

3. Information that is held confidential and exempt under this paragraph may be disclosed with the express written consent of the individual to whom the information pertains or the individual's legally authorized representative, or by court order upon a showing of good cause.

4. This paragraph is subject to the Open Government Sunset Review Act in accordance with s. 119.15 and shall stand repealed on October 2, 2019, unless reviewed and saved from repeal through reenactment by the Legislature.

Section 2. The Legislature finds that it is a public necessity that applications for Alzheimer's disease research grants provided to the Alzheimer's Disease Research Grant

Advisory Board and records generated by the board related to review of the applications be held confidential and exempt from s. 119.07(1), Florida Statutes, and s. 24(a), Article I of the State Constitution and that those portions of meetings of the board during which the applications are discussed be held exempt from s. 286.011, Florida Statutes, and s. 24(b), Article I of the State Constitution. The research grant applications, and the records generated by the board related to review of the applications, contain information of a confidential nature, including ideas and processes, the disclosure of which could injure the affected researchers. Maintaining confidentiality is a hallmark of scientific peer review when awarding grants, is practiced by the National Science Foundation and the National Institutes of Health, and allows for candid exchanges among reviewers critiquing proposals. The Legislature further finds that closing access to those portions of meetings of the board during which the Alzheimer's disease research grant applications are discussed serves a public good by ensuring that decisions are based upon merit without bias or undue influence.

Section 3. This act shall take effect on the same date that HB 709 or similar legislation takes effect, if such legislation is adopted in the same legislative session or an extension thereof and becomes law.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 1131 Emergency Allergy Treatment
SPONSOR(S): Health Quality Subcommittee; Hudson
TIED BILLS: **IDEN./SIM. BILLS:** SB 1122

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	12 Y, 0 N, As CS	Poche	O'Callaghan
2) Health & Human Services Committee		Poche	Calamas

SUMMARY ANALYSIS

An allergy is a disease of the immune system that causes an overreaction to substances called allergens. An allergy is also described as a hypersensitivity disorder in which the immune system reacts to substances in the environment that are normally harmless. An antigen is any substance that causes the human immune system to produce antibodies against it. An antigen may be a foreign substance from the environment, such as pollen, pet dander, or food, which can enter the body through inhalation, ingestion, injection, or absorption. If an antigen causes an allergic reaction when it enters the body, it is considered an allergen.

Anaphylaxis is a severe, whole body allergic reaction to an allergen. The human body releases chemicals during anaphylaxis that can cause shock, resulting in a sudden drop in blood pressure and the release of histamines, which restrict breathing. Symptoms of anaphylaxis include a rapid and weak pulse, skin rash, nausea and vomiting. The number of people with severe allergies has increased significantly during that last ten years, with the current incidence rate estimated to be 49.8 per 100,000 persons. The only treatment for anaphylaxis caused by an allergy is the administration of epinephrine, usually through an auto-injector (EAI), which provides a premeasured dose of the medication based on body weight. An epinephrine auto-injector is only available by prescription.

House Bill 1131 amends the law governing insect sting emergency treatment in s. 381.88, F.S., by creating new and expanding existing provisions related to emergency allergy treatment and making EAIs available in more public places. The bill permits certain authorized entities, such as restaurants and youth sports leagues, to obtain a prescription for EAIs. Authorized entities may stock and store EAIs, and authorized entities' employees who have completed certain training and are certified may provide an EAI to a person suffering a severe allergic reaction for self-administration, administer an EAI to a person suffering a severe allergic reaction, or provide an EAI to a person to administer it to another person suffering a severe allergic reaction. The bill makes any act or omission committed under the Emergency Allergy Treatment Act, consisting of ss. 381.88, F.S., and 381.885, F.S., subject to the civil liability immunity protections of the Good Samaritan Act in s. 768.13, F.S.

