

# **Health & Human Services Committee**

Thursday, April 3, 2014 8:30 AM - 10:30 AM Morris Hall

# Committee Meeting Notice HOUSE OF REPRESENTATIVES

# Health & Human Services Committee

Start Date and Time:

Thursday, April 03, 2014 08:30 am

**End Date and Time:** 

Thursday, April 03, 2014 10:30 am

Location:

Morris Hall (17 HOB)

**Duration:** 

2.00 hrs

#### Consideration of the following bill(s):

CS/HB 27 Statewide Prepaid Dental Program by Health Innovation Subcommittee, Diaz, J.

CS/CS/HB 159 Establishment of Mental Health First Aid Training Program by Health Care Appropriations Subcommittee, Healthy Families Subcommittee, Berman, Wood

CS/HB 211 Community Health Workers by Health Quality Subcommittee, Reed

HB 457 Pub. Rec./Dental Workforce Surveys by Harrell, Williams, A.

CS/HB 479 Substance Abuse Services by Healthy Families Subcommittee, Hager

HB 531 Public Health Trusts by Richardson

HB 799 Transitional Living Facilities by Magar

CS/CS/HB 819 Department of Health by Health Care Appropriations Subcommittee, Health Quality Subcommittee, Pigman, Campbell

CS/HB 1019 Pub. Rec./Location of Safe Houses & Safe Foster Homes by Healthy Families Subcommittee, Spano

CS/HB 1225 HIV Testing by Health Quality Subcommittee, Saunders, Pigman

CS/HB 1275 Physician Assistants by Select Committee on Health Care Workforce Innovation, Ahern

HB 7077 Sterile Compounding by Health Quality Subcommittee, Patronis

HB 7145 Ratification of Rules/Department of Health by Rulemaking Oversight & Repeal Subcommittee, Gaetz

Pursuant to rule 7.12, the deadline for amendments to bills on the agenda by non-appointed members is 6:00 p.m., Wednesday, April 2, 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, April 2, 2014.

### HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #:

CS/HB 27

Cost-effective Purchasing of Health Care

SPONSOR(S): Health Innovation Subcommittee; Diaz

TIED BILLS:

**IDEN./SIM. BILLS:** 

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee	9 Y, 3 N, As CS	McElroy	Shaw
2) Health & Human Services Committee		McElroy	Calamas 🕊

### **SUMMARY ANALYSIS**

In 2011, Florida established the Statewide Medicaid Managed Care (SMMC) program. The SMMC program requires the Agency for Health Care Administration (AHCA) to create an integrated managed care program for Medicaid enrollees to provide all the mandatory and optional Medicaid benefits for primary and acute care, including pediatric dental services. On February 6, 2014, AHCA executed 5-year contracts with the managed care plans selected to provide care, including pediatric dental services, under the SMMC. AHCA will begin implementing the SMMC program in selected regions on May 1, 2014, with the last regions being implemented on August 1, 2014. The SMMC program must be fully implemented in all regions by October, 2014.

The bill removes pediatric dental services from the otherwise integrated SMMC program by creating a new statewide prepaid dental program. AHCA is directed to contract with at least two prepaid dental health plans (PDHP) on a statewide basis. The statewide prepaid dental program will begin no later than September 1, 2015, or when AHCA receives the necessary federal authority to implement the program. AHCA is given authority to seek any state plan amendments or waiver authority necessary to implement the program.

To remove dental services from the SMMC program, AHCA will have to apply for an amendment of the approved section 1115 waiver, and may also have to apply for a new 1915(b) waiver to authority to use a PDHP model to deliver dental services. The federal government has no deadline for acting on a section 1115 waiver application. Until new federal approval is granted, AHCA is required to proceed with the full implementation of the SMMC program.

The bill requires that any child who becomes eligible for Medicaid benefits between the effective date of the act and implementation of the statewide prepaid dental program must receive dental services through the SMMC program. The child will be removed from the SMMC plan and enrolled in the statewide prepaid dental program once it is implemented. The bill requires AHCA to provide recipients with all required notices regarding this transition.

Pediatric dental services are currently provided in many areas of the state through contracts with PDHPs. The existing PDHPs contracts are scheduled to expire with the full implementation of the SMMC program. The bill requires AHCA to extend the existing PDHP contracts. It additionally requires AHCA to amend the existing contracts to include all counties; however, current procurement law prohibits extending these contracts with the existing PDHPs extended beyond March 30, 2017.

The bill requires a medical loss ratio of 85 percent for prepaid dental plans participating in the statewide prepaid dental program.

The bill requires AHCA to provide an annual report to the Governor and Legislature which compares the utilization, benefit and cost data from Medicaid dental contractors as well as compliance reports and access to care to the state's overall Medicaid dental population.

The bill has a significant negative fiscal impact on the Medicaid program.

The bill provides that the act will take effect upon becoming a law.

This document does not reflect the intent or official position of the bill sponsor or House of Representatives. STORAGE NAME: h0027b.HHSC.DOCX

### **FULL ANALYSIS**

### I. SUBSTANTIVE ANALYSIS

### A. EFFECT OF PROPOSED CHANGES:

#### **Present Situation**

### Medicaid

Medicaid is a joint federal- and state-funded program that provides health care for low-income Floridians, administered by AHCA under ch. 409, F.S. Federal law establishes the mandatory services to be covered in order to receive federal matching funds. Benefit requirements can vary by eligibility category. For example, more benefits are required for children than for the adult population. Florida's mandatory and optional benefits are prescribed in state law under ss. 409.905, and 409.906 F.S., respectively.

Dental services are an optional Medicaid benefit. Florida provides full dental services for children and only dentures and medically necessary, emergency dental procedures to alleviate pain or infection for adults.<sup>1</sup>

The delivery of Medicaid services through managed care is not expressly authorized by federal law. If a state wants to use a managed care delivery system, it must seek a waiver of certain requirements of Title XIX of the Social Security Act (Medicaid). Section 1915(b) of the Social Security Act provides authority for Secretary of Health and Human Services to waive requirements of the Act to the extent she "finds it to be cost-effective and efficient and not inconsistent with the purposes of this title."

Florida has received waiver authority for Medicaid recipients receive dental benefits through a managed care delivery system using prepaid dental health plans.

### Prepaid Dental Health Plans

A prepaid dental health plan (PDHP) is:

A managed care plan that is licensed or certified as a risk-bearing entity, or qualified pursuant to s. 409.912(4)(d), F.S., in the state and is paid a prospective per-member, per-month payment by the agency.<sup>2</sup>

In 2001, the state began using PDHPs to deliver dental services to children through a pilot program in Miami-Dade County<sup>3</sup>. In 2003, the Legislature expanded the PDHP initiative beyond Miami-Dade County by authorizing AHCA to contract with PDHPs without specifying the county or the population.<sup>4</sup> The authority excluded Miami-Dade County from this contracting process but did permit AHCA the option<sup>5</sup> of including the Medicaid reform pilot counties in the procurement.<sup>6</sup> Similar language was

STORAGE NAME: h0027b.HHSC.DOCX DATE: 4/1/2014

<sup>&</sup>lt;sup>1</sup> S. 409.906(1), (6), F.S.

<sup>&</sup>lt;sup>2</sup> S. 409.962, F.S., See Agency for Health Care Administration, Model Statewide Prepaid Dental Health Plan (SPDHP) Contract, Attachment II-Core Contract Provisions, p. 17, <a href="http://ahca.myflorida.com/medicaid/pdhp/docs/120120">http://ahca.myflorida.com/medicaid/pdhp/docs/120120</a> Attachment II Core.pdf (last visited February 6, 2014). PDHPs are classified as prepaid ambulatory health plans by 42 CFR Part 438.

<sup>&</sup>lt;sup>3</sup> Proviso language in the 2001 General Appropriations Act (GAA) authorized AHCA to initiate a PDHP pilot program in Miami-Dade County. Similar statutory authority was provided in 2003.

<sup>&</sup>lt;sup>4</sup> S. 409.912(42), F.S. (2003). The 2010-2011 GAA proviso specifically authorized AHCA to contract with PDHPs on either a regional or statewide basis.

<sup>&</sup>lt;sup>5</sup> AHCA elected not to include those counties (children enrolled in managed care plans in the reform counties receive their dental benefits through comprehensive managed care plans; not through PDHPs).

enacted in s. 409.912(41)(a), F.S. However, these provisions made PDHP contracting mandatory, not discretionary, outside the reform counties (and Miami-Dade County). Section 409.912(41)(b), F.S., limited the use of PHDPs by requiring that AHCA may not limit dental services to PDHPs and must allow dental services to be provided on a fee-for-service basis as well.

AHCA issued a competitive procurement for the statewide PDHP program in 2011 and awarded contracts to two PDHPs to provide dental services to Medicaid recipients in all Florida counties with the exceptions noted above. The original procurement period was December 1, 2011 through September 30, 2013. Both contracts were renewed in September 2013. There are two one-year renewal options and a one-time six month extension remaining. Consequently, current contracts with the PDHPs could not be extended beyond March 30, 2017, without having to re-procure. The current PDHP contractors are DentaQuest and MCNA.

### PDHP Performance

AHCA measures the performance of PDHPs based on standards established by the National Committee for Quality Assurance called the Healthcare Effectiveness Data and Information Set (HEDIS). Annual pediatric dental visits in Miami-Dade, statewide, and in the reform pilot counties are reflected below.

HEDIS Annual Dental Visit Scores for Reform Plans and PDHPs11

Calendar	Reform Pilot	Dentaquest Statewide	Dentaquest	MCNA	MCNA
Year	Plans		Miami-Dade	Statewide	Miami-Dade
2012	40.4%	47.3%	41.4%	39.3%	36.8%

Under the terms and conditions of the 1115 waiver, AHCA must work with MMA plans on an oral health quality improvement initiative. AHCA developed the framework for initiative and included it in the contracts with the MMA plans. The MMA contracts have specific performance goals for pediatric dental and penalties for not reaching the performance standards. Each Managed Care Plan is required to provide a Child Health Check Up (CHCUP) to enrollees. The CHCUP includes dental screenings starting at age 3, or earlier if indicated. As part of the integration of care, the Managed Care Plan must provide transportation to and from the child's appointment, if needed.

The Managed Care Plans are required to achieve a preventive dental services rate of at least twenty-eight percent for those enrollees who are continuously eligible for CHCUP for ninety continuous days. Failure to meet this goal could result in a corrective action plan and liquidated damages of \$50,000 per occurrence in addition to \$10,000 for each percentage point less than the target.

http://ahca.myflorida.com/Medicaid/statewide\_mc/index.shtml#SMMC\_Home (last viewed March 10, 2014).

<sup>&</sup>lt;sup>6</sup> In 2005, the Legislature enacted laws to reform the delivery and payment of services through the Medicaid program and directed AHCA to seek a federal waiver for a Medicaid managed care pilot program over five years. The program began in Broward and Duval counties in 2006 and later expanded to Baker, Clay and Nassau counties in 2007, as authorized in statute. The five-year waiver was set to expire June 30, 2011, but has been renewed through June 30, 2014.

<sup>&</sup>lt;sup>7</sup> During 2012, the Agency implemented the statewide PDHP program in Medicaid Area 9 on January 1; Areas 5, 6, and 7 on October 1; and Areas 1, 2, 3, 4, 8, and 11 (Monroe County only) on December 1, 2012.

<sup>&</sup>lt;sup>8</sup> Correspondence from AHCA to Health and Human Services Committee staff, dated March 26, 2014 (currently on file with the Florida House of Representatives Health and Human Services Committee).

<sup>9</sup> Id.

<sup>&</sup>lt;sup>10</sup> Id.

<sup>&</sup>lt;sup>11</sup> Information from AHCA and on file with the Health Innovation Subcommittee.

<sup>12</sup> The Managed Medical Assistance Model Contract is available at:

Additionally, the Managed Care Plans are required to have HEDIS scores of above 50% for pediatric dental or be subject liquidated damages. The liquidated damages will be calculated based on the number of members enrolled in the Managed Care Plan as follows:

PM Ranking	Amount per member
40 <sup>th</sup> – 49 <sup>th</sup> percentile	\$1.25
25 <sup>th</sup> – 39 <sup>th</sup> percentile	\$2.00
10 <sup>th</sup> – 24 <sup>th</sup> percentile	\$2.75
< 10 <sup>th</sup> percentile	\$3.50

### Statewide Medicaid Managed Care

In 2011, Florida established the Statewide Medicaid Managed Care (SMMC) program as Part IV of Chapter 409, F.S. The SMMC requires AHCA to create an integrated managed care program for Medicaid enrollees to provide all the mandatory and optional Medicaid benefits for primary and acute care, including dental. Dental services will be provided by comprehensive managed care organizations (provider service networks and health maintenance organizations) instead of being delivered as a separate benefit under a separate managed care contract, and the fee-for-service option will be eliminated. Each Medicaid recipient will have one managed care organization to coordinate all health care services, rather than various entities as in the current Medicaid program. This comprehensive coordinated system of care was successfully implemented in the 5-county Medicaid reform pilot program. Such coordinated care is particularly important in the area of oral health, which is connected to overall health outcomes. 14

The SMMC program will be the primary method of delivery for Medicaid services. The program's enacting laws repeal many sections of current Medicaid law effective upon the implementation of the SMMC program. Pursuant to this change in policy, the PDHP laws will sunset as well. Section 409.912(41)(b), F.S., expired on July 1, 2013, and s. 409.912(41)(a), F.S., will sunset October 1, 2014. The sunset of these subsections eliminates a conflict with the SMMC program. Even if they were not repealed, they would be preempted by the SMMC program: s. 409.961, F.S., requires any conflict between the SMMC program law and pre-reform laws to be resolved in favor of the SMMC laws.

The SMMC program has two components: the Long-term Care Managed Care Program and the Managed Medical Assistance (MMA) Program. The MMA program provides primary and acute medical assistance and related services. On December 28, 2012, AHCA released an Invitation to Negotiate (ITN) to competitively procure managed care plans on a statewide basis for the MMA program. AHCA subsequently selected managed care plans that it will contract with for the MMA program via the competitive procurement and issued recommended contract awards on September 23, 2013. On February 6, 2014, AHCA executed contracts with the managed care plans selected to provide care under the MMA component of the SMMC program. The contract requires managed care plan to

STORAGE NAME: h0027b.HHSC.DOCX DATE: 4/1/2014

<sup>&</sup>lt;sup>13</sup> S. 409.973, F.S.

<sup>&</sup>lt;sup>14</sup>U.S. Department of Health and Human Services. *Oral Health in America: A Report of the Surgeon General*. Rockville, MD: U.S. Department of Health and Human Services, National Institute of Dental and Craniofacial Research, National Institutes of Health, 2000. <a href="http://profiles.nlm.nih.gov/ps/retrieve/ResourceMetadata/NNBBJT/">http://profiles.nlm.nih.gov/ps/retrieve/ResourceMetadata/NNBBJT/</a> (last viewed February 9, 2014);

AHCA Invitation to Negotiate, *Statewide Medicaid Managed Care*, *Addendum 2* Solicitations Number: AHCA ITN 017-12/13; dated February 26, 2013. <a href="http://myflorida.com/apps/vbs/vbs\_www.ad.view\_ad?advertisement\_key\_num=105774">http://myflorida.com/apps/vbs/vbs\_www.ad.view\_ad?advertisement\_key\_num=105774</a> (February 6, 2014); AHCA Invitation to Negotiate, *Statewide Medicaid Managed Care*, Solicitation Number: AHCA ITN 017-12/13; dated December 28, 2012 <a href="http://myflorida.com/apps/vbs/vbs\_www.ad.view\_ad?advertisement\_key\_num=105774">http://myflorida.com/apps/vbs/vbs\_www.ad.view\_ad?advertisement\_key\_num=105774</a> (last visited February 6, 2014).

maintain an annual medical loss ratio of a minimum of eighty-five percent (85%) for the first full year of MMA program operation. <sup>16</sup>

Under the MMA contracts, all managed care plans are required to provide comprehensive Medicaid services, including all Medicaid covered dental services, to their enrollees. Most of MMA managed care plans will also provide full dental services, not currently covered under Medicaid, to adult enrollees at no additional cost to the state. Full adult dental services have never before been offered by Florida Medicaid. Examples of these additional benefits include twice-yearly exams and cleanings, fluoride treatments, fillings, and yearly x-rays.<sup>17</sup> These additional services are valued at over \$100 million over the 5-year duration of the MMA contracts.<sup>18</sup>

AHCA will begin implementing the SMMC program in selected regions on May 1, 2014 with the last regions being implemented on August 1, 2014. The SMMC must be fully implemented in all regions by October, 2014, as directed in s. 409.971, F.S.

On October 1, 2014, the statutory authority for the Agency to contract with PDHPs to provide dental services to eligible Medicaid recipients is scheduled to sunset with the implementation of the SMMC program. Medicaid recipients who are enrolled in the SMMC program will receive their dental services through the fully integrated managed care plans.

The Managed Care Plans participating in the SMMC program have developed their dental networks by both subcontracting with PDHPs and directly contracting with dentists. Both DentaQuest and MCNA, the current PDHP contractors, have subcontracts in a majority of regions of the state, while two other plans, Liberty Dental Plan and Dental Benefits Provider, Inc. also have subcontracts.<sup>19</sup>

Dental Subcontractor	MMA Region		
DentaQuest	1, 4, 5, 6, 7, 9, 10, 11		
MCNA	2, 3, 4, 5, 6, 7, 8, 9, 10, 11		
Liberty Dental Plan	2, 3, 4, 6, 7, 8, 11		
Dental Benefits Provider, Inc.	3, 7,11		

# Federal Waiver Authority

To use the PDHP model to deliver dental services to Medicaid recipients, AHCA had to obtain section 1915(b) waiver authority. This waiver authority expired on January 31, 2014. AHCA did not seek renewal of the waiver, and the deadline for seeking renewal under federal law has passed. Instead, the federal government has agreed to give a series of temporary extensions to the 1915(b) waiver as AHCA implements the SMMC program, allowing dental services to be gradually folded into the SMMC program and then letting the section 1915(b) waiver expire.<sup>20</sup>

To implement the SMMC program, AHCA applied for and obtained section 1115 waiver authority. Section 1115 of the Social Security Act allows states to use innovative service delivery systems that improve care, increase efficiency, and reduce costs. Federal authority for including dental services in the SMMC program is in the approved section 1115 waiver.<sup>21</sup>

Currently, Florida only has federal authority to provide dental services to Medicaid recipients as an integrated component of the SMMC program.

<sup>&</sup>lt;sup>16</sup> Model Agreement, Attachment II, Exhibit II A, Medicaid Managed Medical Assistance Program, Agency for Health Care Administration, February, 2014, available at <a href="http://ahca.myflorida.com/Medicaid/statewide\_mc/index.shtml#mmaplans">http://ahca.myflorida.com/Medicaid/statewide\_mc/index.shtml#mmaplans</a> (last viewed March 8, 2014).

<sup>&</sup>lt;sup>17</sup> Information provided by AHCA and on file with the subcommittee.

<sup>&</sup>lt;sup>18</sup> AHCA 2014 Agency Legislative Bill Analysis for HB 27, dated November 13, 2014 (currently on file with the Florida House of Representatives Health Innovation Subcommittee).

<sup>&</sup>lt;sup>19</sup> Information from AHCA and on file with the subcommittee.

<sup>&</sup>lt;sup>20</sup> Id.

<sup>&</sup>lt;sup>21</sup> Id.

### **Effect of the Proposed Changes**

The bill removes pediatric dental services from the integrated SMMC program by creating a new statewide prepaid dental program. AHCA is directed to contract with at least two PDHPs on a statewide basis to provide dental services to children enrolled in Medicaid. The bill requires AHCA to contract only with PDHPS that have experience maintaining statewide dental provider networks for Medicaid programs.