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

The bill provides an effective date of July 1, 2014.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Allergies

An allergy is a disease of the immune system that causes an overreaction to substances called allergens.[1] An allergy is also described as a hypersensitivity disorder in which the immune system reacts to substances in the environment that are normally harmless.[2] An antigen is any substance that causes the human immune system to produce antibodies against it.[3] An antigen may be a foreign substance from the environment, such as pollen, pet dander, or food, which can enter the body through inhalation, ingestion, injection, or absorption.[4] If an antigen causes an allergic reaction when it enters the body, it is considered an allergen. Common allergies include indoor allergies, outdoor allergies, food allergies, latex allergies, insect allergies, skin allergies, and eye allergies.[5]

Symptoms

The following are examples of symptoms associated with common allergic diseases.[6]

- Allergic rhinitis ("hay fever," "seasonal," or "nasal" allergy)
  - Nasal stuffiness
  - Sneezing
  - Nasal itching
  - Itching of the roof of the mouth
  - Itching of the ears
- Latex allergy
  - Hand dermatitis
  - Sneezing and other respiratory distress
  - Coughing
  - Wheezing
  - Shortness of breath
- Insect sting or bite allergy
  - Pain, itching, and swelling at site of sting
- Allergic conjunctivitis (eye allergy)
  - Itchy and watery eyes
  - Eyelid distress

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[1] Asthma and Allergy Foundation of America, *Allergy Overview-What Causes Allergies*, available at http://aafa.org/display.cfm?id=9&cont=79 (last viewed on March 16, 2014).
[2] U.S. Dept. of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, *Trends in Allergic Conditions Among Children: United States, 1997-2011*, NCHS Data Brief No. 121, page 1, May 2013, available at www.cdc.gov/nchs/data/databriefs/db121.pdf (last viewed on March 16, 2014).
[3] U.S. Dept. of Health and Human Services, National Institutes of Health, U.S. National Library of Medicine, MedlinePlus, *Antigen*, available at www.nlm.nih.gov/medlineplus/ency/article/002224.htm (last viewed on March 16, 2014).
[4] See supra, FN 1.
[5] Id.
[6] Asthma and Allergy Foundation of America, *Allergy Overview-What Are Allergies*, available at http://aafa.org/display.cfm?id=9&cont=78 (last viewed on March 16, 2014).

Allergies in Children

Allergic conditions are among the most common medical conditions affecting children in the United States.[7] The most common allergies in children include food allergies, skin allergies, and respiratory allergies.[8] The prevalence of food and skin allergies have increased in children aged 0 to 17 years from 1997 to 2011.[9] For food allergies, the prevalence rose from 3.4 percent in 1997 to 1999 to 5.1 percent in 2009 to 2011.[10] For skin allergies, the prevalence rose from 7.4 percent in 1997 to 1999 to 12.5 percent in 2009 to 2011.[11]

Food Allergies

As many as 15 million people in the United States have one or more food allergies- 9 million adults and 6 million children, which translates 4 percent of all adults and 8 percent of all children.[12] Eight foods account for 90 percent of all food allergic reactions:

- Milk
- Eggs
- Peanuts
- Tree nuts, such as walnuts and pecans
- Wheat
- Soy
- Fish, such as salmon
- Shellfish, such as shrimp and lobster

In infants and children, egg, milk, peanut, tree nuts, soy and wheat are the most common food allergies, while adults have the most common food allergies to shellfish, peanut, tree nuts, and fish.[13] According to the National Institute of Allergy and Infectious Disease, children usually outgrow an allergy to egg, milk, and soy. Children do not outgrow a peanut allergy. People who develop an allergy as an adult will usually have the allergy for life.

Symptoms of food allergies appear from within a few minutes to two hours after a person has ingested the food which she or he is allergic.[14] Food allergic reactions can include:

- Hives
- Flushed skin or rash
- Tingling or itchy sensation in the mouth
- Face, tongue, or lip swelling

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[7] See supra, FN 2 (citing, e.g., Friedman, AH, Morris, TL. *Allergies and anxiety in children and adolescents: A review of the literature.* J Clin Psychol Med Settings 13(3):318-31, 2006.).
[8] Id.
[9] Id.
[10] Id. at page 2.
[11] Id.
[12] Food Allergy Research and Education, *Food Allergy Facts and Statistics for the U.S.*, available at www.foodallergy.org/document.doc?id=194 (citing, e.g., Gupta, RS, Springston, MR, et al. *The prevalence, severity, and distribution of childhood food allergy in the United States.* J. Pediatrics.2011; 128.doi: 10.1542/peds.2011-0204, and Liu, AH, Jaramillo, R, et al. *National prevalence and risk factors for food allergy and relationships to asthma: Results from the National Health and Nutrition Examination Survey 2005-2006.* J Allergy ClinImmunol.2010; 126: 798-806)(last viewed on March 16, 2014).
[13] U.S. Dept. of Health and Human Services, National Institutes of Health, National Institute of Allergy and Infectious Diseases, *Common Food Allergies in Infants, Children, and Adults*, available at www.niaid.nih.gov/topics/foodallergy/understanding/Pages/foodAllergy8Allergens.aspx (last viewed on March 16, 2014).
[14] U.S. Food and Drug Administration, *Food Allergies-What You Need to Know*, page 2, available at www.fda.gov/downloads/Food/ResourcesForYou/Consumers/UCM220117.pdf (last viewed on March 16, 2014).

- Vomiting and/or diarrhea
- Abdominal cramps
- Coughing or wheezing
- Dizziness and/or lightheadedness
- Swelling of the throat and vocal cords
- Difficulty breathing
- Loss of consciousness[15]

More severe allergic reactions can result in anaphylaxis, a life-threatening condition discussed in more detail below. Each year in the United States, it is estimated that anaphylaxis caused by food allergies result in 30,000 emergency room visits, 2,000 hospitalizations, and 150 deaths.[16]

There is no cure for food allergies. Only avoidance of food allergens and timely recognition and management of allergic reactions can prevent serious health problems.[17]

Anaphylaxis

Anaphylaxis is a severe, whole body allergic reaction to an allergen.[18] The human body releases chemicals during anaphylaxis that can cause shock, resulting in a sudden drop in blood pressure and the release of histamines, which restrict breathing.[19] Symptoms of anaphylaxis include a rapid and weak pulse, skin rash, nausea and vomiting.[20] The number of persons with a severe allergy has increased significantly during the last ten years, with the current incidence rate estimated to be 49.8 per 100,000 persons.[21]

Anaphylaxis is an emergency situation that requires immediate medical attention. If anaphylaxis is not treated, it will lead to unconsciousness and possible death. Initial treatment of anaphylaxis includes the administration of epinephrine, also known as adrenaline, to improve breathing by relaxing muscles in the airways, stimulate the heart, and tighten the blood vessels to reduce swelling. Epinephrine is classified as a sympathomimetic drug, meaning its effects mimic those of the stimulated sympathetic nervous system, which stimulates the heart and narrows the blood vessels. It is available through a prescription from a physician.

Many individuals with severe allergies that have resulted in, or can result in, anaphylaxis carry an EpiPen[22] or Auvi-Q.[23] Both products are epinephrine auto-injectors (EAIs) which consist of a syringe prefilled with an appropriate dose of epinephrine and a retractable needle that is protected by a safety guard to prevent injury or reuse. There are two dosages available for the EpiPen and Auvi-Q; for children weighing between 33 and 66 pounds, the dosage is .15 mg and for children and adults

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[15] Id.
[16] Id.
[17] See supra, FN 12.
[18] U.S. Dept. of Health and Human Services, National Institutes of Health, U.S. National Library of Medicine, National Center for Biotechnology Information, *Anaphylaxis*, available at: http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0001847/ (last viewed March 16, 2014).
[19] Food Allergy Research and Education, *About Food Allergies-About Anaphylaxis*, available at www.foodallergy.org/anaphylaxis (last viewed on March 16, 2014); see also U.S. Dept. of Health and Human Services, National Institutes of Health, National Institute of Allergy and Infectious Diseases, *Food Allergy: What is Anaphylaxis?*, available at www.niaid.nih.gov/topics/foodallergy/understanding/Pages/anaphylaxis.aspx (last viewed on March 16, 2014).
[20] Id.
[21] Stephanie Guerlain, PhD, et al., *A comparison of 4 epinephrine autoinjector delivery systems: usability and patient preference*, NIH Public Access Author Manuscript, available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2892620/ (citing Decker WW, Campbell, RL, Luke A, et al., *The etiology and incidence of anaphylaxis in Rochester, Minnesota: a report from the Rochester Epidemiology Project,* J Allergy Clin Immunol., 2008;122:1161-1165)(last viewed on March 16, 2014).
[22] EpiPen and EpiPen Jr are manufactured for Mylan Specialty, L.P., a Pfizer company.
[23] Auvi-Q is manufactured by Sanofi.

weighing more than 66 pounds, the dosage is .30 mg.[24] Once injected into the outer thigh, epinephrine eases the symptoms of anaphylaxis until professional medical treatment is received.