To remove dental services from the SMMC program, AHCA will have to apply for an amendment of the approved section 1115 waiver to remove pediatric dental services from the SMMC program's covered benefits. AHCA may also have to seek 1915(b) waiver authority to utilize the PDHP model to deliver dental services. AHCA's prior waiver authority for a PDHP expired on January 31, 2014. AHCA will have to either apply for a new 1915(b) waiver or seek an amendment to the approved section 1115 waiver to reestablish this authority. AHCA is given authority to seek to seek any state plan amendments or waiver authority necessary to implement the program.

The federal government has no time limits for reviewing a request for a section 1115 waiver; therefore, it is unknowable how long the process would take. The bill delays enrollment in the PDHPs until all necessary state plan amendments or federal waivers have been obtained. However, the bill requires that enrollment begin no later than September 1, 2015. The bill appears to require enrollment on this date even if federal approval has not been granted yet. In the interim, AHCA is required to proceed, as required by ch. 409 and the 1115 waiver, with the full implementation of the SMMC program.

The bill requires that any child who is eligible for Medicaid benefits between the effective date of the act and implementation of the PDHP must receive dental services through the SMMC. The child will be removed from the SMMC plan and enrolled in the PDHP once it is implemented. The bill requires AHCA to provide recipients with all required notices regarding this transition, and allows AHCA to assess the PDHPs for the costs of this notification.

Because AHCA and the SMMC plans based their contract negotiations and capitated rates on the current law that requires coverage of pediatric dental services, AHCA may be required to renegotiate rates with all the SMMC plans. Similarly, because the SMMC plans based their provider payment and network development on the current law requirement to cover pediatric dental services, the SMMC plans may have to renegotiate with dental providers to reflect the lower volume of (adult only) care.

The bill requires AHCA to extend the existing contracts with the existing PDHPs, rather than issuing a new competitive procurement.<sup>22</sup> It also requires AHCA to amend the existing contracts to include all counties. The existing statewide PDHPs were procured through a competitive process. The original procurement period was December 1, 2011, through September 30, 2013. The ITN for this procurement allowed for renewal; however, the renewal cannot go beyond September 30, 2016, because s. 287.057(13), F.S. limits state contract renewals to no more than three years. AHCA already renewed the PDHP contracts for one year through September 30, 2014. Consequently, current contracts with the PDHPs would have to be competitively re-procured to continue to program beyond September 30, 2016.

The bill requires a medical loss ratio of 85 percent for prepaid dental plans participating in the PDHP. This is identical to the medical loss ratio requirement for MMA managed care plans providing services in the SMMC program.

STORAGE NAME: h0027b.HHSC.DOCX

<sup>&</sup>lt;sup>22</sup> Since AHCA's waiver authority to provide dental services through PDHPs expired January 31, 2014, subject to temporary extensions during the SMMC rollout, AHCA has no authority to pay the PDHPs for dental services once the SMMC is fully implemented and before new waiver authority is obtained.

The bill requires AHCA to provide an annual report to the Governor and Legislature which compares the utilization, benefit and cost data from Medicaid dental contractors as well as compliance reports and access to care to the state's overall Medicaid dental population.

The bill amends s. s. 409.973, F.S., remove pediatric dental services from the SMMC program and to provide that only adult dental services<sup>23</sup> are a mandatory service for the program.

### **B. SECTION DIRECTORY:**

Section 1. Creating s. 409.91205, F.S., relating to statewide prepaid dental program.

Section 2. Amending s. 409.973, F.S., relating to social and economic assistance benefits.

Section 3. Providing that the act shall take effect upon becoming a law.

# II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

### A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

### 2. Expenditures:

AHCA would need to add two pay grade 24 FTEs to function as contract managers for the two PDHPs. AHCA would also need increased funding for travel expenses to perform additional plan monitoring that is required. Expenditures for these activities would begin in SFY 2014-2015 based on the July 1, 2014, effective date of the bill and have recurring costs of \$131,489.00 annually.<sup>24</sup>

There are indeterminate, but likely significant, costs related to re-negotiation of the MMA contracts, re-procurement of the SMMC program, re-procurement of the PDHPs, legal challenges and system changes required to implement the exclusion of dental services from the SMMC.

### **B. FISCAL IMPACT ON LOCAL GOVERNMENTS:**

1. Revenues:

None.

2. Expenditures:

None.

# C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

For the majority of adult Medicaid enrollees, current dental benefits are extremely limited. Under MMA, AHCA negotiated expanded dental benefits with the managed care organizations at no cost to AHCA. AHCA estimates the value of these additional benefits at \$100 million over 5 years, at no additional cost to taxpayers. However, if the pediatric enrollees are carved out of the MMA contracts, AHCA believes that the managed care organizations will lose leverage with the dental providers and existing dental provider networks resulting in the loss of the expanded benefit for the adults. In all likelihood,

STORAGE NAME: h0027b.HHSC.DOCX

<sup>&</sup>lt;sup>23</sup> Adult dental services include only dentures and medically necessary, emergency dental procedures to alleviate pain or infection. S. 409.906(1), (6), F.S

<sup>&</sup>lt;sup>24</sup> Id.

<sup>&</sup>lt;sup>25</sup> AHCA, supra.

<sup>&</sup>lt;sup>26</sup> AHCA, supra, note 16.

adult Medicaid enrollees will lose access to expanded dental benefits, dental providers may lose the opportunity for increased patients and revenue, and taxpayers will not have the benefit of a no-cost \$100 million negotiated contract term.

### D. FISCAL COMMENTS:

If the SMMC implementation is delayed to re-negotiate rates or obtain amended waivers, AHCA expects that the state will also lose anticipated savings from the MMA contracts. Based on the projected 5 percent aggregate savings per year contemplated in s. 409.966(3)(d), F.S., and the estimated contract value of \$70 billion over 5 years, the minimum impact for a 1 year delay is \$736 million in lost savings.<sup>27</sup>

### III. COMMENTS

### A. CONSTITUTIONAL ISSUES:

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

### 2. Other:

Requiring AHCA to contract with licensed prepaid dental health plans for Medicaid dental services after October 1, 2014, could result in a legal challenge that the bill's provisions create an unconstitutional impairment of contracts.

On December 28, 2012, AHCA released an Invitation to Negotiate (ITN) to competitively procure managed care plans on a statewide basis. <sup>28</sup> Dental services were included in the ITN as one of the enumerated services to be provided under the SMMC. On February 6, 2014, AHCA executed contracts with the managed care plans selected to provide care, including dental services, under the SMMC.

The United States Constitution and the Florida Constitution prohibit the state from passing any law impairing the obligation of contracts. <sup>29</sup> The courts will subject state actions that impact state-held contracts to an elevated form of scrutiny when the Legislature passes laws that impact such contracts. *Cf. Chiles v. United Faculty of Fla.*, 615 So.2d 671 (Fla. 1993). "[T]he first inquiry must be whether the state law has, in fact, operated as a substantial impairment of a contractual relationship. The severity of the impairment measures the height of the hurdle the state legislation must clear."<sup>30</sup>

The estimated annualized value of the MMA contracts is approximately \$70 billion over 5 years. The change in the value of these MMA contracts due to the value of removing the dental benefit may be deemed substantial if AHCA must re-negotiate these contracts or re-procure due to severing dental benefits from the benefits to be provided.

<sup>&</sup>lt;sup>27</sup> Id.

<sup>&</sup>lt;sup>28</sup> AHCA, supra, note 15.

<sup>&</sup>lt;sup>29</sup> U.S. Const. art. I, § 10; art. I, s. 10, Fla. Const.

<sup>&</sup>lt;sup>30</sup> Pomponio v. Claridge of Pompano Condominium, Inc., 378 So. 2d 774 (Fla. 1980). See also General Motors Corp. v. Romein, 503 U.S. 181 (1992).

If a law does impair contracts, the courts will assess whether the law is deemed reasonable and necessary to serve an important public purpose.<sup>31</sup> The court will also consider three factors when balancing the impairment of contracts with the important public purpose:

- Whether the law was enacted to deal with a broad economic or social problem;
- Whether the law operates in an area that was already subject to state regulation at the time the contract was entered into; and,
- Whether the effect on the contractual relationship is temporary; not severe, permanent, immediate, and retroactive. <sup>32</sup>

A law that is deemed to be an impairment of contract will be deemed to be invalid as it applies to any contracts entered into prior to the effective date of the act.

### B. RULE-MAKING AUTHORITY:

None.

### C. DRAFTING ISSUES OR OTHER COMMENTS:

There is a potential that non-winning vendors of the SMMC procurement might initiate litigation. Non-winning vendors who had not included comparable dental benefits might challenge the change in terms and argue a different approach would have been taken if they had known that dental would be carved out later. Similarly, some vendors that chose not to compete due to an inadequate dental network might challenge a re-negotiation.

On December 28, 2012, AHCA released an Invitation to Negotiate (ITN) to competitively procure managed care plans on a statewide basis. Dental services were included in the ITN as one of the enumerated services to be provided under the SMMC. On February 6, 2014, AHCA executed contracts with the managed care plans selected to provide care, including dental services, under the SMMC.

Legal challenges could result to due to the change in the term of the contracts. The contracts were negotiated, rates were set, and provider networks were established based on the requirement that dental services be included. The contacted rates and networks would not be valid under the bill; therefore, AHCA may have to reopen rate negotiations prior to implementing the SMMC program.

AHCA notes that creating a carve-out for any single service would set a bad precedent for the future of the new, reformed Medicaid program, and expects other service providers to seek carve-outs from the Legislature if HB 27 is enacted. <sup>33</sup> A unified, coordinated system of care is a primary characteristic of Medicaid reform, in part because it solves the problem of complexity with which Florida's Medicaid program has been plagued for decades. In 2010, the Florida House of Representatives contracted with a consultant to analyze Florida's Medicaid program and identify problems and possible solutions. One of the consultant's conclusions was that Florida Medicaid's fragmented, complex system makes it difficult to improve value for patients and taxpayers. <sup>34</sup>

# IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On February 11, 2014, the Health Innovation Subcommittee adopted an amendment to HB 27. The amendment:

Establishes that it is the Legislature's intent to provide a statewide Medicaid prepaid dental program
for children which is separate and apart from the Medicaid managed medical care program;

<sup>&</sup>lt;sup>31</sup> Park Benzinger & Co. v. Southern Wine & Spirits, Inc., 391 So. 2d 681 (Fla. 1980); Yellow Cab C., v. Dade County, 412 So. 2d 395 (Fla. 3rd DCA 1982). See also Exxon Corp. v. Eagerton, 462 U.S. 176 (1983).

<sup>&</sup>lt;sup>32</sup> Pomponio v. Cladridge of Pompanio Condo., Inc., 378 So. 2d 774 (Fla. 1980).

<sup>&</sup>lt;sup>33</sup> AHĈA, supra, note 16.

<sup>&</sup>lt;sup>34</sup> Medicaid Managed Care Study, Pacific Health Policy Group, p. 73, March 2010 STORAGE NAME: h0027b.HHSC.DOCX

- Requires AHCA to create a new statewide pediatric dental program by contracting with at least two
  appropriately licensed prepaid dental health plans;
- Authorizes AHCA to apply and implement any state plan amendments or waivers necessary to implement statewide pediatric dental plan;
- Authorizes AHCA to extend any existing contracts with licensed prepaid dental health plans;
- Delays enrollment in the statewide pediatric dental plan until all required state plan amendments and federal waivers have been obtained;
- Authorizes children who become eligible to receive Medicaid benefits prior to the implementation of the statewide pediatric dental health plan to receive dental services through Medicaid Managed Care:
- Requires AHCA to provide notice to recipients regarding the transition from managed care to the statewide pediatric prepaid dental plan;
- Requires prepaid dental health plans to submit encounter data to AHCA;
- Requires a medical loss ratio of 85 percent for prepaid dental plans participating in statewide prepaid dental program; and
- Requires AHCA to provide an annual report on the statewide pediatric dental program to the Governor, President of the Senate and Speaker of the House.
- Removes pediatric dental services from the services required under the SMMC program.

The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute.

**PAGE: 10** 

A bill to be entitled 1 2 An act relating to the statewide prepaid dental 3 program; creating s. 409.91205, F.S.; providing 4 legislative findings and intent; creating the Medicaid 5 statewide prepaid dental program; directing the Agency for Health Care Administration to contract with 6 7 prepaid dental health plans meeting specified 8 criteria; directing the agency to apply for and 9 implement state plan amendments or waivers of 10 applicable federal laws and regulations necessary to 11 implement the statewide prepaid dental program; directing the agency to extend certain contracts with 12 13 prepaid dental health plans; providing that enrollment 14 in the statewide prepaid dental program shall not begin until the necessary state plan amendments or 15 waivers of applicable federal laws and regulations are 16 17 obtained and implemented; providing that a child who 18 is eligible to receive Medicaid benefits during a 19 specified period shall receive dental services through 20 the Medicaid managed medical assistance program; 21 directing the agency to provide any required notice to 22 recipients regarding the transition from the Medicaid 23 managed medical assistance program to the statewide 24 prepaid dental program; providing that the agency may 25 assess the costs incurred in providing the notice to 26 plans participating in the statewide prepaid dental

Page 1 of 5

program; requiring prepaid dental plans participating in the statewide prepaid dental program to submit encounter data; providing that the agency shall require a medical loss ratio for prepaid dental plans participating in the statewide prepaid dental program; requiring the agency to submit an annual report to the Governor and Legislature; specifying the contents of the report; amending s. 409.973, F.S.; removing the requirement that managed care plans participating in the Medicaid managed assistance program provide pediatric dental services; providing an effective date.

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

Section 1. Section 409.91205, Florida Statutes, is created to read:

44 409.91205 Statewide prepaid dental program.-

(1) The Legislature finds and declares that the design and delivery of children's Medicaid dental services should be directed by the principle that the health of children is an overriding concern. The Legislature also finds that the delivery of dental services as compared to other health care services is considerably different and, considering the historical shortcomings of access to dental care in Florida, special attention must be given to children's accessibility to dental

Page 2 of 5

care and provider network sustainability. Therefore, it is the intent of the Legislature that a Medicaid prepaid dental program be established, on a statewide basis in all counties, separate and apart from the Medicaid managed medical assistance program described in ss. 409.961-409.985. Further, the Legislature finds that it is of paramount interest to the Medicaid program that continuous and high-quality dental care be provided to Medicaid recipients, and thus the agency shall ensure a seamless transition of the responsibility for the provision of dental services to children from the managed medical assistance program to the statewide prepaid dental program.

- (2) Notwithstanding ss. 409.961-409.985, the agency shall implement the statewide prepaid dental program by contracting on a prepaid or fixed-sum basis with at least two appropriately licensed prepaid dental health plans to provide dental services to children statewide that demonstrate extensive experience in administering dental benefits for children enrolled in Medicaid and that have experience in constructing and maintaining statewide dental and specialty dental provider networks for Medicaid programs.
- (a) The agency shall apply for and implement state plan amendments or waivers of applicable federal laws and regulations necessary to implement the statewide prepaid dental program.
- (b) In order to ensure that continuous and high-quality dental care is provided to Medicaid recipients upon receiving the necessary federal approval for the statewide prepaid dental

Page 3 of 5

program, the agency shall extend the existing contracts with licensed prepaid dental health plans as described in s.

409.912(41). The agency shall amend the existing contracts to include all counties.

- (c) Enrollment in the statewide prepaid dental program shall not begin until the necessary state plan amendments or waivers of applicable federal laws and regulations are obtained and implemented; however, enrollment shall begin no later than September 1, 2015.
- (d) A child who is eligible to receive Medicaid benefits between the date that this act takes effect and the implementation of the statewide prepaid dental plans shall receive dental services as provided in ss. 409.961-409.985 until the child is eligible to enroll in the statewide prepaid dental program.
- (e) Before enrollment in the statewide prepaid dental program, the agency shall provide any required notice to recipients regarding the transition. The agency may assess the costs incurred in providing the notice to the plans participating in the statewide prepaid dental program.
- (f) The prepaid dental plans participating in the statewide prepaid dental program shall be required by contract to submit encounter data as described in s. 409.967(2)(d).
- (g) The agency shall require a medical loss ratio of 85 percent for prepaid dental plans participating in the statewide prepaid dental program. The calculation shall use uniform

Page 4 of 5

105 financial data collected from all plans and shall be computed 106 for each plan on a statewide basis. The method for calculating 107 the medical loss ratio shall require that expenditures be 108 classified in a manner consistent with 45 C.F.R. part 158. 109 (3) The agency shall submit a report by January 15 of each 110 year on operation of the statewide prepaid dental program to the 111 Governor, the President of the Senate, and the Speaker of the 112 House of Representatives which compares the combined annual 113 benefits utilization and encounter data reported by all 114 participating prepaid dental plans, along with the agency's 115 findings with respect to projected and budgeted annual program 116 costs, the extent to which each plan is complying with all 117 contract terms and conditions, the effect that each plan's 118 operation is having on access to care for Medicaid recipients in 119 the plan's service area, and the statistical trends associated 120 with indicators of good oral health among all recipients served 121 in comparison with the state's population as a whole. 122 Section 2. Paragraph (e) of subsection (1) of section 123 409.973, Florida Statutes, is amended to read: 124 409.973 Benefits.-125 MINIMUM BENEFITS. - Managed care plans shall cover, at a 126 minimum, the following services: 127 Adult dental services as described in s. 409.906(1). 128 Section 3. This act shall take effect upon becoming a law.

Page 5 of 5



# COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. CS/HB 27 (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)				
l	WITHDRAWN (Y/N)				
	OTHER				
1	Committee/Subcommittee hearing bill: Health & Human Services				
2	Committee				
3	Representative Diaz, J. offered the following:				
4					
5	Amendment (with title amendment)				
6	Remove lines 76-82 and insert:				
7	(b) Upon receiving the necessary federal approval for the				
8	statewide prepaid dental program, the agency shall competitively				
9	procure at least two appropriately licensed prepaid dental				
10	health plans to provide dental services to children statewide.				
11	The agency shall not extend the existing contracts with licensed				
12	prepaid dental health plans as described in s. 409.912(41).				
13					
14					
15					
16					
17	TITLE AMENDMENT				

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# COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. CS/HB 27 (2014)

# Amendment No. 1

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Remove lines 12-13 and insert:
directing the agency to competitively procure contracts;
prohibiting the agency from extending certain contracts with
prepaid dental health plans; providing that enrollment

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# COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. CS/HB 27 (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
İ	
1	Committee/Subcommittee hearing bill: Health & Human Services
2	Committee
3	Representative Diaz, J. offered the following:
4	
5	Amendment
6	Remove line 86 and insert:
7	begin no later than and implemented; however, it is the intent
8	of the legislature that enrollment should

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# **HOUSE OF REPRESENTATIVES STAFF ANALYSIS**

BILL #:

CS/HB 211

Community Health Workers

SPONSOR(S): Health Quality Subcommittee: Reed

TIED BILLS:

IDEN./SIM. BILLS: SB 306

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	11 Y, 0 N, As CS	Dunn	O'Callaghan
2) Health & Human Services Committee		Dunn C	Calamas 060

### **SUMMARY ANALYSIS**

Community health workers (CHWs) assume a wide range of roles in various settings to assist individuals with health care services. CHWs generally perform patient advocacy, prevention and disease management education, and direct care in isolated, underserved, and low socioeconomic neighborhoods. CHWs work as paid or unpaid volunteers within the community in which they live or have strong ties.

The bill defines the activities CHWs perform and requires the Department of Health (DOH) to create a twelve member Community Health Worker Task Force (Task Force) within a Florida College System institution or state university. The Task Force is comprised of:

- A member of the Senate appointed by the President of the Senate;
- A member of the House of Representatives appointed by the Speaker of the House of Representatives;
- A state official appointed by the Governor; and
- Nine culturally and regionally diverse CHWs appointed by the Surgeon General, three of whom are recommended by the chair of the Florida Community Health Worker Coalition.

The DOH, at the request of the Task Force's chair, must provide administrative support and services to the Task Force within available department resources.