Recent Florida Laws about EAIs

In 2012, the Legislature passed House Bill 509,[25] which authorizes a pharmacist to administer epinephrine using an EAI in the event of an allergic reaction from a vaccine.[26] Pharmacists who obtain certification and are authorized to provide vaccines are required to complete a 3-hour continuing education course every two years on the safe and effective administration of vaccines.[27] The 3-hour course must be offered by a statewide professional association of physicians in this state and is considered part of the 30-hour continuing education requirement for biennial licensure renewal and recertification.[28] If a pharmacist fails to take the 3-hour course, the authorization to administer vaccines or epinephrine is revoked.[29]

In 2013, the Legislature passed Senate Bill 284,[30] which gives an option to public and private schools to purchase and store EAIs on campus.[31] A school that stores EAIs must adopt a physician's protocol for administering the device.[32] The law provides that except for willful and wanton conduct, trained school employees and the physicians who develop the school's protocol on administering the EAIs are protected from liability that may result from administering EAIs.[33]

Good Samaritan Act

The Good Samaritan Act, found in s. 768.13, F.S., provides immunity from civil liability for those who render emergency care and treatment to individuals in need of assistance. The statute provides immunity from liability for civil damages to any person who:

- Gratuitously and in good faith renders emergency care or treatment either in direct response to emergency situations or at the scene of an emergency, without objection of the injured victim, if that person acts as an ordinary reasonably prudent person would have acted under the same or similar circumstances.[34]
- Participates in emergency response activities of a community emergency response team if that person acts prudently and within scope of his or her training.[35]
- Gratuitously and in good faith renders emergency care or treatment to an injured animal at the scene of an emergency if that person acts as an ordinary reasonably prudent person would have acted under the same or similar circumstances.[36]

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[24] Mylan Specialty, L.P., *Epipen and Epipen Jr Patient Information*, available at www.epipen.com/~/media/BBAC09E9BE9346A3B9C81EC175B7FD3E.ashx (last viewed on March 16, 2014); see also Sanofi, *Auvi-Q Patient Brochure*, available at www.auvi-q.com/media/pdf/Patient-Brochure.pdf (last viewed on March 16, 2014).
[25] Ch. 2012-60, Laws of Fla.
[26] S. 465.189(3), F.S.
[27] S. 465.009(6)(a), F.S.
[28] Id.
[29] S. 465.009(6)(c), F.S.
[30] Ch. 2013-63, Laws of Fla.
[31] S. 1002.20(3)(i)2., F.S. (public schools) and s. 1002.42(17)(a), F.S. (private schools).
[32] Id.
[33] S. 1002.20(3)(i)3., F.S. (public schools) and s. 1002.42(17)(b), F.S. (private schools).
[34] Section 768.13(2)(a), F.S.
[35] Section 768.13(2)(d), F.S.
[36] Section 768.13(3), F.S.

Effect of Proposed Changes

House Bill 1131 amends the law governing insect sting emergency treatment by creating new and expanding existing provisions in s. 381.88, F.S., related to emergency allergy treatment, and by creating s. 381.885, F.S. Together, these laws are to be referred to as the "Emergency Allergy Treatment Act" ("the Act").

The bill defines several terms for the purposes of the Act, including "administer," "authorized health care practitioner," "department," and "self-administration." The following definitions are important for the operation of the Act:

- "Authorized entity" is defined as an entity or organization at or in connection with which allergens capable of causing a severe allergic reaction may be present. The term includes, but is not limited to, restaurants, recreation camps, youth sports leagues, theme parks and resorts, and sports arenas. The term also includes a school for the purposes of the educational training programs for recognizing the symptoms of a severe allergic reaction and administering an epinephrine auto-injector.
- "Epinephrine auto-injector" is defined as a single-use device used for the automatic injection of a premeasured dose of epinephrine into the human body. Examples of EAIs are the EpiPen and the Auvi-Q, discussed above.

Section 381.88, F.S., provides for the certification of individuals who administer life-saving treatment to persons who have a severe adverse reaction to an insect sting. The bill deletes references to insect stings and includes the more general term "allergic reactions." Current law only authorizes physicians to conduct educational training programs to teach people to recognize the symptoms of a reaction to an insect sting and the proper administration of epinephrine. The bill authorizes, instead, a nationally recognized organization that trains individuals in emergency health treatment or an entity or individual approved by the Department of Health (DOH) to conduct the training programs. The bill also slightly changes the requirements for training, which must prepare persons to recognize the symptoms of a reaction to food, insect stings, and other allergens and administer an EAI.