The bill requires the Task Force to develop recommendations for inclusion of CHWs in health care or Medicaid reform, inclusion of CHWs in assisting residents with navigation and with provision of information on preventative health care, and inclusion of CHWs into health care delivery teams. The Task Force will coordinate with The Florida Community Health Worker Coalition, colleges, universities, and other organizations to determine a procedure for standardization of qualifications and skills for CHWs employed by state-supported health care programs.

The bill requires the Task Force to submit a report by June 30, 2015, to the Governor, the President of the Senate, and the Speaker of the House of Representatives which states the findings, conclusions, and recommendations of the Task Force.

The bill has an insignificant negative fiscal impact on the DOH. The bill has no fiscal impact on local governments.

The bill provides a repeal date of December 1, 2015.

The bill shall take effect upon becoming law.

This document does not reflect the intent or official position of the bill sponsor or House of Representatives. STORAGE NAME: h0211b.HHSC.DOCX

#### **FULL ANALYSIS**

# I. SUBSTANTIVE ANALYSIS

### A. EFFECT OF PROPOSED CHANGES:

### **Current Situation**

Community Health Workers (CHWs) serve in local health care systems for pay or as volunteers to help alleviate health care disparities in communities. CHWs deliver health care services with cultural competency, in part through intimate knowledge of the neighborhoods they serve. A report prepared for the U.S. Department of Health and Human Services examined 53 studies between 1980 and 2008 and found evidence that CHWs improve health outcomes. A workgroup under the Centers for Disease Control and Prevention (CDC) reviewed literature on CHWs and reported that the profession is uniquely qualified to strengthen community ties, build partnerships, and foster community action in health care. Research supports that CHWs augment health care utilization, access, and education. <sup>2</sup>

CHWs are recognized under a variety of names, including lay health educators, peer health promoters, community health outreach workers, and in Spanish, *promotores de salud*.<sup>3</sup> In 2010, CHWs received a Standard Occupational Classification.<sup>4</sup> Fifteen states and the District of Columbia have enacted laws addressing CHW infrastructure, professional identity, workforce development, or financing.<sup>5</sup> Massachusetts, New Mexico, Oregon, Rhode Island, Texas, Utah, and Virginia have established CHW advisory boards.<sup>6</sup> Due to mounting visibility, organizations including the Institute of Medicine are calling for CHW integration into health care strategies.<sup>7</sup>

The Patient Protection and Affordable Care Act of 2010 created a grant award for eligible entities to promote positive health behaviors and outcomes for populations in medically underserved communities through the use of community health workers. The Act defines a community health worker as an individual who promotes health or nutrition within the community in which the individual resides by:

- Serving as a liaison between communities and healthcare agencies;
- Providing guidance and social assistance to community residents;
- Enhancing community residents' ability to effectively communicate with healthcare providers:
- Providing culturally and linguistically appropriate health or nutrition education;
- Advocating for individual and community health;
- Providing referral and follow-up services or otherwise coordinating care; and

<sup>&</sup>lt;sup>1</sup> RTI International-University of North Carolina Evidence-Based Practice Center, *Evidence Report/Technology*Assessment Number 181, Outcomes of Community Health Worker Interventions, June 2009, available at
<a href="http://www.ahrq.gov/downloads/pub/evidence/pdf/comhealthwork/comhwork.pdf">http://www.ahrq.gov/downloads/pub/evidence/pdf/comhealthwork/comhwork.pdf</a> (last visited Mar. 31, 2014).

<sup>2</sup> National Center for Chronic Disease Prevention and Health Promotion, Division of Diabetes Translation, Community Health Workers/Promotores de Salud: Critical Connections in Communities, May 20, 2011, available at
<a href="http://www.cdc.gov/diabetes/projects/comm.htm">http://www.cdc.gov/diabetes/projects/comm.htm</a> (last visited Mar. 31, 2014).

<sup>&</sup>lt;sup>4</sup> Bureau of Labor Statistics, *Standard Occupational Classification 21-1094 Community Health Workers*, March 11, 2010, available at

http://www.bls.gov/soc/2010/soc211094.htm (last visited Mar. 31, 2014).

<sup>&</sup>lt;sup>5</sup> Centers for Disease Control and Prevention, State Law Fact Sheet: A Summary of State Community Health Worker Laws at 2, (July 2013), available at <a href="http://www.cdc.gov/dhdsp/pubs/docs/CHW">http://www.cdc.gov/dhdsp/pubs/docs/CHW</a> State Laws.pdf (last visited Mar. 31, 2014).

<sup>&</sup>lt;sup>6</sup> Id at 3

<sup>&</sup>lt;sup>7</sup> Hector Balcazar et al., Community Health Workers Can be a Public Health Force for Change in The United States: Three Actions for a New Paradigm, 101 Am. J. Pub. HEALTH 2199, 2199 (2011), available at <a href="http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3222447/#R19">http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3222447/#R19</a> (last visited Mar. 31, 2014).

<sup>&</sup>lt;sup>8</sup> 42 U.S.C.A. § 280g-11(a).

<sup>&</sup>lt;sup>9</sup> 42 U.S.C.A. § 280g-11(k).

Proactively identifying and enrolling eligible individuals in Federal, State, local, private or nonprofit health and human services programs.

In 2007, one study reported that Florida has 2,640 paid and 1,556 volunteer CHWs for a total of 4,205 CHWs, the fourth highest number in the country. 10

In October 2010, the Department of Health (DOH) received the Policy, Environmental and System Change grant from the CDC to assist cancer coalitions. 11 The Florida Cancer Control and Research Advisory Council (CCRAB)<sup>12</sup> called for utilization of CHWs as a priority strategy to facilitate treatment and access to services for minorities. 13 The CDC funds and CCRAB permitted the DOH to develop the Florida Community Health Worker Taskforce initiative in 2010 that evolved into the Florida Community Health Worker Coalition. 14 The group promotes the profession of CHWs. The coalition is composed of five committees: Policy, Curriculum, Networking/Sustainability, Research, and Practice. 15

# **Effect of Proposed Changes**

The bill states that a community health worker (CHW) is a front line health care worker who is a trusted member of a community or has an unusually close understanding of the community. The bill states that a CHW works in a medically underserved community, which is defined as a geographic area with a shortage of health care professionals that has a population with income at or below 185 percent of the federal poverty level and contains persons who lack public or private health insurance or are unable to pay for health care.

The bill delineates activities CHWs perform in communities to assist local residents, including clinical services, education, outreach, advocacy, and data collection. The bill stats that CHWs provide residents information on local resources, give social support, educate and deliver information on wellness and disease prevention, and help administer first aid and blood pressure screenings. CHWs advocate for oral health, mental health, and nutritional needs. CHWs facilitate communication with health care providers by fostering communication skills in residents and ensuring appropriate coordination of care.

The bill directs the Department of Health (DOH) to establish the Community Health Worker Task Force (Task Force) within a Florida College System institution or state university. The Task Force is comprised of:

- A member of the Senate appointed by the President of the Senate;
- A member of the House of Representatives appointed by the Speaker of the House of Representatives:
- A state official appointed by the Governor; and
- Nine culturally and regionally diverse CHWs appointed by the Surgeon General, three of whom are recommended by the chair of the Florida Community Health Worker Coalition.

STORAGE NAME: h0211b.HHSC.DOCX

<sup>&</sup>lt;sup>10</sup> U.S. Department of Health and Human Services, Health Resources Services Administration, Bureau of Health Professionals, Community Health Worker National Workforce Study, March 2007, available at http://bhpr.hrsa.gov/healthworkforce/reports/chwstudy2007.pdf (last visited Mar. 31, 2014) (noting that paid and volunteer CHW totals do not sum to total because of rounding and adjustments made for the estimates of volunteer CHWs).

<sup>&</sup>lt;sup>11</sup> Department of Health Bill Analysis of HB 241, January 22, 2013, on file with committee staff.

<sup>&</sup>lt;sup>12</sup> Section 1004.435, F.S.

<sup>&</sup>lt;sup>13</sup> Florida Cancer Control and Research Advisory Council, Florida Cancer Plan Council: 2012-2013, available at http://ccrab.org/Libraries/Document Library/2012-2013 Florida Cancer Plan Priority Strategies.sflb.ashx (last visited

<sup>&</sup>lt;sup>14</sup> University of Florida, College of Pharmacy, Coalition: Development of the Coalition, available at http://floridachwn.pharmacy.ufl.edu/coalition-2/ (last visited Mar. 31, 2014). <sup>15</sup> Id.

The Task Force members must elect a chair and vice chair, serve without compensation, and meet at least quarterly. Meetings may be held in person, by teleconference, or by other electronic means. The DOH, at the request of the Task Force's chair, must provide administrative support and services to the Task Force within available department resources. The bill states that a quorum shall consist of seven members, and in order to take final action, the concurring vote of a majority of the members present is required.

The bill requires the Task Force to develop recommendations for inclusion of CHWs in health care or Medicaid reform, inclusion of CHWs in assisting residents with navigation and with provision of information on preventative health care, and inclusion of CHWs into health care delivery teams. The Task Force will coordinate with The Florida Community Health Worker Coalition, colleges, universities, and other organizations to determine a procedure for standardization of qualifications and skills for CHWs employed by state-supported health care programs.

The bill requires the Task Force to submit a report by June 30, 2015, to the Governor, the President of the Senate, and the Speaker of the House of Representatives which states the findings, conclusions, and recommendations of the Task Force.

The bill provides a repeal date of December 1, 2015, for the section created by the bill.

### B. SECTION DIRECTORY:

Section 1. Creates an unnumbered section of law entitled "Community Health Worker Task Force".

Section 2. Provides the act shall take effect upon becoming a law.

# **II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT**

### A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

The bill has an insignificant negative fiscal impact on the DOH associated with establishing the Task Force and providing administrative support and services to the Task Force.

# **B. FISCAL IMPACT ON LOCAL GOVERNMENTS:**

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

STORAGE NAME: h0211b.HHSC.DOCX

### III. COMMENTS

### A. CONSTITUTIONAL ISSUES:

- Applicability of Municipality/County Mandates Provision:
   Not applicable. This bill does not appear to affect county or municipal governments.
- 2. Other:

None.

**B. RULE-MAKING AUTHORITY:** 

The DOH has appropriate rule-making authority to implement this provision.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

### IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 24, 2014, the Health Quality Subcommittee adopted an amendment to HB 211 and reported the bill favorably as a committee substitute. The amendment provides the Surgeon General with appointment authority over three persons recommended by the chair of the Florida Community Health Worker Coalition to be appointed to the Community Health Worker Task Force. This analysis is drafted to the committee substitute.

STORAGE NAME: h0211b.HHSC.DOCX DATE: 4/1/2014

PAGE: 5

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A bill to be entitled An act relating to community health workers; providing definitions; specifying the duties and activities of community health workers; creating the Community Health Worker Task Force within a Florida College System institution or state university; requiring the Department of Health to provide administrative support and services; providing membership and duties of the task force; requiring the members of the task force to elect a chair and vice chair; providing that task force members serve without compensation and are not entitled to reimbursement for per diem or travel expenses; requiring that the task force meet at least quarterly; authorizing the task force members to meet in person or by teleconference or other electronic means; specifying the number of members required for a quorum; requiring the task force to submit a report to the Governor and the Legislature by a specified date; providing for future repeal of the task force; providing an effective date.

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WHEREAS, Florida continues to experience critical shortages of providers in primary health care, oral health care, and behavioral health care, particularly in rural and inner-city areas, and

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WHEREAS, there is substantial evidence that comprehensive

Page 1 of 6

coordination of care for individuals who have chronic diseases and the provision of information regarding preventive care can improve individual health, create a healthier population, reduce the costs of health care, and increase appropriate access to health care, and

WHEREAS, community health workers have demonstrated success in increasing access to health care in underserved communities, providing culturally appropriate education regarding disease prevention and management, providing translating and interpreting services for non-English speakers, improving health outcomes through the coordination of care, increasing individual health care literacy and advocacy, and organizing to improve the health care of medically underserved communities while reducing costs in the state's health care system, and

WHEREAS, the Legislature recognizes that community health workers are important members of the health care delivery system in this state, and the Florida Community Health Worker Coalition has begun to explore options that would allow community health workers to earn a living wage and be part of an integrated health delivery team, NOW, THEREFORE,

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

- Section 1. Community Health Worker Task Force.-
- 51 (1) As used in this section, the term:
  - (a) "Community health worker" means a front-line health

Page 2 of 6

care worker who is a trusted member or has an unusually close understanding of the community that he or she serves and who:

- 1. Serves as a liaison, link, or intermediary between the health care services or social services and the community in order to facilitate access to health care services and improve the quality of health care services and the cultural competency of health care providers.
- 2. Performs the following activities in a community
  setting:
  - a. Provides information regarding available resources.
  - b. Provides social support.

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- c. Advocates for individuals and their health care needs.
- d. Provides services, such as first aid and blood pressure screening.
- 3. Builds individual and community capacity to prevent disease and promote health by increasing knowledge regarding wellness, disease prevention, and self-sufficiency among the members of the community through a range of activities, such as community outreach, education, and advocacy.
- 4. Collects data to help identify the health care needs in a medically underserved community by:
- a. Enhancing the communication skills of members of the community in order to assist them in effectively communicating with health care providers.
- 77 <u>b. Providing culturally and linguistically appropriate</u> 78 health or nutrition education.

Page 3 of 6

c. Advocating for better individual and community health, including oral health, mental health, and nutritional needs.

d. Providing referral services, followup services, and coordination of care.

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- (b) "Department" means the Department of Health.
- (c) "Medically underserved community" means a community in a geographic area that has a shortage of health care professionals and has a population that includes persons who do not have public or private health insurance, are unable to pay for health care, and have incomes at or below 185 percent of the federal poverty level.
- (d) "Task force" means the Community Health Worker Task Force established by the department under this section.
- (2)(a) The department shall establish the Community Health Worker Task Force within a Florida College System institution or state university. The department shall provide administrative support and services to the task force to the extent requested by the chair of the task force and within available resources of the department.
- (b) The task force shall consist of the following 12 members:
- 100 <u>1. One member of the Senate appointed by the President of</u>
  101 the Senate.
- 2. One member of the House of Representatives appointed by
  the Speaker of the House of Representatives.
- 3. One state official appointed by the Governor.

Page 4 of 6

2014 CS/HB 211

4. Nine culturally and regionally diverse community health 105 106 workers appointed by the State Surgeon General, three of whom 107 are recommended by the chair of the Florida Community Health 108 Worker Coalition. 109 (c) The task force shall develop recommendations for: 110 1. Including community health workers in the development of proposals for health care or Medicaid reform in this state as part of the outreach efforts for enrolling residents of this 113 state in Medicaid managed care programs or other health care 114 delivery services. 2. Including community health workers in providing assistance to residents in navigating the health care system and providing information and guidance regarding preventive health care. 3. Providing support to community health centers and other "safety net" providers through the integration of community health workers as part of health care delivery teams. The task force shall also collaborate with the Florida Community Health Worker Coalition, colleges and universities in 123 the state, and other organizations and institutions to recommend a process that leads to the standardization of qualifications and skills of community health workers who are employed in state-supported health care programs.

Page 5 of 6

(f) Members of the task force shall serve without

(e) The members of the task force shall elect a chair and

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

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vice chair.

131	compensation and are not entitled to reimbursement for per drem
132	and travel expenses.
133	(g) The task force shall meet at least quarterly and may
134	meet at other times upon the call of the chair or as determined
135	by a majority of members. Meetings of the task force may be held
136	in person or by teleconference or other electronic means.
137	(h) A quorum shall consist of seven members, and the
138	concurring vote of a majority of the members present is required
139	for final action.
140	(i) The task force shall submit a report by June 30, 2015,
141	to the Governor, the President of the Senate, and the Speaker of
142	the House of Representatives which states the findings,
143	conclusions, and recommendations of the task force.
144	(3) This section is repealed December 1, 2015.
145	Section 2 This act shall take effect upon becoming a law

Page 6 of 6

### HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #:

HB 7145

**PCB RORS 14-06** 

Ratification of Rules/Department of Health

SPONSOR(S): Rulemaking Oversight & Repeal Subcommittee, Gaetz

TIED BILLS:

IDEN./SIM. BILLS:

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
Orig. Comm.: Rulemaking Oversight & Repeal Subcommittee	12 Y, 0 N	Miller	Rubottom
1) Health & Human Services Committee		Poche M	Calamas (C

### **SUMMARY ANALYSIS**

The Department of Health (DOH) amended Rule 64J-2.006, F.A.C., implementing statutory authority to adopt standards for verification of hospitals designated by DOH as trauma centers. The rule amendment requires Level I and Level II verified trauma centers to maintain participation in the American College of Surgeons Trauma Quality Improvement Program.

The Statement of Estimated Regulatory Costs (SERC) showed Rule 64J-2.006, F.A.C., would have a specific, adverse economic effect, or would increase regulatory costs, exceeding \$1 million over the first 5 years the rule was in effect. Accordingly, the rule must be ratified by the Legislature before it may go into effect.

The rule was adopted on July 12, 2013, and initially submitted for ratification on February 20, 2014.

HB 7145 authorizes the rule to go into effect. The scope of the bill is limited to this rulemaking condition and does not adopt the substance of any rule into the statutes.

The bill is effective upon becoming law.

### **FULL ANALYSIS**

### I. SUBSTANTIVE ANALYSIS

### A. EFFECT OF PROPOSED CHANGES:

### **Present Situation**

### Rulemaking Authority and Legislative Ratification

A rule is an agency statement of general applicability interpreting, implementing, or prescribing law or policy, including the procedure and practice requirements of an agency as well as certain types of forms.<sup>1</sup> Rulemaking authority is delegated by the Legislature<sup>2</sup> through statute and authorizes an agency to "adopt, develop, establish, or otherwise create" a rule. Agencies do not have discretion whether to engage in rulemaking.<sup>4</sup> To adopt a rule an agency must have a general grant of authority to implement a specific law by rulemaking.<sup>5</sup> The grant of rulemaking authority itself need not be detailed.<sup>6</sup> The specific statute being interpreted or implemented through rulemaking must provide specific standards and guidelines to preclude the administrative agency from exercising unbridled discretion in creating policy or applying the law.<sup>7</sup>

An agency begins the formal rulemaking process by giving notice of the proposed rule. The notice is published by the Department of State in the Florida Administrative Register and must provide certain information, including the text of the proposed rule, a summary of the agency's statement of estimated regulatory costs (SERC) if one is prepared, and how a party may request a public hearing on the proposed rule. The SERC must include an economic analysis projecting a proposed rule's adverse effect on specified aspects of the state's economy or increase in regulatory costs. 10

The economic analysis mandated for each SERC must analyze a rule's potential impact over the 5 year period from when the rule goes into effect. First is the rule's likely adverse impact on economic growth, private-sector job creation or employment, or private-sector investment.<sup>11</sup> Next is the likely adverse impact on business competitiveness, <sup>12</sup> productivity, or innovation.<sup>13</sup> Finally, the analysis must discuss whether the rule is likely to increase regulatory costs, including any transactional costs.<sup>14</sup> If the analysis shows the projected impact of the proposed rule in any one of these areas will exceed \$1 million in the aggregate for the 5 year period, the rule cannot go into effect until ratified by the Legislature pursuant to s. 120.541(3), F.S.

Present law distinguishes between a rule being "adopted" and becoming enforceable or "effective." A rule must be filed for adoption before it may go into effect and cannot be filed for adoption until

STORAGE NAME: h7145.HHSC.DOCX

<sup>&</sup>lt;sup>1</sup> Section 120.52(16); Florida Department of Financial Services v. Capital Collateral Regional Counsel-Middle Region, 969 So. 2d 527, 530 (Fla. 1<sup>st</sup> DCA 2007).

<sup>&</sup>lt;sup>2</sup> Southwest Florida Water Management District v. Save the Manatee Club, Inc., 773 So. 2d 594 (Fla. 1st DCA 2000).

<sup>&</sup>lt;sup>3</sup> Section 120.52(17), F.S.