The bill expands the category of persons who may receive a certificate of training to include a person who has, or reasonably expects to have, responsibility for or contact with at least one other person. This provision would allow anyone who works around at least one other person to obtain a certificate of training in recognizing a severe allergic reaction and administering an EAI, if necessary. Current law restricts the category of persons who may receive a certificate to only those who are responsible for someone who has severe adverse reactions to insect stings, which requires a measure of prior knowledge.

The bill permits the holder of a certificate of training to receive a prescription for EAIs from a physician or the department. The bill also authorizes a certificate holder to possess an EAI and administer it when a person is experiencing a severe allergic reaction.

The bill creates s. 381.885, F.S., relating to EAIs and the emergency administration of EAIs. The new section of law permits an authorized health care practitioner to prescribe, and a pharmacist to dispense, EAIs to authorized entities. The law permits a certificate holder, either on the premises of an authorized entity or in connection with an authorized entity, to provide and administer an EAI to a person if the certificate holder has a good faith belief the person is suffering a severe allergic reaction.

The bill allows an authorized entity to acquire and stock a supply of EAIs pursuant to a prescription and in accordance with the EAI instructions for use and any other requirements established by the DOH. An authorized entity is required to designate someone who is a certificate holder to be responsible for the EAIs storage, maintenance, and general oversight.

The bill permits an authorized entity to make an EAI available to a non-certified individual for administration to a person believed in good faith to be suffering a severe allergic reaction if the following occurs:

- The EAI is stored in a secure, locked container; and
- The EAI is provided to the non-certified person after remote authorization by an authorized health care practitioner after consulting the practitioner by audio, televideo, or other similar means of electronic communication.

The bill applies the civil liability immunity protections in the Good Samaritan Act[37] to any person, as defined in s. 1.01,[38] including:

- An authorized health care practitioner;
- A dispensing health care practitioner;
- Any person certified under the Act;
- Any non-certified individual who receives an EAI from an authorized entity for purposes of administering it to another person suffering from a severe allergic reaction; and
- A trainer who conducts an educational training program for recognizing the symptoms of a severe allergic reaction and administering an EAI.

The bill would extend civil liability immunity protections under the Good Samaritan Act to an authorized entity as it is captured within the definition of "person."

The bill provides an effective date of July 1, 2014.

B. SECTION DIRECTORY:

Section 1: Amends s. 381.88, F.S., relating to insect sting emergency treatment.
Section 2: Creates s. 381.885, F.S., relating to epinephrine auto-injectors; emergency administration.
Section 3: Provides an effective date of July 1, 2014.

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.

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[37] S. 768.13, F.S.
[38] S. 1.01, F.S., defines "person" to include individuals, children, firms, associations, joint adventures, partnerships, estates, trusts, business trusts, syndicates, fiduciaries, corporations, and all other groups or combinations.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

An authorized entity which opts to stock EAIs must ensure at least one individual holds a certificate from an education training program which is evidence the individual can recognize the symptoms of a severe allergic reaction and administer an EAI. Each certificate costs $25.

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 local governments.

2. Other:

The bill grants civil liability immunity protection under the Good Samaritan Act in s. 768.13, F.S., to several individuals and entities involved with the provision or administration of, or the failure to provide or administer, EAIs including authorized entities, individuals suffering from a severe allergic reaction, or other individuals who administer EAIs to a person suffering from a severe allergic reaction. Immunity provisions may restrict an injured person's ability to seek redress for injury and damages in court.

The state constitution provides that the "courts shall be open to every person for redress of any injury, and justice shall be administered without sale, denial or delay." In *Kluger v. White*, the Florida Supreme Court held that:

> [w]here a right of access to the courts for redress for a particular injury has been provided the Legislature is without power to abolish such a right without providing a reasonable alternative to protect the rights of the people of the State to redress for injuries, unless the Legislature can show an overpowering public necessity for the abolishment of such right, and no alternative method of meeting such public necessity can be shown.[39]

B. RULE-MAKING AUTHORITY:

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

C. DRAFTING ISSUES OR OTHER COMMENTS:

At line 47, the word "department" is capitalized in current law.

At line 106, to clarify what instructions must be followed regarding the storage of EAIs by an authorized entity, it is suggested that the new language be changed to read, "<u>accordance with the epinephrine auto-injector manufacturer's instructions for</u>."

[39] See *Kluger v. White*, 281 So.2d 1, 4 (Fla. 1973).

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 18, 2014, the Health Quality Subcommittee adopted two amendments and reported the bill favorable as a committee substitute. The amendments made the following changes to the bill:

- Removed the broad civil liability immunity provisions;
- Provided civil liability immunity protections under the Good Samaritan Act in s. 768.13, F.S., to persons, as defined in s. 1.01, F.S., including:
    - An authorized health care practitioner;
    - A dispensing health care practitioner;
    - Any person certified under the Act;
    - Any non-certified individual who receives an EAI from an authorized entity for purposes of administering it to another person suffering from a severe allergic reaction; and
    - A trainer who conducts an educational training program for recognizing the symptoms of a severe allergic reaction and administering an EAI.
- Corrected a cross-reference to subsection (5) within the bill.

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

A bill to be entitled

An act relating to emergency allergy treatment; amending s. 381.88, F.S.; defining terms; expanding provisions to apply to all emergency allergy reactions, rather than to insect bites only; creating s. 381.885, F.S.; authorizing certain health care practitioners to prescribe epinephrine auto-injectors to an authorized entity; authorizing such entities to maintain a supply of epinephrine auto-injectors; authorizing certified individuals to use epinephrine auto-injectors; authorizing uncertified individuals to use epinephrine auto-injectors under certain circumstances; providing immunity from liability; providing an effective date.

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

Section 1. Section 381.88, Florida Statutes, is amended to read:

381.88 ~~Insect sting~~ Emergency allergy treatment.—

(1) This section and s. 381.885 may be cited as the "~~Insect Sting~~ Emergency Allergy Treatment Act."

(2) As used in this section and s. 381.885, the term:

(a) "Administer" means to directly apply an epinephrine auto-injector to the body of an individual.

(b) "Authorized entity" means an entity or organization at

or in connection with which allergens capable of causing a severe allergic reaction may be present. The term includes, but is not limited to, restaurants, recreation camps, youth sports leagues, theme parks and resorts, and sports arenas. However, a school as described in s. 1002.20(3)(i) is an authorized entity for the purposes of subsection (5) only.

(c) "Authorized health care practitioner" means a licensed practitioner authorized by the laws of the state to prescribe drugs.

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

(e) "Epinephrine auto-injector" means a single-use device used for the automatic injection of a premeasured dose of epinephrine into the human body.

(f) "Self-administration" means an individual's discretionary administration of an epinephrine auto-injector on herself or himself.

(3) ~~(2)~~ The purpose of this section is to provide for the certification of persons who administer lifesaving treatment to persons who have severe allergic ~~adverse~~ reactions ~~to insect stings~~ when a physician is not immediately available.

(4) ~~(3)~~ The department ~~of Health~~ may:

(a) Adopt rules necessary to administer this section.

(b) Conduct educational training programs as described in subsection (5) ~~(4),~~ and approve programs conducted by other persons or governmental agencies.

(c) Issue and renew certificates of training to persons

who have complied with this section and the rules adopted by the department.

(d) Collect fees necessary to administer this section.

(5) ~~(4)~~ Educational training programs required by this section must be conducted by a nationally recognized organization experienced in training laypersons in emergency health treatment or an entity or individual approved by the department ~~physician licensed to practice medicine in this state~~. The curriculum must include at a minimum:

(a) Recognition of the symptoms of systemic reactions to food, insect stings, and other allergens; and

(b) The proper administration of an ~~a subcutaneous injection of~~ epinephrine auto-injector.

(6) ~~(5)~~ A certificate of training may be given to a person who:

(a) Is 18 years of age or older;

(b) Has, or reasonably expects to have, responsibility for or contact with at least one other person ~~who has severe adverse reactions to insect stings~~ as a result of his or her occupational or volunteer status, including, but not limited to, a camp counselor, scout leader, school teacher, forest ranger, tour guide, or chaperone; and

(c) Has successfully completed an educational training program as described in subsection (5) ~~(4)~~.