<sup>&</sup>lt;sup>4</sup> Section 120.54(1)(a), F.S.

<sup>&</sup>lt;sup>5</sup> Section 120.52(8), F.S., and s. 120.536(1), F.S.

<sup>&</sup>lt;sup>6</sup> Save the Manatee Club, Inc., supra at 599.

<sup>&</sup>lt;sup>7</sup> Sloban v. Florida Board of Pharmacy,982 So. 2d 26, 29-30 (Fla. 1<sup>st</sup> DCA 2008); Board of Trustees of the Internal Improvement Trust Fund v. Day Cruise Association, Inc., 794 So. 2d 696, 704 (Fla. 1<sup>st</sup> DCA 2001).

<sup>&</sup>lt;sup>8</sup> Section 120.54(3)(a)1, F.S..

<sup>&</sup>lt;sup>9</sup> Sections 120.54(3)(a)2., 120.55(1)(b)2, F.S.

<sup>&</sup>lt;sup>10</sup> Section 120.541(2)(a), F.S.

<sup>&</sup>lt;sup>11</sup> Section 120.541(2)(a)1., F.S.

<sup>12</sup> Including the ability of those doing business in Florida to compete with those doing business in other states or domestic markets.
13 Section 120.541(2)(a) 2., F.S.

<sup>&</sup>lt;sup>14</sup> Section 120.541(2)(a) 3., F.S.

<sup>&</sup>lt;sup>15</sup> Section 120.54(3)(e)6. Before a rule becomes enforceable, thus "effective," the agency first must complete the rulemaking process and file the rule for adoption with the Department of State.

completion of the rulemaking process.<sup>17</sup> A rule projected to have a specific economic impact exceeding \$1 million in the aggregate over 5 years<sup>18</sup> must be ratified by the Legislature before going into effect.<sup>19</sup> As a rule submitted under s. 120.541(3), F.S., becomes effective if ratified by the Legislature, a rule must be filed for adoption before being submitted for legislative ratification.

# Impact of Rule 64J-2.006, F.A.C.

DOH is required to plan and establish a statewide inclusive trauma system.<sup>20</sup> As part of its responsibilities DOH must establish by rule the procedures for the creation and approval of trauma agencies<sup>21</sup> and the minimum requirements for a trauma agency to conduct annual performance evaluations and submit the results to DOH.<sup>22</sup> Hospitals are selected as trauma centers by DOH.<sup>23</sup>

Only verified or designated hospitals may be identified as trauma centers.<sup>24</sup> DOH is required to adopt standards for trauma center verification based on national guidelines, including standards established by the American College of Surgeons (ACS) in its publication "Hospital and Prehospital Resources for Optimal Care of the Injured Patient"<sup>25</sup> and any appendices.<sup>26</sup> There are currently 24 verified trauma centers in Florida.<sup>27</sup>

Trauma centers must submit trauma registry data required by rule for DOH to monitor patient outcomes and ensure compliance with the standards of approval.<sup>28</sup> DOH by rule also may prescribe the submission of trauma care and registry data to evaluate trauma system effectiveness.<sup>29</sup>

Previously, Rule 64J-2.006, F.A.C., directed the completion and submission of required data through the incorporation by reference of the Florida Trauma Registry Manual (February 2008). The amended rule, for which DOH seeks ratification, additionally requires all Level I and Level II trauma centers in Florida to maintain participation in the ACS Trauma Quality Improvement Program (TQIP). Participation is limited to designated or verified trauma centers. Participants pay an annual fee of \$9,000, submit treatment and certain patient data into the National Trauma Data Bank, undergo periodic reviews of

<sup>&</sup>lt;sup>16</sup> Section 120.54(3)(e)6., F.S.

<sup>&</sup>lt;sup>17</sup> Section 120.54(3)(e), F.S.

<sup>&</sup>lt;sup>18</sup> Section 120.541(2)(a), F.S.

<sup>&</sup>lt;sup>19</sup> Section 120.541(3), F.S.

<sup>&</sup>lt;sup>20</sup> Section 395.40(3), F.S.

<sup>&</sup>lt;sup>21</sup> Section 395.401(1)(a), F.S.

<sup>&</sup>lt;sup>22</sup> Section 395.401(1)(c), F.S.

<sup>&</sup>lt;sup>23</sup> Section 395.4025(1), F.S.

<sup>&</sup>lt;sup>24</sup> Section 395.401(1)(k), F.S. DOH may designate as Level II trauma centers hospitals in areas with limited access to trauma center services, provided the designated hospital has a certificate of trauma center verification from the American College of Surgeons. Section 395.4025(14), F.S.

<sup>&</sup>lt;sup>25</sup> "In June of 1986, the Board of Regents of the American College of Surgeons approved this report and authorized its publication as an official College document. ... It is generally recognized that this document is a set of guidelines representing current thinking for optimal care of the injured. Further revisions may be indicated as systems are developed to meet the complex demands of severely injured patients." From "Abstract," *Bulletin of the American College of Surgeons*, 71(10):4-23 (Oct. 1986), available at <a href="http://www.ncbi.nlm.nih.gov/pubmed/10278815">http://www.ncbi.nlm.nih.gov/pubmed/10278815</a> (last viewed on March 30, 2014). "*Resources for Optimal Care of the Injured Patient* outlines the resources necessary for optimal care and is used as a guide for the development of trauma centers throughout the United States. It is the document by which trauma centers are reviewed by the ACS-approved site surveyors." ACS, "Consultation Verification Program," at <a href="http://www.facs.org/trauma/vcprogram.html">http://www.facs.org/trauma/vcprogram.html</a> (last viewed on March 30, 2014). The ACS program "verifies the presence of the resources listed in *Resources for Optimal Care of the Injured Patient...*" in a particular hospital. ACS, "Verified Trauma Centers," available at <a href="http://www.facs.org/trauma/verified.html">http://www.facs.org/trauma/verified.html</a> (last viewed on March 30, 2014).

<sup>&</sup>lt;sup>27</sup> DOH, Bureau of Emergency Medical Oversight – Trauma Program, "Statement of Estimated Regulatory Costs (SERC)," page 3 (on file with Health and Human Services Committee staff).

<sup>&</sup>lt;sup>28</sup> Section 395.404(1)(a), F.S. This trauma registry data is confidential and exempted from s. 119.07(1), F.S., and s. 24(a), Art. I, of the State Constitution. Section 395.404(1)(b), F.S.

<sup>&</sup>lt;sup>29</sup> Section 395.4025(9), F.S.

their collection and submission processes, agree for certain personnel to participate in monthly conference calls, and commit to attend an annual TQIP national meeting.<sup>30</sup>

DOH prepared a SERC showing the rule increases regulatory costs by \$1,240,800 over the first five years of implementation.<sup>31</sup> The SERC was prepared prior to March 18, 2013, using an annual fee amount of \$8,100.<sup>32</sup> Applying the annual fee amount of \$9,000 currently listed for participation in the ACS/TQIP<sup>33</sup> to the methodology used in the SERC yields a present projected increase of regulatory costs of \$1,348,800<sup>34</sup> over the first five years of implementation.

# **Effect of Proposed Change**

The bill ratifies Rule 64J-2.006, F.A.C., allowing the rule to go into effect.

### **B. SECTION DIRECTORY:**

Section 1: Ratifies Rule 64J-2.006, F.A.C., solely to meet the condition for effectiveness imposed by s. 120.541(3), F.S. Expressly limits ratification to the effectiveness of the rules. Directs the act shall not be codified in the Florida Statutes but only noted in the historical comments to each rule by the Department of State.

Section 2: Provides the act goes into effect upon becoming law.

#### II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

# A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

The bill creates no additional source of state revenues.

2. Expenditures:

The bill requires no state expenditures.

### **B. FISCAL IMPACT ON LOCAL GOVERNMENTS:**

1. Revenues:

The bill itself has no impact on local government revenues.

STORAGE NAME: h7145.HHSC.DOCX

<sup>&</sup>lt;sup>30</sup> ACS, "Getting Started with TQIP," available at <a href="http://www.facs.org/trauma/ntdb/tqip-gs.html">http://www.facs.org/trauma/ntdb/tqip-gs.html</a> (last viewed on March 30, 2014).

<sup>31</sup>{(\$8,100 annual fee) x (24 verified trauma centers) = \$194,400 total annual fees) + (\$53,760 total annual cost for all trauma centers to attend annual TQIP national conference) = \$248,160 increased annual regulatory costs.} \$248,160 total annual costs x 5 years = \$1,240,800. DOH, "SERC," supra at 3.

<sup>&</sup>lt;sup>32</sup> The SERC is not dated but the checklist "Proposed Rule: Is a SERC Required?" is signed by the State Surgeon General/DOH Secretary and dated March 13, 2013. The Notice of Proposed Rule published on March 18, 2013, relied upon the SERC to state ratification likely would be required.

<sup>33</sup> See supra, FN 30.

 $<sup>^{34}</sup>$  {(\$9,000 annual fee) x (24 verified trauma centers) = \$216,000 total annual fees} + (\$53,760 total annual cost for all trauma centers to attend annual TQIP national conference) = \$269,760 increased annual regulatory costs. (\$269,760 total annual costs) x (5 years) = \$1,348,800.

# 2. Expenditures:

The bill does not impose additional expenditures on local governments.

### C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill itself does not directly impact the private sector.

### D. FISCAL COMMENTS:

The economic impacts projected in the statement of estimated regulatory costs would result from the annual costs for each verified trauma center in Florida to maintain participation in the ACS/TQIP.

#### III. COMMENTS

# A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

The legislation does not appear to require counties or municipalities to take any action requiring the expenditure of funds, reduce the authority that counties or municipalities have to raise revenue in the aggregate, nor reduce the percentage of state tax shared with counties or municipalities.

2. Other:

No other constitutional issues are presented by the bill.

# **B. RULE-MAKING AUTHORITY:**

The bill meets the final statutory requirement for the agency to exercise its rulemaking authority concerning the verification of trauma centers based on national guidelines. No additional rulemaking authority is required.

# C. DRAFTING ISSUES OR OTHER COMMENTS:

None

# IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

STORAGE NAME: h7145.HHSC.DOCX DATE: 4/1/2014

HB 7145 2014

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A bill to be entitled An act relating to ratification of rules of the Department of Health; ratifying specified rules requiring certain trauma centers to maintain participation in a specified trauma quality improvement program, for the sole and exclusive purpose of satisfying any condition on effectiveness pursuant to s. 120.541(3), F.S., which requires ratification of any rule meeting any of specified thresholds for likely adverse impact or increase in regulatory costs; providing an effective date. Be It Enacted by the Legislature of the State of Florida: (1) The following rule is ratified for the sole and exclusive purpose of satisfying any condition on effectiveness imposed under s. 120.541(3), Florida Statutes: Rule 64J-2.006, Florida Administrative Code, titled "Trauma Registry and Trauma Quality Improvement Program," as filed for adoption with the Department of State pursuant to the certification package dated July 12, 2013. This act serves no other purpose and shall not be codified in the Florida Statutes. After this act becomes law, its enactment and effective dates shall be noted in the Florida Administrative Code or the Florida Administrative Register or

Page 1 of 2

both, as appropriate. This act does not alter rulemaking

HB 7145

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authority delegated by prior law, does not constitute
legislative preemption of or exception to any provision of law
governing adoption or enforcement of the rules cited, and is
intended to preserve the status of any cited rule as a rule
under chapter 120, Florida Statutes. This act does not cure any
rulemaking defect or preempt any challenge based on a lack of
authority or a violation of the legal requirements governing the
adoption of any rule cited.

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

Page 2 of 2

# HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #:

CS/CS/HB 159 Establishment of Mental Health First Aid Training Program

SPONSOR(S): Health Care Appropriations Subcommittee; Healthy Families Subcommittee; Berman

**TIED BILLS:** 

IDEN./SIM. BILLS:

CS/SB 574

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Healthy Families Subcommittee	10 Y, 0 N, As CS	Entress	Brazzell
2) Health Care Appropriations Subcommittee	12 Y, 0 N, As CS	Fontaine	Pridgeon
3) Health & Human Services Committee		Entress (4)	Calamas 🕊

### **SUMMARY ANALYSIS**

The CS/CS for HB 159 requires the Department of Children and Families to establish a mental health first aid training program (program). The program is intended to train individuals to identify and understand the signs of mental illnesses and substance use disorders and help someone who is developing or experiencing a mental health or substance use problem.

The bill directs that training be provided through contract providers and that first priority for the training be given to the staff of schools.

An appropriation of \$300,000 from nonrecurring funds is provided to implement provisions of the bill.

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

This document does not reflect the intent or official position of the bill sponsor or House of Representatives. STORAGE NAME: h0159e.HHSC.DOCX

### **FULL ANALYSIS**

### I. SUBSTANTIVE ANALYSIS

# A. EFFECT OF PROPOSED CHANGES:

#### **Present Situation**

In 2011, 41.4 million adults in the United States experienced mental illness.1

### Mental Health First Aid, USA

Mental Health First Aid, USA (MHFA) is a public education program that helps the public identify, understand, and respond to signs of mental illnesses and substance use disorders.<sup>2</sup> Mental Health First Aid was developed in Australia in 2001, by Professor Anthony Jorm, a mental health literacy professor, and Betty Kitchener, a nurse specializing in health education. The MHFA program is currently being used around the world including the United States.<sup>3</sup> MHFA is managed, operated, and disseminated by the National Council for Community Behavioral Healthcare, the Maryland Department of Health and Mental Hygiene, and the Missouri Department of Mental Health.<sup>4</sup>

# Training

MHFA is an interactive 8-hour course that presents an overview of mental illness and substance use disorders in the U.S. and introduces participants to risk factors and warning signs of mental health problems, builds understanding of their impact, and overviews common treatments.<sup>5</sup> Those who take the 8-hour course to certify as Mental Health First Aiders learn a 5-step action plan encompassing the skills, resources and knowledge to help an individual in crisis connect with appropriate professional, peer, social, and self-help care.<sup>6</sup>

The MHFA can be conducted as one two-day seminar, two one day events spaced over a short period of time or as four 2-hour sessions. MHFA certification must be renewed every three years.<sup>7</sup>

Specifically, participants learn:

- The potential risk factors and warning signs for a range of mental health problems, including: depression, anxiety/trauma, psychosis, eating disorders, substance use disorders, and selfinjury.
- An understanding of the prevalence of various mental health disorders in the U.S. and the need for reduced stigma in their communities.
- A 5-step action plan encompassing the skills, resources and knowledge to assess the situation, to select and implement appropriate interventions, and to help the individual in crisis connect with appropriate professional care.

http://www.mentalhealthfirstaid.org/cs/what\_you\_learn (Last viewed 2/4/14).
STORAGE NAME: h0159e.HHSC.DOCX

<sup>&</sup>lt;sup>1</sup> "The NSDUH Report," SAMHSA, accessible at: http://www.samhsa.gov/data/spotlight/spot111-adults-mental-illness-substance-use-disorder.pdf (Last viewed 2/4/14).

<sup>&</sup>lt;sup>2</sup> "Other States' Mental Health First Aid Initiatives," Florida Council for Community Mental Health, accessible at: http://www.fccmh.org/resources/docs/OtherStatesMHFAInitiatives2-15-13.pdf (Last viewed 2/4/14).

<sup>&</sup>lt;sup>3</sup> "About the Program: Frequently Asked Questions," Mental Health First Aid USA, accessible at: http://www.mentalhealthfirstaid.org/cs/faqs (Last viewed 2/4/14)...

<sup>&</sup>lt;sup>4</sup> "Other States' Mental Health First Aid Initiatives," Florida Council for Community Mental Health, February 15, 2013, accessible at: http://www.fccmh.org/resources/docs/OtherStatesMHFAInitiatives2-15-13.pdf.

<sup>&</sup>lt;sup>5</sup> "About the Program: What You Learn" Mental Health First Aid USA, *accessible at*: http://www.mentalhealthfirstaid.org/cs/what\_you\_learn (Last viewed 2/4/14).

<sup>&</sup>lt;sup>6</sup> "About the Program: Overview," Mental Health First Aid USA, accessible at: http://www.mentalhealthfirstaid.org/cs/program\_overview/(Last viewed 2/4/14).

<sup>&</sup>lt;sup>7</sup> "About the Program: What You Learn" Mental Health First Aid USA, accessible at:

 The evidence-based professional, peer, social, and self-help resources available to help someone with a mental health problem.

The 8-hour MHFA course has been used by a variety of audiences and key professions, including: primary care professionals, employers and business leaders, faith communities, school personnel and educators, state police and corrections officers, nursing home staff, mental health authorities, state policymakers, volunteers, young people, families and the general public.<sup>9</sup>

The MHFA instructor training is held throughout the country. There are no open instructor training opportunities in Florida for 2014. There are currently 17 remaining instructor training opportunities for 2014 elsewhere in the country.<sup>10</sup>

# State Use of Mental Health First Aid, USA

Arizona, Colorado, Georgia, Maryland, and Missouri have statewide programs requiring some people to complete this training as part of their job. For example, in Rhode Island, the course is part of police officer training and in Austin, Texas, the course is offered to every public library employee. Health First Aid Colorado is implemented through a statewide private-public partnership of local mental health centers, the Colorado Department of Public Safety, the Colorado Sheriff's Association, the Colorado Division of Behavioral Health, Mental Health America of Colorado, and the Western Interstate Commission for Higher Education. Mental Health First Aid was introduced in Colorado in 2008 and the program has grown to include 136 Instructors reaching a variety of audiences statewide.

### **Outcomes**

There do not appear to be any studies regarding the impact of the Mental Health First Aid training program on mental health outcomes. Instead, studies focus on whether the Mental Health First Aid training program made participants feel that they are able to aid and assist individuals experiencing mental health issues.

Participants of Mental Health First Aid training have reported favorable results. An evaluation of the Mental Health First Aid England reported that the proportion of participants rating their knowledge in supporting people with mental health problems as 'Good' or 'Excellent' increase from 32% to 90% with the use of the Mental Health First Aid Program. The program also reported that use of the program caused individuals rating their confidence in supporting people with mental health problems as 'Good' or 'Excellent' to increase from 27% to 89%. An evaluation of the Mental Health Fist Aid Training in Wales produced similar results: 58% of participants reported that they felt better prepared to help someone in mental distress after attending the training.

STORAGE NAME: h0159e.HHSC.DOCX

PAGE: 3

<sup>&</sup>lt;sup>8</sup> *Id.* 

<sup>9</sup> About the Program: Overview," Mental Health First Aid USA, accessible at: http://www.mentalhealthfirstaid.org/cs/program\_overview/(Last viewed 2/4/14).
10 "Find Instructor Training Programs in Your Community", Mental Health First Aid USA, accessible at:

http://www.mentalhealthfirstaid.org/current\_instructor\_courses.php?CourseType=&city=&State=Florida&postcode=&search= (Last viewed 2/4/14).

11 "Other States' Mental Health First Aid Initiatives," Florida Council for Community Mental Health, February 15, 2013, accessible at:

<sup>&</sup>quot;"Other States' Mental Health First Aid Initiatives," Florida Council for Community Mental Health, February 15, 2013, accessible at http://www.fccmh.org/resources/docs/OtherStatesMHFAInitiatives2-15-13.pdf (Last viewed 2/4/14).

12 Id

<sup>13 &</sup>quot;Mental Health First Aid England and North East Mental Health Development Unit Partnership Project," Mental Health First Aid England, accessible at: http://www.nemhdu.org.uk/silo/files/mhfa-england-evaluation-report-march-2011.pdf (Last viewed 2/4/14).