(7) ~~(6)~~ A person who successfully completes an educational training program may obtain a certificate upon payment of an

application fee of $25.

(8) ~~(7)~~ A certificate issued pursuant to this section authorizes the holder ~~thereof~~ to receive, upon presentment of the certificate, ~~from any physician licensed in this state or from the department,~~ a prescription for ~~premeasured doses of~~ epinephrine auto-injectors from an authorized health care practitioner or the department ~~and the necessary paraphernalia for administration~~. The certificate also authorizes the holder ~~thereof to possess and administer~~, in an emergency situation when a physician is not immediately available, to possess and administer a ~~the~~ prescribed epinephrine auto-injector to a person experiencing ~~suffering~~ a severe allergic ~~adverse~~ reaction ~~to an insect sting~~.

Section 2. Section 381.885, Florida Statutes, is created to read:

381.885 Epinephrine auto-injectors; emergency administration.—

(1) PRESCRIBING TO AN AUTHORIZED ENTITY.—An authorized health care practitioner may prescribe epinephrine auto-injectors in the name of an authorized entity for use in accordance with this section, and pharmacists may dispense epinephrine auto-injectors pursuant to a prescription issued in the name of an authorized entity.

(2) MAINTENANCE OF SUPPLY.—An authorized entity may acquire and stock a supply of epinephrine auto-injectors pursuant to a prescription issued in accordance with this

section. Such epinephrine auto-injectors must be stored in accordance with the epinephrine auto-injector's instructions for use and with any additional requirements that may be established by the department. An authorized entity shall designate employees or agents who hold a certificate issued pursuant to s. 381.88 to be responsible for the storage, maintenance, and general oversight of epinephrine auto-injectors acquired by the authorized entity.

(3) USE OF EPINEPHRINE AUTO-INJECTORS.—An individual who holds a certificate issued pursuant to s. 381.88 may, on the premises of or in connection with the authorized entity, use epinephrine auto-injectors prescribed pursuant to subsection (1) to:

(a) Provide an epinephrine auto-injector to a person who the certified individual in good faith believes is experiencing a severe allergic reaction for that person's immediate self-administration, regardless of whether the person has a prescription for an epinephrine auto-injector or has previously been diagnosed with an allergy.

(b) Administer an epinephrine auto-injector to a person who the certified individual in good faith believes is experiencing a severe allergic reaction, regardless of whether the person has a prescription for an epinephrine auto-injector or has previously been diagnosed with an allergy.

(4) EXPANDED AVAILABILITY.—An authorized entity that acquires a stock supply of epinephrine auto-injectors pursuant

to a prescription issued by an authorized health care practitioner in accordance with this section may make the auto-injectors available to individuals other than certified individuals identified in subsection (3) who may administer the auto-injector to a person believed in good faith to be experiencing a severe allergic reaction if the epinephrine auto-injectors are stored in a locked, secure container and are made available only upon remote authorization by an authorized health care practitioner after consultation with the authorized health care practitioner by audio, televideo, or other similar means of electronic communication. Consultation with an authorized health care practitioner for this purpose is not considered the practice of telemedicine or otherwise construed as violating any law or rule regulating the authorized health care practitioner's professional practice.

(5) IMMUNITY FROM LIABILITY.—Any person, as defined under s. 1.01, including an authorized health care practitioner, dispensing health care practitioner, an individual trainer under s. 381.88(5), a person certified pursuant to s. 381.88(7), and any uncertified person who administers an epinephrine auto-injector as authorized under subsection (4), is afforded the civil liability immunity protections provided under s. 768.13.

Section 3. This act shall take effect July 1, 2014.

COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. CS/HB 1131 (2014)

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 & Human Services Committee

Representative Hudson offered the following:

Amendment

Remove lines 146-152 and insert:

(5) IMMUNITY FROM LIABILITY.—Any person, as defined under s. 1.01, including an authorized health care practitioner, a dispensing health care practitioner or pharmacist, an individual trainer under s. 381.88(5), and a person certified pursuant to s. 381.88(7), who possesses, administers, or stores an epinephrine auto-injector in compliance with this act, and an uncertified person who administers an epinephrine auto-injector as authorized under subsection (4) in compliance with this act, is afforded the civil liability immunity protections provided under s. 768.13.