14 "Evaluations of the Mental Health First Aid Training Course," Welsh Assembly Government, accessible at: http://www.google.com/url?sa=t&rct=j&q=&esrc=s&frm=1&source=web&cd=1&cad=rja&ved=0CCUQFjAA&url=http%3A%2F%2Fwww.mentalhealthfirstaid.ca%2FEN%2Fabout%2FDocuments%2FEvaluation%2520of%2520the%2520Mental%2520Health%2520First%2520Aid%2520Training%2520Course%2520-%2520Wales.pdf&ei=yM\_vUtjmE9G0kQfu9lHoBA&usg=AFQjCNE53-enYbO4TyrF-Wpzwm2aneFwGQ&sig2=CkgzjTTzlAFxe4l59-LlcA (Last viewed 2/4/14).

# Additional Mental Health Training Programs in Florida

As of March 2013, the Miami-Dade school district began training each of its middle school and high school teachers to identify early warning signs of mental illness through a program called "Typical or Troubled?" The program was created by the American Psychiatric Foundation and is provided at no cost to the district.<sup>15</sup>

The National Alliance on Mental Illness (NAMI) is a mental health organization dedicated to improving the lives of the millions of Americans affected by mental illness. NAMI/Florida is an affiliate of this organization. NAMI/Florida works to provide education, advocacy and support group programs for people in communities living with mental illness and their loved ones. An example of programs offered is the NAMI Basics, a free six-week education course for parents and other family caregivers of children and adolescents living with mental illness. NAMI/Florida also provides Parents & Teachers as Allies which is a two-hour in-service mental health education program for school professionals. This program focuses on helping school professionals and families within the school community better understand the early warning signs of mental illness in children and adolescents and how best to intervene so youth with mental health treatment needs are linked with services.

# **Effect of Proposed Changes**

The bill requires the Department of Children and Families (DCF) to establish a mental health first aid training program (program). The program is required to provide an interactive, mental health first aid training course through contracts with Behavioral Health Managing Entities or other appropriate community providers. The bill requires the contracting entity to work cooperatively with local school districts to give first priority for training to the staff in public schools as appropriate.

The bill does not specify how the program would operate. Thus, the organization that contracted with DCF could perhaps pay for staff or individuals in the community to become certified as instructors of MHFA, contract with MHFA instructors who already possess certification, or decide to operate the program in an innovative way.

The bill requires the mental health first aid training to contain:

- An overview of mental illnesses and substance use disorders and the need to reduce the stigma of mental illness;
- Information on the potential risk factors and warning signs and common treatments of mental illnesses or substance use disorders, including depression, anxiety, psychosis, eating disorders, and self-injury; and,
- An action plan that encompasses the skills, resources, and knowledge to assess the situation, select and implement appropriate interventions, and help an individual with appropriate professional, peer, social, or self-help care.

The bill requires DCF to ensure that instructors have been certified by a national authority for mental health. At this time, the only program that clearly meets the specified criteria is the Mental Health First Aid, USA; however, it is possible that other programs may qualify.

The bill requires DCF to submit a report on the effectiveness of the program to the President of the Senate, the Speaker of the House, and the Governor by December 31, 2016.

<sup>&</sup>lt;sup>15</sup> Mental Health First Aid: *Become an Instructor, available at*: http://www.mentalhealthfirstaid.org/cs/become-an-instructor/find-upcoming-instructor-training-courses (last viewed 2/10/14).

<sup>&</sup>lt;sup>6</sup> About NAMI, available at http://www.nami.org (last viewed 2/10/14).

<sup>&</sup>lt;sup>17</sup> NAMIFlorida.org/About NAMI, *available at* http://www.namiflorida.org/(last last viewed 2/10/14).

<sup>&</sup>lt;sup>18</sup> NAMI Basics Education Program: The fundamentals of Caring for You, Your Family and Your Child with Mental Illness, *available at* 1,100 http://www.nami.org/basics (last viewed 2/10/14).

<sup>&</sup>lt;sup>19</sup> NAMI.org/parents and teachers: NAMI Parents and Teachers as Allies: An In-Service Mental Health Education Program for School Professionals, *available at* http://www.nami.org/parentsandteachers (last viewed 2/10/14).

The bill provides an appropriation of \$300,000 in nonrecurring funds to DCF from the Federal Grants Trust Fund for the implementation of the program.

The bill provides an effective date of July 1, 2014, and an expiration date of June 30, 2017.

### **B. SECTION DIRECTORY:**

Section 1: Creates an unnumbered section of law, relating to mental health first aid training

program.

**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.

2. Expenditures:

The bill provides \$300,000 of unrestricted cash from the Federal Grants Trust Fund. The cost per course is \$2,000 for one trainer should Mental Health First Aid USA be selected to provide the program curriculum.<sup>20</sup>

### **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 provides DCF the discretion to determine how to allocate these training opportunities.

While an appropriation of \$300,000 is provided to DCF, the number of qualified mental health first aid trainers produced by the bill remains indeterminate because the number of course enrollees is unknown. At a minimum, Mental Health First Aid USA recommends a community train at least two students; at a maximum, no more than 25 students are recommended per course. The cost for instruction could range from \$4,000 to \$50,000 based on the Expenditure section above. Considering the appropriation of \$300,000, at least 75 courses could be made available. The number of newly instructed trainers is a function of how many complete the courses.

<sup>20</sup> See Footnote 15. STORAGE NAME: h0159e.HHSC.DOCX

### 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

The Healthy Families Subcommittee adopted an amendment on February 11, 2014, which allows the mental health first aid program to be taught by instructors certified by any national authority on mental health, rather than restricting the program to only instructors certified by Mental Health First Aid USA.

The Health Care Appropriations Subcommittee adopted an amendment on March 11, 2014, which provides a nonrecurring appropriation of \$300,000.

This analysis is drafted to the committee substitute for the committee substitute for HB 159.

STORAGE NAME: h0159e.HHSC.DOCX **DATE: 4/1/2014** 

CS/CS/HB 159 2014

A bill to be entitled 1 2 An act relating to the establishment of a mental 3 health first aid training program; requiring the Department of Children and Families to establish a 4 5 mental health first aid training program; providing 6 for a mental health first aid course to be offered by 7 behavioral health managing entities or other community 8 providers; providing course requirements; requiring 9 instructors to be certified; requiring the department to submit a report to the Governor and Legislature; 10 providing for expiration of the program; providing an 11 appropriation; providing an effective date. 12

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

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- Section 1. Mental health first aid training program.-
- (1) The Department of Children and Families shall establish a mental health first aid training program to help the public identify and understand the signs of mental illness and substance use disorders and provide the public with skills to help a person who is developing or experiencing a mental health or substance use problem.
- (2) The training program shall provide an interactive mental health first aid training course through contracts with behavioral health managing entities or other appropriate community providers. The contracting entity shall work

Page 1 of 3

CS/CS/HB 159 2014

cooperatively with local schools to provide for training to the staff in schools as a first priority, when appropriate.

- (3) The training program shall include, but is not limited to:
- (a) An overview of mental illnesses and substance use disorders and the need to reduce the stigma of mental illness.
- (b) Information on the potential risk factors and warning signs of mental illness or substance use disorders, including depression, anxiety, psychosis, eating disorders, and selfinjury, and common treatments for those conditions.
- (c) An action plan that encompasses the skills, resources, and knowledge required to assess the situation, select and implement appropriate interventions, and help an individual with appropriate professional, peer, social, or self-help care.
- (4) The department shall ensure that instructors in the training program have been certified by a national authority on mental health first aid programs.
- (5) The department shall submit a report on the effectiveness of the mental health first aid training program provided pursuant to this act, with recommendations regarding continued implementation of the program. The report shall be submitted to the Governor, the President of the Senate, and the Speaker of the House of Representatives by December 31, 2016.
  - (6) This section expires June 30, 2017.
- Section 2. For fiscal year 2014-2015, the sum of \$300,000 in nonrecurring funds is appropriated from the Federal Grants

Page 2 of 3

CS/CS/HB 159 2014

53	Trust Fund to the Department of Children and Families to
54	implement the provisions of this act.
55	Section 3. This act shall take effect July 1, 2014.

Page 3 of 3



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					
1	Committee/Subcommittee hearing bill: Health & Human Services					
2	Committee					
3	Representative Berman offered the following:					
4						
5	Amendment (with title amendment)					
6	Remove everything after the enacting clause and insert:					
7	Section 1. Mental health first aid training program.					
8	(1) The Department of Children and Families shall					
9	establish a mental health first aid training program to help the					
10	public identify and understand the signs of mental illness and					
11	substance use disorders and provide the public with skills to					
12	help a person who is developing or experiencing a mental health					
13	or substance use problem.					
14	(2) The department shall use a competitive procurement					

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and manage the program.

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process to select a statewide association for mental health or

substance abuse awareness or treatment to develop, implement,



Amendment No.

	(3)	The	training	program	shall	include,	but	is	not	limited
to:				•						

- (a) An overview of mental illnesses and substance use disorders and the need to reduce the stigma of mental illness.
- (b) Information on the potential risk factors and warning signs of mental illness or substance use disorders, including but not limited to depression, anxiety, psychosis, eating disorders, and self-injury, and common treatments for those conditions.
- (c) An action plan that encompasses the skills, resources, and knowledge required to assess the situation, select and implement appropriate interventions, and help an individual with appropriate professional, peer, social, or self-help care.
- (4) The contractor shall administer the program in a way that maximizes the availability of mental health first aid training throughout the state, which may include, but is not limited to, contracting with trained instructors or training additional instructors. However, the contractor shall ensure that all instructors in the training program have a current certification by a national authority on mental health first aid programs.
- (5) The contractor shall prioritize training to staff in educational institutions, including all components of the K-20 education system as defined in section 1000.04, private schools as defined in section 1002.42, and colleges and universities as defined in section 1005.02. After staff in educational

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Amendment No.

institutions, the contractor shall prioritize training to first responders. The contractor may provide training to additional individuals.

- implementation and effectiveness of the mental health first aid training program provided pursuant to this act. The report shall describe the implementation of this program and include, but not be limited to, the number of individuals trained by geographic area, their employment or affiliation, the impact of the training, and recommendations regarding continued implementation of the program. The report shall be submitted to the Governor, the President of the Senate, and the Speaker of the House of Representatives by February 1, 2017.
  - (7) This section expires June 30, 2017.
- Section 2. For fiscal year 2014-2015, the sum of \$300,000 in nonrecurring funds is appropriated from the Federal Grants

  Trust Fund to the Department of Children and Families to implement the provisions of this act

Section 3. The Office of Program Policy Analysis and Government Accountability shall conduct a study on mental health training programs in the state which help the public identify and understand the signs of mental illness and substance use disorders and provide the public with skills to help a person who is developing or experiencing a mental health or substance use problem. The study shall identify major providers of such mental health training programs, the cost of such programs to

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Amendment No.

70 recipients, the availability of such programs by the general 71 public and specified groups including employees of educational 72 institutions, which comprises all components of the K-20 education system as defined in section 1000.04, private schools 73 as defined in section 1002.42, and colleges and universities as 74 defined in section 1005.02,, first responders, and other 75 personnel who are likely to have contact with individuals with 76 mental health and substance abuse disorders who are in need of 77 assistance. The Office of Program Policy Analysis and Government 78 Accountability shall survey organizations including, but not 79 limited to, managing entities and not-for-profit organizations 80 providing mental health training in conducting its research. All 81 82 state agencies and contractors receiving state funds shall comply with each request for data and information from the 83 84 Office of Program Policy Analysis and Government Accountability. The study shall include recommendations for enhancing 85 availability of such mental health training programs in the 86 87 state. The Office of Program Policy Analysis and Government 88 Accountability shall report its findings to the President of the 89 Senate and the Speaker of the House of Representatives by February 1, 2015. 90 91 Section 4. This act shall take effect July 1, 2014. 92 93 94

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TITLEAMENDMENT



Amendment No.

Remove everything before the enacting clause and insert:
An act relating to the establishment of a mental health first
aid training program; requiring the Department of Children and
Families to establish a mental health first aid training
program; providing for a mental health first aid course to be
offered by behavioral health managing entities or other
community providers; providing course requirements; requiring
instructors to be certified; requiring the department to submit
a report to the Governor and Legislature; providing for
expiration of the program; providing an appropriation; providing
an effective date.

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### HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 799 Transitional Living Facilities

SPONSOR(S): Magar

TIED BILLS: IDEN./SIM. BILLS:

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee	12 Y, 0 N	Guzzo	Shaw
2) Health Care Appropriations Subcommittee	12 Y, 0 N	Clark	Pridgeon
3) Health & Human Services Committee		Guzzo -	Calamas (C

### **SUMMARY ANALYSIS**

Transitional Living Facilities (TLFs) provide specialized health care services including, but not limited to, rehabilitative services, community re-entry training, aids for independent living, and counseling to individuals who sustain brain or spinal cord injuries. The bill consolidates the oversight, care and services of clients of TLFs under specific licensure requirements of the Agency for Health Care Administration (AHCA).

The bill promotes coordination between various state agencies involved in the regulation of TLFs by requiring AHCA, the Department of Health, the Agency for Persons with Disabilities, and the Department of Children and Families to develop an electronic database to ensure relevant client data is communicated timely and effectively.

Specifically, the bill makes the following changes:

- Requires TLFs to maintain accreditation by an accrediting organization specializing in evaluating rehabilitation facilities;
- Adds specific admission requirements and requires a client to be admitted by a licensed physician, physician assistant, or advanced registered nurse practitioner;
- Adds specific discharge requirements and clarifies the conditions that a client must meet to be eligible for discharge;
- Adds care and service plan requirements detailing orders for medical care, client functional capability and goals, and transition plans;
- Requires TLFs to provide specific professional services directed toward improving the client's functional status;
- Enables TLF clients to manage their funds and personal possessions, have visitors;
- Requires TLFs to establish grievance procedures and a system for investigating, tracking, managing, and responding to complaints, which must include an appeals process;
- Provides standards for medication management, assistance with medication, use of restraints, seclusion procedures, infection control, safeguards for clients' funds, and emergency preparedness;
- Adds provisions to protect clients from abuse including, proper staff screening, training, prevention, identification, and investigation;
- Provides AHCA the authority to develop rules for physical plant standards, personnel, and services to clients;
- Provides standard licensure criteria, including compliance with local zoning, liability insurance, fire-safety inspection, and sanitation requirements;
- Creates sanctions for violations and provides authority to place a court-ordered receiver if the licensee fails to take responsibility for the facility and places clients at risk;
- Clarifies that providers already licensed by AHCA, who serve brain and spinal-cord injured persons, are not required to obtain a separate license as a TLF; and
- Revises the Brain and Spinal Cord Injury Advisory Council's rights to entry and inspection of TLFs.

The bill has an indeterminate, but likely insignificant, fiscal impact on state government.

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

### **FULL ANALYSIS**

### I. SUBSTANTIVE ANALYSIS

# A. EFFECT OF PROPOSED CHANGES:

### **Current Situation**

Transitional living facilities (TLFs) provide specialized health care services, including, but not limited to, rehabilitative services, community reentry training, aids for independent living, and counseling to spinal-cord-injured persons and head-injured persons.<sup>1</sup> There are currently thirteen TLFs licensed in Florida.<sup>2</sup> Three state agencies have a role in regulating TLFs.

The Agency for Health Care Administration (AHCA) is the licensing authority for TLFs pursuant to chapter 408, part II, chapter 400, part V, F.S., and Rule 59A-17, F.A.C.

Compared to other types of facilities regulated by AHCA, the detail and scope of regulations for TLFs in statute and administrative rule is significantly narrower and less restrictive, as the regulations focus more on solvency than resident care.

Section 400.805, F.S., is the specific licensure authority for TLFs. However, this section only addresses fees for operation of a TLF, level 2 background screening requirements for TLF personnel, and rights to entry and inspection by AHCA investigative personnel. The current licensure fee is \$4,588.00 with a \$90 per bed fee per biennium.<sup>3</sup> Further, this section requires AHCA, in consultation with the Department of Health (DOH), to adopt rules governing the physical plant and the fiscal management of TLFs. Like the authorizing statute, the corresponding rule, Rule 59A-17, F.A.C., provides minimal regulatory guidance.

Section 381.75, F.S., requires DOH to administer the Brain and Spinal Cord Injury Program (BSCIP) to provide services for persons with traumatic brain and spinal cord injuries. Services provided by the BSCIP include:

- Case management;
- Acute care, and inpatient and outpatient rehabilitation;
- Transitional living;
- Assistive technology;
- Home and vehicle modifications:
- Nursing home transition facilitation; and
- Long-term support for survivors and families through contractual agreements with community based agencies.

Section 381.76, F.S., provides that a participant in the BSCIP must be a legal Florida resident who has sustained a brain or spinal cord injury. For purposes of the BSCIP, a brain or spinal cord injury means "a lesion to the spinal cord or cauda equina, resulting from external trauma." However, s. 400.805 (1), F.S., relating to TLFs, provides that residents of a TLF must be "spinal-cord-injured persons or headinjured persons." These inconsistent definitions have led to uncertainty as to whether or not TLFs can provide services to individuals who are not participants in the BSCIP or to individuals who have a brain or spinal cord injury that was not the result of external trauma.

Section 400.805(1)(c), F.S.

<sup>&</sup>lt;sup>2</sup> HB 799, Agency Legislative Bill Analysis, Agency For Health Care Administration, February 7, 2014 (on file with the Health Innovation subcommittee).

<sup>&</sup>lt;sup>3</sup> *Id*.

<sup>&</sup>lt;sup>4</sup> Section 381.745(2), F.S.

The Brain and Spinal Cord Injury Advisory Council (Council), created within DOH pursuant to s. 381.78, F.S., is tasked with providing advice and expertise to DOH in the preparation, implementation, and periodic review of the BSCIP. The Council has the same rights to entry and inspection of TLFs as those granted to AHCA under s. 400.805(4), F.S.

Investigations concerning allegations of abuse and neglect of vulnerable adults, including those in TLFs, are performed by the Department of Children and Families (DCF).<sup>5</sup>

According to a news report from Bloomberg, dated January 24, 2012, clients at the Florida Institute for Neurologic Rehabilitation in Wauchula, Florida were abused, neglected and confined. The news report was based on information from 20 current and former clients and their family members, criminal charging documents, civil complaints and advocates for the disabled. In August, 2012, a multi-agency investigation was conducted at the Wauchula facility. As a result of the investigation, it was determined that 50 of the 98 residents reviewed did not have an appropriate diagnosis of spinal-cord injured or head injured, and thus may have been admitted to the TLF inappropriately.

AHCA is responsible for the licensure of TLFs, while DOH monitors services for persons with traumatic brain and spinal cord injuries, and DCF investigates allegations of abuse and neglect of vulnerable adults. In working together during the investigation, gaps and deficiencies in the three-agency TLF regulatory structure were discovered.

# **Effect of Proposed Changes**

The bill consolidates the oversight of care and services of clients of TLFs under specific licensure requirements of AHCA and promotes coordination between AHCA, DOH, and DCF.

This bill repeals the current TLF regulations in s. 400.805, F.S. and creates Part XI of chapter 400, to include ss. 400.997-400.9985, F.S.

This bill creates s. 400.997, F.S., and states the intent of the legislation is to provide for the development, establishment and enforcement of basic standards for TLFs to ensure quality of care and services to residents. Further, the bill provides that it is the policy of this state that the use of restraint and seclusion of TLF clients is justified only as an emergency safety measure to be used in response to danger to the client or others. Therefore, it is the intent of the legislature to achieve an ongoing reduction in the use of restraint and seclusion in programs and facilities serving individuals with brain or spinal-cord injuries.

Section 400.9971, F.S., is created to define terms relating to TLFs, and adds new terminology to include seclusion, and chemical and physical restraints and their use. The bill adds "behavior modification" services to the list of specialized health care services contained in the definition of a TLF.

Section 400.9972, F.S., is created to provide licensure requirements for TLFs, including compliance with local zoning, liability insurance, fire-safety inspection, and sanitation requirements. This section also provides the application fees for TLFs and adds language to clarify that the fees must be adjusted to conform with the annual cost of living adjustment, pursuant to s. 408.805(2), F.S. In addition, the bill requires TLFs to maintain accreditation by an accrediting organization specializing in evaluating rehabilitation facilities whose standards incorporate comparable licensure regulations required by the state. Applicants for licensure as a TLF must acquire accreditation within 12 months of the issuance of

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<sup>&</sup>lt;sup>5</sup> Section 415.107, F.S.

<sup>&</sup>lt;sup>6</sup> Bloomberg, *Abuse of Brain Injured Americans Scandalizes U.S.*, (Jan. 7, 2012) *available at* <a href="http://www.bloomberg.com/news/2012-07-24/brain-injured-abuse-at-for-profit-center-scandalizes-u-s-.html">http://www.bloomberg.com/news/2012-07-24/brain-injured-abuse-at-for-profit-center-scandalizes-u-s-.html</a> (last visited March 22, 2014).

<sup>&</sup>lt;sup>7</sup> Agency for Health Care Administration, Statement of Deficiencies and Plan of Correction (August 3, 2012), available at <a href="http://www.upps.ahca.myflorida.com/dm\_web/(s(ner1fpywccezpxoyuqpyogfn))/doc\_results.aspx?file\_number=35930769&provider\_t ype=TRANSITIONAL+LIVING+FACILITY++&client\_code=34&provider\_name=FLORIDA+INSTITUTE+FOR+NEUROLOGIC+REHAB%2c+INC&lic\_id=28343 (last visited March 22, 2014).</a>

an initial license. The bill authorizes AHCA to accept an accreditation survey report by the accrediting organization in lieu of conducting a licensure inspection. Further, the bill authorizes AHCA to conduct inspections to assure compliance with licensure requirements, validate the inspection process of accrediting organizations, and to respond to licensure complaints or to protect public health and safety.

The bill clarifies that providers already licensed by AHCA, serving brain and spinal-cord injured persons under their existing license, are not required to obtain a separate license as a TLF.

# Admission, Transfer and Discharge Requirements

The bill creates s. 400.9973, F.S., to establish requirements that TLFs must have in place for client admission, transfer and discharge from the facility. The facility is required to have admission, transfer and discharge policies and procedures in writing. The client's admission to the facility must be in line with facility policies and procedures.

Each resident admitted to the facility is required to be admitted upon prescription by a licensed physician, physician assistant (PA), or advanced registered nurse practitioner (ARNP), and must remain under the care of the physician for the duration of the client's stay in the facility. Clients admitted to the facility must have a brain and spinal cord injury, such as a lesion to the spinal cord or cauda equine syndrome, with evidence of significant involvement of two of the following deficits or dysfunctions:

- Motor deficit.
- Sensory deficit.
- Bowel and bladder dysfunction.
- An injury to the skull, brain, or tis covering which produces an altered state of consciousness or anatomic motor, sensory, cognitive, or behavioral deficits.

This definition of a brain or spinal cord injury, as it relates to admission requirements of TLFs, differs from the definition of a brain or spinal cord injury for purposes of the BSCIP, in that it does not require the injury to be the result of external trauma.

In cases where a client's medical diagnosis does not positively identify a cause of the client's condition, or whose symptoms are inconsistent with the known cause of injury, or whose recovery is inconsistent with the known medical condition, the bill allows for an individual to be admitted for an evaluation period not to exceed ninety-days.

The bill prohibits TLFs from admitting a client whose primary diagnosis is mental illness or an intellectual or developmental disability. In addition, the bill provides that a person may not be admitted to a TLF if the person:

- Presents a significant risk of infection to other clients or personnel;
  - o In addition the bill requires a health care practitioner to provide documentation that the person is free of apparent signs and symptoms of communicable disease.
- Is a danger to self or others as determined by a physician, PA, ARNP, or mental health practitioner, unless the facility provides adequate staffing and support to ensure patient safety;
- Is bedridden; or
- Requires 24-hour nursing supervision.

Upon a client meeting the admission criteria, the medical or nursing director must complete an initial evaluation of the client's functional skills, behavioral status, cognitive status, educational/vocational potential, medical status, psychosocial status, sensorimotor capacity, and other related skills and abilities within the first seventy-two hours of admission. Further, the bill requires the facility to implement an initial comprehensive treatment plan that delineates services to be provided within the first four days of admission.

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The bill requires TLFs to develop a discharge plan for each client prior to or upon admission to the facility. The discharge plan is required to identify intended discharge sites and possible alternate discharge sites. For each discharge site identified, the discharge plan must identify the skills, behaviors, and other conditions that the client must achieve to be eligible for discharge. The bill requires discharge plans to be reviewed and updated at least once a month.

The bill allows for the discharge of clients, as soon as practicable, if the TLF is no longer the most appropriate, least restrictive treatment option, and for clients who:

- No longer require any of the specialized services described in s. 400.9971(7), F.S.; or
- Are not making measurable progress in accordance with their comprehensive treatment plan.

The bill requires TLFs to provide at least a thirty-days' notice to clients of transfer or discharge plans, which must include an acceptable transfer location if the client is unable to live independently, unless the client voluntarily terminates residency.

# Client Treatment Plans and Client Services

The bill creates s. 400.9974, F.S., to require each client in the facility to have a comprehensive treatment plan which is developed by an interdisciplinary team, consisting of the case manager. program director, ARNP, appropriate therapists, and the client and/or the client's representative. The comprehensive treatment plan must be completed no later than 30 days after development of the initial comprehensive treatment plan. Treatment plans must be reviewed and updated at least once a month. The plan must be reevaluated and updated if a client fails to meet the projected improvements outlined in the plan or if a significant change in the client's condition occurs. The facility must have qualified staff to carry out and monitor interventions in accordance with the stated goals of the individual's program plan.

Each comprehensive treatment plan must include the following:

- Orders obtained from the client's physician, PA, or ARNP, and the client's diagnosis, medical history, physical exams and rehab needs:
- A preliminary nursing evaluation, including orders for immediate care provided by the physician, PA, or ARNP, to be completed upon admission;
- A standardized assessment of the client's functional capability; and
- A plan to achieve transition to the community and the estimated length of time to achieve transition goals.

The bill requires a client or their representative to consent to the continued treatment at the TLF. The consent may be for a period of up to three months, and if consent is not given, the TLF must discharge the client as soon as possible.

The bill requires licensees to employ available qualified professional staff to carry out the various professional interventions in accordance with the goals and objectives of the individual program plan. Each client must receive a continuous treatment program that includes appropriate, consistent implementation of a program of specialized and general training, treatment, and services.

# Provider Responsibilities

The bill creates s. 400.9975, F.S., to require TLF licensees to ensure that every client:

- Lives in a safe environment;
- Is treated with respect, recognition of personal dignity and privacy;
- Retains use of their own clothes and personal property:

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- Has unrestricted private communications which includes mail, telephone and visitors;
- Participates in community services and activities;
- Manages their financial affairs unless the client or the client's representative authorizes the administrator of the facility to provide safekeeping for funds;
- Has reasonable opportunity for regular exercise and be outdoors more than once per week.
- · Exercises civil and religious liberties;
- Has adequate access and appropriate health care services:
- Has the opportunity to present grievances and recommend changes in policies, procedures and services:
- Is enabled to have a representative participate in the process of treatment for the client;
- Receives prompt responses from the facility to communications from family and friends;
- Have visits by individuals with a relationship to the client and any reasonable hour; and
- Has the opportunity to leave the facility to visit, take trips or vacations.

To facilitate a client's ability to present grievances, the facility is required to provide a system for investigating, tracking, managing, and responding to complaints, which must include an appeals process.

Additionally, the client's representative must be promptly notified of any significant incidents or changes in the client's condition.

The administrator is required to ensure a written notice of provider responsibilities is posted in a prominent place in the facility which includes the statewide toll-free telephone number for reporting complaints to the AHCA and the statewide toll-free number of Disability Rights of Florida. The facility must ensure the client has access to a telephone, which must have the telephone numbers posted for the AHCA, central abuse hotline, Disabilities Rights of Florida and the local advocacy council. The facility cannot take retaliatory action against any person for filing a complaint or grievance, or for appearing as a witness in any hearing.

# Administration of Medication

The bill creates s. 400.9976, F.S., to require TLFs to maintain a medication administration record for each client, and for each dose, including medications that are self-administered. Each patient who is self-administering must be given a pill organizer, and a nurse must place the medications inside the pill organizer and document the date and time the pill organizer is filled. All medications, including those that are self-administered, must be administered as ordered by the physician, PA, or ARNP. Drug administration errors and adverse drug reactions must be recorded and reported immediately to the physician, PA, or ARNP. The interdisciplinary team determines if a client is capable of self-administration of medications if the physician, PA, or ARNP does not specify otherwise. The physician, PA, or ARNP must instruct the client to self-administer medication.

# Assistance with Medication

The bill creates s. 400.9977, F.S., which provides that notwithstanding the Nurse Practice Act, Part I of chapter 464, F.S., unlicensed direct care services staff who provide client services under chapter 400 or 429, F.S., may administer prescribed, prepackaged and premeasured medications under the supervision of a registered nurse. The medication administration training for unlicensed direct care services staff must be conducted by a physician, pharmacist or registered nurse.

The bill requires TLFs that allow unlicensed direct care services staff to administer medications to:

- Develop and implement policies and procedures;
- Maintain written evidence of a client's consent:
- Maintain a copy of the written prescription; and

Maintain required training documentation.

# Client Protection

The bill creates s. 400.9977, F.S., to establish provisions relating to the protection of clients from abuse, neglect, mistreatment, and exploitation. The bill provides that the facility is responsible for developing and implementing policies and procedures for screening and training employees, protection of clients and for the prevention, identification, investigation, and reporting of abuse, neglect, mistreatment, and exploitation. The facility is also required to identify clients whose history renders them at risk for abusing other clients. Further, the bill requires facilities to implement procedures to:

- Screen potential employees for a history of abuse, neglect or mistreatment of client;
- Train employees through orientation and on-going sessions on abuse prohibition practices;
- Implement procedures to provide clients, families and staff information on how and to whom they may report concerns, incidents and grievances without the fear of retribution;
- Implement procedures to identify events such as suspicious bruising of clients that may constitute abuse to determine the direction of the investigation;
- Investigate different types of incidents and identify staff members responsible for the initial reporting and reporting of results to the proper authorities;
- Protect clients from harm during an investigation; and
- Report all alleged violations and all substantiated incidents as required under chapters 39 and 415, F.S., and to the appropriate licensing authorities.

The facility must identify, correct, and intervene in situations in which abuse, neglect, mistreatment or exploitation is likely to occur, including, the physical environment that makes abuse and/or neglect more likely to occur, such as secluded areas.

The facility is required to have a sufficient number of staff to meet the needs of the clients, and must assure that staff has knowledge of the individual client's care needs. The facility must analyze the occurrences of abuse, exploitation, mistreatment or neglect and determine what changes are needed to policies and procedures to prevent further occurrences.

### Restraints and Seclusion

The bill creates s. 400.9979, F.S., to require physical and chemical restraints to be, ordered and documented, by the client's physician, PA, or ARNP with the consent of the client or client's representative. The bill provides that the use of chemical restraints is limited to the prescribed dosage of medications by the client's physician, PA, or ARNP. The use of physical restraint and seclusion may only be used as authorized by the facility's written physical restraint and seclusion policies. Facilities are required to notify the parent or guardian within 24-hours of the use of restraint or seclusion.

The bill authorizes a physician, PA, or ARNP to issue an emergency treatment order to immediately administer rapid response psychotropic medications or other chemical restraints when a client exhibits symptoms that present an immediate risk of injury or death to themselves or others. Each emergency treatment order must be documented and maintained in the client's record and is only effective for 24-hours.

Clients receiving medications that can serve as a restraint must be evaluated by their physician, PA, or ARNP at least monthly to assess the:

- Continued need for the medication;
- Level of the medication in client's blood; and
- Need for adjustments in the prescription.

The facility is required to ensure that clients are free from unnecessary drugs and physical restraints. All interventions to manage inappropriate client behaviors must be administered with sufficient safeguards and supervision.

The bill authorizes AHCA to adopt rules for standards and procedures relating to:

- Use of restraint, restraint positioning, seclusion and emergency orders for psychotropic medications:
- Duration of restraint use;
- Staff training;
- Client observation during restraint; and
- Documentation and reporting standards.

# Background Screening and Administration/Management

Background Screening and Administration/Management

The bill creates s. 400.998, F.S., to require all facility personnel to complete a level 2 background screening as required in s. 408.809(1)(e), F.S. pursuant to Chapter 435. The facility must maintain personnel records which contain the staff's background screening, job description, documentation of compliance with training requirements, and a copy of all licenses or certifications held by staff who perform services for which licensure or certification is required. The record must also include a copy of all job performance evaluations.

The bill requires the facility to:

- Implement infection control policies and procedures.
- Maintain liability insurance as defined by section 624.605, F.S., at all times.
- Designate one person as administrator who is responsible for the overall management of the facility.
- Designate in writing a person responsible for the facility when the administrator is absent for 24 hours
- Designate in writing a program director who is responsible for supervising the therapeutic and behavioral staff, determining the levels of supervision, and room placement for each client.
- Designate in writing a person to be responsible when the program director is absent from the facility for more than 24 hours.
- Obtain approval of the comprehensive emergency management plan from their local emergency management agency.
- Maintain written records in a form and system in accordance with medical and business practices and be available for submission to AHCA upon request. The records must include:
  - o A daily census record;
  - A report of all accident or unusual incidents involving clients or staff members that caused or had the potential to cause injury or harm to any person or property within the facility:
  - o Agreements with third party providers; and
  - o Agreements with consultants employed by the facility and documentation of each consultant's visits and required written, dated reports.

# Property and Personal Affairs of Clients

The bill creates s. 400.9981, F.S., to require facilities to give clients options of using their own personal belongings, and to choose their own roommate whenever possible. The bill provides that the admission of a client to a facility, and their presence therein, shall not confer on a licensee, administrator, employee, or representative any authority to manage, use, or dispose of any property of

the client. The licensee, administrator employee or representative may not act as the client's guardian, trustee, payee for social security or other benefits. The licensee, administrator, employee or representative may act as the power of attorney for a client if the licensee has filed a surety bond with AHCA in an amount equal to twice the average monthly income of the client. When the power of attorney is granted to the licensee, administrator, staff, or representative, they must notify the client on a monthly basis of any transactions made on their behalf and a copy of such statement given to the client must be retained in the client's file and be available for inspection.

The bill requires the facility to, upon consent from the client, provide for the safekeeping of personal effects. The personal effects may not be in excess of \$1,000 and funds of the client may not be in excess of \$500 in cash, and the facility must keep complete and accurate records of all funds and personal effects received.

The bill provides that for any funds or other property belonging to or due to a client, such funds shall be trust funds which shall be kept separate from the funds and property of the licensee or shall be specifically credited to the client. At least once every month, unless upon order of a court of competent jurisdiction, the facility must furnish the client and the client's representative a complete and verified statement of all funds and other property, detailing the amount and items received, together with their sources and disposition.

The bill provides that any licensee, administrator, or staff, or representative thereof, who is granted power of attorney for any client of the facility and who misuses or misappropriates funds obtained through this power commits a felony of the third degree.

In the event of the death of a client, the facility must return all refunds, funds, and property held in trust to the client's personal representative. If the client has no spouse or adult next of kin or such person cannot be located, funds due the client must be placed in an interest-bearing account, and all property held in trust by the licensee shall be safeguarded until such time as the funds and property are disbursed pursuant to the Florida Probate Code.

The bill authorizes AHCA to adopt rules to clarify terms and specify procedures and documentation necessary to administer the provisions relating to the proper management of clients' funds and personal property and the execution of surety bonds.

# Rules Establishing Standards

The bill creates s. 400.9981, F.S., to authorize AHCA to publish and enforce rules, which include criteria to ensure reasonable and consistent quality of care and client safety. Further, the bill authorizes AHCA to adopt and enforce rules which must include reasonable and fair criteria with respect to the:

- Location of TLFs:
- Qualifications of all personnel having responsibility for any part of the client's care and services;
- Requirements for personnel procedures and reporting procedures;
- Services provided to clients; and the
- Preparation and annual update of a comprehensive emergency management plan.

### Penalties and Violations

The bill creates s. 400.9983, F.S., to authorize AHCA to adopt rules to enforce penalties, and require AHCA to classify each violation according to the nature of the violation and the gravity of its probable effect on the client. The classification of violations, as defined in s. 408.813, F.S., must be included on the written notice of the violation in the following categories:

• Class "I" violations will result in issuance of a citation regardless of correction and impose an administrative fine up to \$10,000 for a widespread violation.

- Class "II" violations will result in an administrative fine up to \$5,000 for a widespread violation.
- Class "III" violations will result in an administrative fine up to \$1,000 for an uncorrected deficiency of a widespread violation.
- Class "IV" violations will result in an administrative fine of at least \$100 but not exceeding \$200 for an uncorrected deficiency.

The bill allows TLFs to avoid imposition of a fine for a class IV violation, if the deficiency is corrected within a specified period of time.

# Receivership Proceedings

The bill creates s. 400.9984, F.S., to authorize AHCA access the provisions of s. 429.22, F.S., regarding receivership proceedings for TLFs. As a result, AHCA is authorized to petition a court for the appointment of a receiver when any of the following conditions exist:

- The facility is closing or has informed the Agency that it intends to close;
- The Agency determines the conditions exit in the facility that presents danger to the health, safety or welfare of the clients of the facility; or
- The facility cannot meet its financial obligation for providing food, shelter, care and utilities.

Petitions for receivership take priority over other court business. A hearing must be conducted within five days of the petition filing. AHCA must notify the owner or administrator of the facility named in the petition and the date of the hearing. The court may grant the petition only upon a finding that the health, safety or welfare of the client is threatened if a condition existing at the time the petition was filed is allowed to continue.

A receiver may be appointed from a list of qualified persons developed by AHCA. The receiver must make provisions for the continued health, safety and welfare of all clients and perform all duties set out by the court. The receiver must operate the facility to assure the safety and adequate health care for the clients. The receiver may use all resources and consumable goods in the provision of care services to the client and correct or eliminate any deficiency in the structure or furnishings of the facility which endangers the safety of clients and staff. The receiver may hire or contract staff to carry out the duties of the receiver. The receiver must also honor all leases and mortgages, and has the power to direct and manage, and to discharge employees of the facility.

### Interagency Communication

The bill creates s. 400.9985, F.S., to require AHCA, DOH, APD, and DCF to develop electronic systems to ensure relevant data pertaining to the regulation of TLFs is communicated timely among the agencies for the protection of clients. The bill requires the system to include a brain and spinal cord injury registry and a client abuse registry.

### B. SECTION DIRECTORY:

- **Section 1:** Creates ss. 400.997 through 400.9985, F.S., as part XI of chapter 400, to be entitled "Transitional Living Facilities.
- **Section 2:** Creates s. 400.9978, F.S., relating to protection of clients from abuse, neglect, mistreatment, and exploitation.
- **Section 3:** Repeals s. 400.805, F.S., relating to transitional living facilities.
- **Section 4:** Redesignates the title of part V of chapter 400, F.S., as "Intermediate Care Facilities".
- **Section 5:** Amends s. 381.745, F.S., relating to definitions.
- Section 6: Amends s. 381.75, F.S., relating to duties and responsibilities of the department.
- Section 7: Amends s. 381.78, F.S., relating to the advisory council on brain and spinal cord injuries.
- **Section 8:** Amends s. 400.93, F.S., relating to licensure required; exemptions; unlawful act; penalties.
- Section 9: Amends s. 408.802, F.S., relating to applicability.

Section 10: Amends s. 408.820, F.S., relating to exemptions.

**Section 11:** Provides that effective July1, 2015, a TLF licensed before the effective date of this act pursuant to s. 400.805, F.S., must be licensed under part XI of chapter 400, F.S., as created by this act.

**Section 12:** Provides an effective date of July1, 2014, except as otherwise expressly provided in this act.

# II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

### A. FISCAL IMPACT ON STATE GOVERNMENT:

# 1. Revenues:

AHCA is responsible for the licensing of TLFs. The current licensure fee is \$4,588.00 with a \$90 per bed fee per biennium. There are currently 13 facilities located within the state. The amount of revenue collected for licensure is expected to remain constant. Additionally, AHCA is responsible for the regulation and collection of administrative fines for TLFs. Based upon historical experience, there is expected to be minimal to no revenues associated with administrative fine collection. Finally, the bill requires that personal property funds of deceased residents that are not disbursed pursuant to Florida Probate Code within two years after death are to be deposited within AHCA's Health Care Trust Fund. The amount of funds expected to be deposited within AHCA's Health Care Trust Fund is indeterminate, but likely insignificant.

# 2. Expenditures:

The bill requires AHCA, DOH, APD, and DCF to develop electronic systems to share relevant information pertaining to regulation of TLFs. The cost of developing this system is estimated to be insignificant and can be absorbed within each department's existing resources. Additionally, AHCA's current staff that is responsible for the regulation of TLFs will continue to provide these functions in the future and will not require additional staff or resources.

### B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1	Revenues	•
- 1	revenues	١,

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:

AHCA is authorized to adopt rules related to assistance with medication, restraints, seclusion, client safety, and quality of care.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

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HB 799 2014

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A bill to be entitled An act relating to transitional living facilities; creating part XI of chapter 400, F.S.; providing legislative intent; providing definitions; requiring the licensure of transitional living facilities; providing license fees and application requirements; requiring accreditation of licensed facilities; providing requirements for transitional living facility policies and procedures governing client admission, transfer, and discharge; requiring a comprehensive treatment plan to be developed for each client; providing plan and staffing requirements; requiring certain consent for continued treatment in a transitional living facility; providing licensee responsibilities; providing notice requirements; prohibiting a licensee or employee of a facility from serving notice upon a client to leave the premises or take other retaliatory action under certain circumstances; requiring the client and client's representative to be provided with certain information; requiring the licensee to develop and implement certain policies and procedures; providing licensee requirements relating to administration of medication; requiring maintenance of medication administration records; providing requirements for administration of medications by unlicensed staff;

Page 1 of 42

HB 799 2014

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specifying who may conduct training of staff; requiring licensees to adopt policies and procedures for administration of medications by trained staff; requiring the Agency for Health Care Administration to adopt rules; providing requirements for the screening of potential employees and training and monitoring of employees for the protection of clients; requiring licensees to implement certain policies and procedures to protect clients; providing conditions for investigating and reporting incidents of abuse, neglect, mistreatment, or exploitation of clients; providing requirements and limitations for the use of physical restraints, seclusion, and chemical restraint medication on clients; providing a limitation on the duration of an emergency treatment order; requiring notification of certain persons when restraint or seclusion is imposed; authorizing the agency to adopt rules; providing background screening requirements; requiring the licensee to maintain certain personnel records; providing administrative responsibilities for licensees; providing recordkeeping requirements; providing licensee responsibilities with respect to the property and personal affairs of clients; providing requirements for a licensee with respect to obtaining surety bonds; providing recordkeeping requirements relating to the safekeeping of personal

Page 2 of 42

HB 799 2014

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effects; providing requirements for trust funds or other property received by a licensee and credited to the client; providing a penalty for certain misuse of a client's personal funds, property, or personal needs allowance; providing criminal penalties for violations; providing for the disposition of property in the event of the death of a client; authorizing the agency to adopt rules; providing legislative intent; authorizing the agency to adopt and enforce rules establishing standards for transitional living facilities and personnel thereof; classifying violations and providing penalties therefor; providing administrative fines for specified classes of violations; authorizing the agency to apply certain provisions with regard to receivership proceedings; requiring the agency, the Department of Health, the Agency for Persons with Disabilities, and the Department of Children and Families to develop electronic information systems for certain purposes; repealing s. 400.805, F.S., relating to transitional living facilities; revising the title of part V of chapter 400, F.S.; amending s. 381.745, F.S.; revising the definition of the term "transitional living facility," to conform; amending s. 381.75, F.S.; revising the duties of the Department of Health and the agency relating to transitional living facilities;

Page 3 of 42

amending ss. 381.78, 400.93, 408.802, and 408.820, F.S.; conforming provisions to changes made by the act; providing applicability with respect to transitional living facilities licensed before a specified date; providing effective dates.

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

Section 1. Part XI of chapter 400, Florida Statutes, consisting of sections 400.997 through 400.9985, is created to read:

## 90 PART XI

## TRANSITIONAL LIVING FACILITIES

400.997 Legislative intent.—It is the intent of the Legislature to provide for the licensure of transitional living facilities and require the development, establishment, and enforcement of basic standards by the Agency for Health Care Administration to ensure quality of care and services to clients in transitional living facilities. It is the policy of the state that the least restrictive appropriate available treatment be used based on the individual needs and best interest of the client, consistent with optimum improvement of the client's condition. The goal of a transitional living program for persons who have brain or spinal cord injuries is to assist each person who has such an injury to achieve a higher level of independent functioning and to enable the person to reenter the community.

Page 4 of 42

It is also the policy of the state that the restraint or seclusion of a client is justified only as an emergency safety measure used in response to danger to the client or others. It is therefore the intent of the Legislature to achieve an ongoing reduction in the use of restraint or seclusion in programs and facilities that serve persons who have brain or spinal cord injuries.

- 400.9971 Definitions.—As used in this part, the term:
- (1) "Agency" means the Agency for Health Care Administration.

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- (2) "Chemical restraint" means a pharmacologic drug that physically limits, restricts, or deprives a person of movement or mobility, is used for client protection or safety, and is not required for the treatment of medical conditions or symptoms.
- (3) "Client's representative" means the parent of a child client or the client's guardian, designated representative, designee, surrogate, or attorney in fact.
  - (4) "Department" means the Department of Health.
- (5) "Physical restraint" means a manual method to restrict freedom of movement of or normal access to a person's body, or a physical or mechanical device, material, or equipment attached or adjacent to the person's body that the person cannot easily remove and that restricts freedom of movement of or normal access to the person's body, including, but not limited to, a half-bed rail, a full-bed rail, a geriatric chair, or a Posey restraint. The term includes any device that is not specifically

Page 5 of 42

manufactured as a restraint but is altered, arranged, or otherwise used for this purpose. The term does not include bandage material used for the purpose of binding a wound or injury.

- in any fashion or the involuntary isolation of a person in a room or area from which the person is prevented from leaving.

  Such prevention may be accomplished by imposition of a physical barrier or by action of a staff member to prevent the person from leaving the room or area. For purposes of this part, the term does not mean isolation due to a person's medical condition or symptoms.
- (7) "Transitional living facility" means a site where specialized health care services are provided to persons who have brain or spinal cord injuries, including, but not limited to, rehabilitative services, behavior modification, community reentry training, aids for independent living, and counseling.

400.9972 License required; fee; application.—

(1) The requirements of part II of chapter 408 apply to the provision of services that require licensure pursuant to this part and part II of chapter 408 and to entities licensed by or applying for licensure from the agency pursuant to this part. A license issued by the agency is required for the operation of a transitional living facility in this state. However, this part does not require a provider licensed by the agency to obtain a separate transitional living facility license to serve persons

Page 6 of 42

who have brain or spinal cord injuries as long as the services provided are within the scope of the provider's license.

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- (2) In accordance with this part, an applicant or a licensee shall pay a fee for each license application submitted under this part. The license fee shall consist of a \$4,588 license fee and a \$90 per-bed fee per biennium and shall conform to the annual adjustment authorized in s. 408.805.
  - (3) An applicant for licensure must provide:
- (a) The location of the facility for which the license is sought and documentation, signed by the appropriate local government official, which states that the applicant has met local zoning requirements.
- (b) Proof of liability insurance as provided in s.
  624.605(1)(b).
- (c) Proof of compliance with local zoning requirements, including compliance with the requirements of chapter 419 if the proposed facility is a community residential home.
- (d) Proof that the facility has received a satisfactory firesafety inspection.
- (e) Documentation that the facility has received a satisfactory sanitation inspection by the county health department.
- (4) The applicant's proposed facility must attain and continuously maintain accreditation by an accrediting organization that specializes in evaluating rehabilitation facilities whose standards incorporate licensure regulations

Page 7 of 42

183 l comparable to those required by the state. An applicant for 184 licensure as a transitional living facility must acquire 185 accreditation within 12 months after issuance of an initial 186 license. The agency shall accept the accreditation survey report 187 of the accrediting organization in lieu of conducting a licensure inspection if the standards included in the survey 188 189 report are determined by the agency to document that the 190 facility substantially complies with state licensure 191 requirements. Within 10 days after receiving the accreditation 192 survey report, the applicant shall submit to the agency a copy 193 of the report and evidence of the accreditation decision as a 194 result of the report. The agency may conduct an inspection of a 195 transitional living facility to ensure compliance with the 196 licensure requirements of this part, to validate the inspection 197 process of the accrediting organization, to respond to licensure 198 complaints, or to protect the public health and safety. 400.9973 Client admission, transfer, and discharge. 199 200 (1)A transitional living facility shall have written 201 policies and procedures governing the admission, transfer, and 202 discharge of clients. 203 The admission of a client to a transitional living 204 facility must be in accordance with the licensee's policies and 205 procedures.

(3) A client admitted to a transitional living facility must have a brain or spinal cord injury, such as a lesion to the spinal cord or cauda equina syndrome, with evidence of

Page 8 of 42

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209 significant involvement of at least two of the following 210 deficits or dysfunctions: 211 (a) A motor deficit. 212 (b) A sensory deficit. 213 (c) Bowel and bladder dysfunction. 214 (d) An acquired internal or external injury to the skull, the brain, or the brain's covering, whether caused by a 215 216 traumatic or nontraumatic event, which produces an altered state of consciousness or an anatomic motor, sensory, cognitive, or 217 218 behavioral deficit. 219 (4) A client whose medical condition and diagnosis do not 220 positively identify a cause of the client's condition, whose 221 symptoms are inconsistent with the known cause of injury, or 222 whose recovery is inconsistent with the known medical condition 223 may be admitted to a transitional living facility for evaluation 224 for a period not to exceed 90 days. 225 A client admitted to a transitional living facility (5) 226 must be admitted upon prescription by a licensed physician, 227 physician assistant, or advanced registered nurse practitioner 228 and must remain under the care of a licensed physician, 229 physician assistant, or advanced registered nurse practitioner 230 for the duration of the client's stay in the facility. 231 (6) A transitional living facility may not admit a person 232 whose primary admitting diagnosis is mental illness or an

Page 9 of 42

(7) A person may not be admitted to a transitional living

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intellectual or developmental disability.

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facility if the person:

- (a) Presents significant risk of infection to other clients or personnel. A health care practitioner must provide documentation that the person is free of apparent signs and symptoms of communicable disease;
- (b) Is a danger to himself or herself or others as determined by a physician, physician assistant, or advanced registered nurse practitioner or a mental health practitioner licensed under chapter 490 or chapter 491, unless the facility provides adequate staffing and support to ensure patient safety;
  - (c) Is bedridden; or
  - (d) Requires 24-hour nursing supervision.
- medical or nursing director of the facility must complete an initial evaluation of the client's functional skills, behavioral status, cognitive status, educational or vocational potential, medical status, psychosocial status, sensorimotor capacity, and other related skills and abilities within the first 72 hours after the client's admission to the facility. An initial comprehensive treatment plan that delineates services to be provided and appropriate sources for such services must be implemented within the first 4 days after admission.
- (9) A transitional living facility shall develop a discharge plan for each client before or upon admission to the facility. The discharge plan must identify the intended discharge site and possible alternative discharge sites. For

Page 10 of 42

each discharge site identified, the discharge plan must identify the skills, behaviors, and other conditions that the client must achieve to be eligible for discharge. A discharge plan must be reviewed and updated as necessary but at least once monthly.

- (10) A transitional living facility shall discharge a client as soon as practicable when the client no longer requires the specialized services described in s. 400.9971(7), when the client is not making measurable progress in accordance with the client's comprehensive treatment plan, or when the transitional living facility is no longer the most appropriate and least restrictive treatment option.
- (11) A transitional living facility shall provide at least 30 days' notice to a client of transfer or discharge plans, including the location of an acceptable transfer location if the client is unable to live independently. This subsection does not apply if a client voluntarily terminates residency.
- 400.9974 Client comprehensive treatment plans; client services.—
- (1) A transitional living facility shall develop a comprehensive treatment plan for each client as soon as practicable but no later than 30 days after the initial comprehensive treatment plan is developed. The comprehensive treatment plan must be developed by an interdisciplinary team consisting of the case manager, the program director, the advanced registered nurse practitioner, and appropriate therapists. The client or, if appropriate, the client's

Page 11 of 42

representative must be included in developing the comprehensive treatment plan. The comprehensive treatment plan must be reviewed and updated if the client fails to meet projected improvements outlined in the plan or if a significant change in the client's condition occurs. The comprehensive treatment plan must be reviewed and updated at least once monthly.

- (2) The comprehensive treatment plan must include:
- (a) Orders obtained from the physician, physician assistant, or advanced registered nurse practitioner and the client's diagnosis, medical history, physical examination, and rehabilitative or restorative needs.
- (b) A preliminary nursing evaluation, including orders for immediate care provided by the physician, physician assistant, or advanced registered nurse practitioner, which shall be completed when the client is admitted.
- (c) A comprehensive, accurate, reproducible, and standardized assessment of the client's functional capability; the treatments designed to achieve skills, behaviors, and other conditions necessary for the client to return to the community; and specific measurable goals.
- (d) Steps necessary for the client to achieve transition into the community and estimated length of time to achieve those goals.
- (3) The client or, if appropriate, the client's representative must consent to the continued treatment at the transitional living facility. Consent may be for a period of up

Page 12 of 42

313	to 3 months. If such consent is not given, the transitional
314	living facility shall discharge the client as soon as
315	practicable.
316	(4) A client must receive the professional program
317	services needed to implement the client's comprehensive
318	treatment plan.
319	(5) The licensee must employ qualified professional staff
320	to carry out and monitor the various professional interventions
321	in accordance with the stated goals and objectives of the
322	client's comprehensive treatment plan.
323	(6) A client must receive a continuous treatment program
324	that includes appropriate, consistent implementation of
325	specialized and general training, treatment, health services,
326	and related services and that is directed toward:
327	(a) The acquisition of the behaviors and skills necessary
328	for the client to function with as much self-determination and
329	independence as possible.
330	(b) The prevention or deceleration of regression or loss
331	of current optimal functional status.
332	(c) The management of behavioral issues that preclude
333	independent functioning in the community.
334	400.9975 Licensee responsibilities
335	(1) The licensee shall ensure that each client:
336	(a) Lives in a safe environment free from abuse, neglect,
337	and exploitation.
338	(b) Is treated with consideration and respect and with due

Page 13 of 42

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recognition of personal dignity, individuality, and the need for privacy.

- (c) Retains and uses his or her own clothes and other personal property in his or her immediate living quarters to maintain individuality and personal dignity, except when the licensee demonstrates that such retention and use would be unsafe, impractical, or an infringement upon the rights of other clients.
- (d) Has unrestricted private communication, including receiving and sending unopened correspondence, access to a telephone, and visits with any person of his or her choice. Upon request, the licensee shall modify visiting hours for caregivers and guests. The facility shall restrict communication in accordance with any court order or written instruction of a client's representative. Any restriction on a client's communication for therapeutic reasons shall be documented and reviewed at least weekly and shall be removed as soon as no longer clinically indicated. The basis for the restriction shall be explained to the client and, if applicable, the client's representative. The client shall retain the right to call the central abuse hotline, the agency, and Disability Rights Florida at any time.
- (e) Has the opportunity to participate in and benefit from community services and activities to achieve the highest possible level of independence, autonomy, and interaction within the community.

Page 14 of 42

(f) Has the opportunity to manage his or her financial affairs unless the client or, if applicable, the client's representative authorizes the administrator of the facility to provide safekeeping for funds as provided under this part.

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- (g) Has reasonable opportunity for regular exercise more than once per week and to be outdoors at regular and frequent intervals except when prevented by inclement weather.
- (h) Has the opportunity to exercise civil and religious liberties, including the right to independent personal decisions. However, a religious belief or practice, including attendance at religious services, may not be imposed upon any client.
- (i) Has access to adequate and appropriate health care consistent with established and recognized community standards.
- (j) Has the opportunity to present grievances and recommend changes in policies, procedures, and services to the staff of the licensee, governing officials, or any other person without restraint, interference, coercion, discrimination, or reprisal. A licensee shall establish a grievance procedure to facilitate a client's ability to present grievances, including a system for investigating, tracking, managing, and responding to complaints by a client or, if applicable, the client's representative and an appeals process. The appeals process must include access to Disability Rights Florida and other advocates and the right to be a member of, be active in, and associate with advocacy or special interest groups.

Page 15 of 42

391 (2) The licensee shall:

- (a) Promote participation of the client's representative in the process of providing treatment to the client unless the representative's participation is unobtainable or inappropriate.
- (b) Answer communications from the client's family, guardians, and friends promptly and appropriately.
- (c) Promote visits by persons with a relationship to the client at any reasonable hour, without requiring prior notice, in any area of the facility that provides direct care services to the client, consistent with the client's and other clients' privacy, unless the interdisciplinary team determines that such a visit would not be appropriate.
- (d) Promote opportunities for the client to leave the facility for visits, trips, or vacations.
- (e) Promptly notify the client's representative of a significant incident or change in the client's condition, including, but not limited to, serious illness, accident, abuse, unauthorized absence, or death.
- written notice of licensee responsibilities is posted in a prominent place in each building where clients reside and is read or explained to clients who cannot read. This notice shall be provided to clients in a manner that is clearly legible, shall include the statewide toll-free telephone number for reporting complaints to the agency, and shall include the words:

Page 16 of 42

417	please call toll-free[telephone number] or Disability
118	Rights Florida[telephone number]" The statewide toll-
119	free telephone number for the central abuse hotline shall be
120	provided to clients in a manner that is clearly legible and
421	shall include the words: "To report abuse, neglect, or
422	exploitation, please call toll-free[telephone number]"
423	The licensee shall ensure a client's access to a telephone where
424	telephone numbers are posted as required by this subsection.
425	(4) A licensee or employee of a facility may not serve
426	notice upon a client to leave the premises or take any other
427	retaliatory action against another person solely because of the
428	following:
429	(a) The client or other person files an internal or
430	external complaint or grievance regarding the facility.
431	(b) The client or other person appears as a witness in a
432	hearing inside or outside the facility.
433	(5) Before or at the time of admission, the client and, if
434	applicable, the client's representative shall receive a copy of
435	the licensee's responsibilities, including grievance procedures
436	and telephone numbers, as provided in this section.
437	(6) The licensee must develop and implement policies and
438	procedures governing the release of client information,
439	including consent necessary from the client or, if applicable,
440	the client's representative.
441	400.9976 Administration of medication.
442	(1) An individual medication administration record must be

Page 17 of 42

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maintained for each client. A dose of medication, including a self-administered dose, shall be properly recorded in the client's record. A client who self-administers medication shall be given a pill organizer. Medication must be placed in the pill organizer by a nurse. A nurse shall document the date and time that medication is placed into each client's pill organizer. All medications must be administered in compliance with orders of a physician, physician assistant, or advanced registered nurse practitioner.

If an interdisciplinary team determines that self-(2) administration of medication is an appropriate objective, and if the physician, physician assistant, or advanced registered nurse practitioner does not specify otherwise, the client must be instructed by the physician, physician assistant, or advanced registered nurse practitioner to self-administer his or her medication without the assistance of a staff person. All forms of self-administration of medication, including administration orally, by injection, and by suppository, shall be included in the training. The client's physician, physician assistant, or advanced registered nurse practitioner must be informed of the interdisciplinary team's decision that self-administration of medication is an objective for the client. A client may not self-administer medication until he or she demonstrates the competency to take the correct medication in the correct dosage at the correct time, to respond to missed doses, and to contact the appropriate person with questions.

Page 18 of 42

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(3) Medication administration discrepancies and adverse drug reactions must be recorded and reported immediately to a physician, physician assistant, or advanced registered nurse practitioner. 400.9977 Assistance with medication.-Notwithstanding any provision of part I of chapter (1)464, the Nurse Practice Act, unlicensed direct care services staff who provide services to clients in a facility licensed under chapter 400 or chapter 429 may administer prescribed, prepackaged, and premeasured medications under the general supervision of a registered nurse as provided under this section and applicable rules. (2) Training required by this section and applicable rules shall be conducted by a registered nurse licensed under chapter 464, a physician licensed under chapter 458 or chapter 459, or a pharmacist licensed under chapter 465. (3) A facility that allows unlicensed direct care service staff to administer medications pursuant to this section shall: Develop and implement policies and procedures that (a) include a plan to ensure the safe handling, storage, and

- administration of prescription medications.

  (b) Maintain written evidence of the expressed and
- (b) Maintain written evidence of the expressed and informed consent for each client.
- (c) Maintain a copy of the written prescription, including the name of the medication, the dosage, and the administration schedule and termination date.

Page 19 of 42

495 (d) Maintain documentation of compliance with required 496 training. 497 The agency shall adopt rules to implement this 498 section. 499 Section 2. Section 400.9978, Florida Statutes, is created 500 to read: 501 400.9978 Protection of clients from abuse, neglect, 502 mistreatment, and exploitation. - The licensee shall develop and 503 implement policies and procedures for the screening and training 504 of employees; the protection of clients; and the prevention, 505 identification, investigation, and reporting of abuse, neglect, 506 mistreatment, and exploitation. The licensee shall identify 507 clients whose personal histories render them at risk for abusing 508 other clients, develop intervention strategies to prevent 509 occurrences of abuse, monitor clients for changes that would 510 trigger abusive behavior, and reassess the interventions on a 511 regular basis. A licensee shall: (1) Screen each potential employee for a history of abuse, 512 513 neglect, mistreatment, or exploitation of clients. The screening 514 shall include an attempt to obtain information from previous and 515 current employers and verification of screening information by 516 the appropriate licensing boards. 517 Train employees through orientation and ongoing 518 sessions regarding issues related to abuse prohibition 519 practices, including identification of abuse, neglect,

Page 20 of 42

mistreatment, and exploitation; appropriate interventions to

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address aggressive or catastrophic reactions of clients; the process for reporting allegations without fear of reprisal; and recognition of signs of frustration and stress that may lead to abuse.

- (3) Provide clients, families, and staff with information regarding how and to whom they may report concerns, incidents, and grievances without fear of retribution and provide feedback regarding the concerns that are expressed. A licensee shall identify, correct, and intervene in situations in which abuse, neglect, mistreatment, or exploitation is likely to occur, including:
- (a) Evaluating the physical environment of the facility to identify characteristics that may make abuse or neglect more likely to occur, such as secluded areas.
- (b) Providing sufficient staff on each shift to meet the needs of the clients and ensuring that the assigned staff have knowledge of each client's care needs.
- (c) Identifying inappropriate staff behaviors, such as using derogatory language, rough handling of clients, ignoring clients while giving care, and directing clients who need toileting assistance to urinate or defecate in their beds.
- (d) Assessing, monitoring, and planning care for clients with needs and behaviors that might lead to conflict or neglect, such as a history of aggressive behaviors including entering other clients' rooms without permission, exhibiting selfinjurious behaviors or communication disorders, requiring

Page 21 of 42

intensive nursing care, or being totally dependent on staff.

- (4) Identify events, such as suspicious bruising of clients, occurrences, patterns, and trends that may constitute abuse and determine the direction of the investigation.
- (5) Investigate alleged violations and different types of incidents, identify the staff member responsible for initial reporting, and report results to the proper authorities. The licensee shall analyze the incidents to determine whether policies and procedures need to be changed to prevent further incidents and take necessary corrective actions.
  - (6) Protect clients from harm during an investigation.
- (7) Report alleged violations and substantiated incidents, as required under chapters 39 and 415, to the licensing authorities and all other agencies, as required, and report any knowledge of actions by a court of law that would indicate an employee is unfit for service.
  - 400.9979 Restraint and seclusion; client safety.-
- (1) A facility shall provide a therapeutic milieu that supports a culture of individual empowerment and responsibility.

  The health and safety of the client shall be the facility's primary concern at all times.
- (2) The use of physical restraints must be ordered and documented by a physician, physician assistant, or advanced registered nurse practitioner and must be consistent with the policies and procedures adopted by the facility. The client or, if applicable, the client's representative shall be informed of

Page 22 of 42

the facility's physical restraint policies and procedures when the client is admitted.

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- (3) The use of chemical restraints shall be limited to prescribed dosages of medications as ordered by a physician, physician assistant, or advanced registered nurse practitioner and must be consistent with the client's diagnosis and the policies and procedures adopted by the facility. The client and, if applicable, the client's representative shall be informed of the facility's chemical restraint policies and procedures when the client is admitted.
- assistant, or advanced registered nurse practitioner, if a client exhibits symptoms that present an immediate risk of injury or death to himself or herself or others, a physician, physician assistant, or advanced registered nurse practitioner may issue an emergency treatment order to immediately administer rapid-response psychotropic medications or other chemical restraints. Each emergency treatment order must be documented and maintained in the client's record.
- (a) An emergency treatment order is not effective for more than 24 hours.
- (b) Whenever a client is medicated under this subsection, the client's representative or a responsible party and the client's physician, physician assistant, or advanced registered nurse practitioner shall be notified as soon as practicable.
  - (5) A client who is prescribed and receives a medication

Page 23 of 42

that can serve as a chemical restraint for a purpose other than an emergency treatment order must be evaluated by his or her physician, physician assistant, or advanced registered nurse practitioner at least monthly to assess:

(a) The continued need for the medication.

(b) The level of the medication in the client's blood.

(c) The need for adjustments to the prescription.

- (6) The licensee shall ensure that clients are free from unnecessary drugs and physical restraints and are provided treatment to reduce dependency on drugs and physical restraints.
- (7) The licensee may only employ physical restraints and seclusion as authorized by the facility's written policies, which shall comply with this section and applicable rules.
- (8) Interventions to manage dangerous client behavior shall be employed with sufficient safeguards and supervision to ensure that the safety, welfare, and civil and human rights of a client are adequately protected.
- (9) A facility shall notify the parent, guardian, or, if applicable, the client's representative when restraint or seclusion is employed. The facility must provide the notification within 24 hours after the restraint or seclusion is employed. Reasonable efforts must be taken to notify the parent, guardian, or, if applicable, the client's representative by telephone or e-mail, or both, and these efforts must be documented.
  - (10) The agency may adopt rules that establish standards

Page 24 of 42

625 and procedures for the use of restraints, restraint positioning, seclusion, and emergency treatment orders for psychotropic 626 627 medications, restraint, and seclusion. These rules must include 628 duration of restraint, staff training, observation of the client 629 during restraint, and documentation and reporting standards. 630 400.998 Personnel background screening; administration and 631 management procedures .-(1) The agency shall require level 2 background screening 632 for licensee personnel as required in s. 408.809(1)(e) and 633 pursuant to chapter 435 and s. 408.809. 634 635 The licensee shall maintain personnel records for each 636 staff member that contain, at a minimum, documentation of background screening, a job description, documentation of 637 638 compliance with the training requirements of this part and 639 applicable rules, the employment application, references, a copy 640 of each job performance evaluation, and, for each staff member 641 who performs services for which licensure or certification is 642 required, a copy of all licenses or certification held by that 643 staff member. 644 The licensee must: (3) 645 Develop and implement infection control policies and procedures and include the policies and procedures in the 646 647 licensee's policy manual. 648 (b) Maintain liability insurance as defined in s. 649 624.605(1)(b). 650 (c) Designate one person as an administrator to be

Page 25 of 42

responsible and accountable for the overall management of the facility.

- (d) Designate in writing a person to be responsible for the facility when the administrator is absent from the facility for more than 24 hours.
- (e) Designate in writing a program director to be responsible for supervising the therapeutic and behavioral staff, determining the levels of supervision, and determining room placement for each client.
- (f) Designate in writing a person to be responsible when the program director is absent from the facility for more than 24 hours.
- management plan, pursuant to s. 400.9982(2)(e), from the local emergency management agency. Pending the approval of the plan, 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 Health, the Agency for Health Care Administration, and the Division of Emergency Management. Appropriate volunteer organizations shall also be given the opportunity to review the plan. The local emergency management agency shall complete its review within 60 days after receipt of the plan and either approve the plan or advise the licensee of necessary revisions.
- (h) Maintain written records in a form and system that comply with medical and business practices and make the records

Page 26 of 42

available by the facility for review or submission to the agency upon request. The records shall include:

- 1. A daily census record that indicates the number of clients currently receiving services in the facility, including information regarding any public funding of such clients.
- 2. A record of each accident or unusual incident involving a client or staff member that caused, or had the potential to cause, injury or harm to any person or property within the facility. The record shall contain a clear description of each accident or incident; the names of the persons involved; a description of medical or other services provided to these persons, including the provider of the services; and the steps taken to prevent recurrence of such accident or incident.
- 3. A copy of current agreements with third-party providers.
- 4. A copy of current agreements with each consultant employed by the licensee and documentation of a consultant's visits and required written and dated reports.
  - 400.9981 Property and personal affairs of clients.-
- (1) A client shall be given the option of using his or her own belongings, as space permits; choosing a roommate if practical and not clinically contraindicated; and, whenever possible, unless the client is adjudicated incompetent or incapacitated under state law, managing his or her own affairs.
- (2) The admission of a client to a facility and his or her presence therein does not confer on a licensee or administrator,

Page 27 of 42

or an employee or representative thereof, any authority to manage, use, or dispose of the property of the client, and the admission or presence of a client does not confer on such person any authority or responsibility for the personal affairs of the client except that which may be necessary for the safe management of the facility or for the safety of the client.

(3) A licensee or administrator, or an employee or representative thereof, may:

- (a) Not act as the guardian, trustee, or conservator for a client or a client's property.
- (b) Act as a competent client's payee for social security, veteran's, or railroad benefits if the client provides consent and the licensee files a surety bond with the agency in an amount equal to twice the average monthly aggregate income or personal funds due to the client, or expendable for the client's account, that are received by a licensee.
- (c) Act as the attorney in fact for a client if the licensee files a surety bond with the agency in an amount equal to twice the average monthly income of the client, plus the value of a client's property under the control of the attorney in fact.

The surety bond required under paragraph (b) or paragraph (c) shall be executed by the licensee as principal and a licensed surety company. The bond shall be conditioned upon the faithful compliance of the licensee with the requirements of licensure

Page 28 of 42

729 and is payable to the agency for the benefit of a client who 730 suffers a financial loss as a result of the misuse or 731 misappropriation of funds held pursuant to this subsection. A 732 surety company that cancels or does not renew the bond of a 733 licensee shall notify the agency in writing at least 30 days 734 before the action, giving the reason for cancellation or 735 nonrenewal. A licensee or administrator, or an employee or 736 representative thereof, who is granted power of attorney for a 737 client of the facility shall, on a monthly basis, notify the 738 client in writing of any transaction made on behalf of the 739 client pursuant to this subsection, and a copy of the 740 notification given to the client shall be retained in the 741 client's file and available for agency inspection. 742 (4) A licensee, with the consent of the client, shall

- provide for safekeeping in the facility of the client's personal effects of a value not in excess of \$1,000 and the client's funds not in excess of \$500 cash and shall keep complete and accurate records of the funds and personal effects received. If a client is absent from a facility for 24 hours or more, the licensee may provide for safekeeping of the client's personal effects of a value in excess of \$1,000.
- (5) Funds or other property belonging to or due to a client or expendable for the client's account that are received by a licensee shall be regarded as funds held in trust and shall be kept separate from the funds and property of the licensee and other clients or shall be specifically credited to the client.

Page 29 of 42

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755 The funds held in trust shall be used or otherwise expended only 756 for the account of the client. At least once every month, except 757 pursuant to an order of a court of competent jurisdiction, the 758 licensee shall furnish the client and, if applicable, the 759 client's representative with a complete and verified statement 760 of all funds and other property to which this subsection 761 applies, detailing the amount and items received, together with 762 their sources and disposition. The licensee shall furnish the 763 statement annually and upon discharge or transfer of a client. A 764 governmental agency or private charitable agency contributing 765 funds or other property to the account of a client is also 766 entitled to receive a statement monthly and upon the discharge 767 or transfer of the client. 768

- (6)(a) In addition to any damages or civil penalties to which a person is subject, a person who:
- 1. Intentionally withholds a client's personal funds, personal property, or personal needs allowance;
- 2. Demands, beneficially receives, or contracts for payment of all or any part of a client's personal property or personal needs allowance in satisfaction of the facility rate for supplies and services; or
- 3. Borrows from or pledges any personal funds of a client,
  other than the amount agreed to by written contract under s.
  429.24,

780 commits a misdemeanor of the first degree, punishable as

Page 30 of 42

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provided in s. 775.082 or s. 775.083.

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(b) A licensee or administrator, or an employee, or representative thereof, who is granted power of attorney for a client and who misuses or misappropriates funds obtained through this power commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

- In the event of the death of a client, a licensee shall return all refunds, funds, and property held in trust to the client's personal representative, if one has been appointed at the time the licensee disburses such funds, or, if not, to the client's spouse or adult next of kin named in a beneficiary designation form provided by the licensee to the client. If the client does not have a spouse or adult next of kin or such person cannot be located, funds due to be returned to the client shall be placed in an interest-bearing account, and all property held in trust by the licensee shall be safequarded until such time as the funds and property are disbursed pursuant to the Florida Probate Code. The funds shall be kept separate from the funds and property of the licensee and other clients of the facility. If the funds of the deceased client are not disbursed pursuant to the Florida Probate Code within 2 years after the client's death, the funds shall be deposited in the Health Care Trust Fund administered by the agency.
- (8) The agency, by rule, may clarify terms and specify procedures and documentation necessary to administer the provisions of this section relating to the proper management of

Page 31 of 42

clients' funds and personal property and the execution of surety 807 l 808 bonds. 809 400.9982 Rules establishing standards.-810 It is the intent of the Legislature that rules adopted 811 and enforced pursuant to this part and part II of chapter 408 812 include criteria to ensure reasonable and consistent quality of care and client safety. The rules should make reasonable efforts 813 814 to accommodate the needs and preferences of the client to 815 enhance the client's quality of life while residing in a 816 transitional living facility. 817 The agency may adopt and enforce rules to implement 818 this part and part II of chapter 408, which shall include 819 reasonable and fair criteria with respect to: 820 The location of transitional living facilities. 821 The qualifications of personnel, including management, (b) 822 medical, nursing, and other professional personnel and nursing 823 assistants and support staff, who are responsible for client 824 care. The licensee must employ enough qualified professional 825 staff to carry out and monitor interventions in accordance with 826 the stated goals and objectives of each comprehensive treatment 827 plan. 828

(c) Requirements for personnel procedures, reporting procedures, and documentation necessary to implement this part.

- (d) Services provided to clients of transitional living facilities.
  - (e) The preparation and annual update of a comprehensive

Page 32 of 42

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833 emergency management plan in consultation with the Division of 834 Emergency Management. At a minimum, the rules must provide for 835 plan components that address emergency evacuation 836 transportation; adequate sheltering arrangements; postdisaster 837 activities, including provision of emergency power, food, and 838 water; postdisaster transportation; supplies; staffing; 839 emergency equipment; individual identification of clients and 840 transfer of records; communication with families; and responses 841 to family inquiries. 842 400.9983 Violations; penalties.—A violation of this part 843 or any rule adopted pursuant thereto shall be classified 844 according to the nature of the violation and the gravity of its 845 probable effect on facility clients. The agency shall indicate 846 the classification on the written notice of the violation as 847 follows: 848 (1) Class "I" violations are defined in s. 408.813. The 849 agency shall issue a citation regardless of correction and 850 impose an administrative fine of \$5,000 for an isolated 851 violation, \$7,500 for a patterned violation, or \$10,000 for a 852 widespread violation. Violations may be identified, and a fine 853 must be levied, notwithstanding the correction of the deficiency 854 giving rise to the violation. 855 (2) Class "II" violations are defined in s. 408.813. The 856 agency shall impose an administrative fine of \$1,000 for an

Page 33 of 42

isolated violation, \$2,500 for a patterned violation, or \$5,000

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for a widespread violation. A fine must be levied

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notwithstanding the correction of the deficiency giving rise to the violation.

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- (3) Class "III" violations are defined in s. 408.813. The agency shall impose an administrative fine of \$500 for an isolated violation, \$750 for a patterned violation, or \$1,000 for a widespread violation. If a deficiency giving rise to a class III violation is corrected within the time specified by the agency, the fine may not be imposed.
- (4) Class "IV" violations are defined in s. 408.813. The agency shall impose for a cited class IV violation an administrative fine of at least \$100 but not exceeding \$200 for each violation. If a deficiency giving rise to a class IV violation is corrected within the time specified by the agency, the fine may not be imposed.
- 400.9984 Receivership proceedings.—The agency may apply s.
  429.22 with regard to receivership proceedings for transitional
  living facilities.
- department, the Agency for Persons with Disabilities, and the Department of Children and Families shall develop electronic systems to ensure that relevant information pertaining to the regulation of transitional living facilities and clients is timely and effectively communicated among agencies in order to facilitate the protection of clients. Electronic sharing of information shall include, at a minimum, a brain and spinal cord injury registry and a client abuse registry.

Page 34 of 42

885	Section 3. Section 400.805, Florida Statutes, is repealed.
886	Section 4. The title of part V of chapter 400, Florida
887	Statutes, consisting of sections 400.701 and 400.801, is
888	redesignated as "INTERMEDIATE CARE FACILITIES."
889	Section 5. Subsection (9) of section 381.745, Florida
890	Statutes, is amended to read:
891	381.745 Definitions; ss. 381.739-381.79.—As used in ss.
892	381.739-381.79, the term:
893	(9) "Transitional living facility" means a state-approved
894	facility $_{m{ au}}$ as defined and licensed under chapter 400 $_{m{ au}}$ chapter
895	429, or a facility approved by the brain and spinal cord injury
896	program in accordance with this chapter.
897	Section 6. Section 381.75, Florida Statutes, is amended to
898	read:
899	381.75 Duties and responsibilities of the department, of
900	transitional living facilities, and of residents.—Consistent
901	with the mandate of s. 381.7395, the department shall develop
902	and administer a multilevel treatment program for individuals
903	who sustain brain or spinal cord injuries and who are referred
904	to the brain and spinal cord injury program.
905	(1) Within 15 days after any report of an individual who
906	has sustained a brain or spinal cord injury, the department
907	shall notify the individual or the most immediate available
908	family members of their right to assistance from the state, the
909	services available, and the eligibility requirements.
910	(2) The department shall refer individuals who have brain

Page 35 of 42

or spinal cord injuries to other state agencies to <u>ensure</u> assure that rehabilitative services, if desired, are obtained by that individual.

- (3) The department, in consultation with emergency medical service, shall develop standards for an emergency medical evacuation system that will ensure that all individuals who sustain traumatic brain or spinal cord injuries are transported to a department-approved trauma center that meets the standards and criteria established by the emergency medical service and the acute-care standards of the brain and spinal cord injury program.
- (4) The department shall develop standards for designation of rehabilitation centers to provide rehabilitation services for individuals who have brain or spinal cord injuries.
- (5) The department shall determine the appropriate number of designated acute-care facilities, inpatient rehabilitation centers, and outpatient rehabilitation centers, needed based on incidence, volume of admissions, and other appropriate criteria.
- (6) The department shall develop standards for designation of transitional living facilities to provide transitional living services for individuals who participate in the brain and spinal cord injury program the opportunity to adjust to their disabilities and to develop physical and functional skills in a supported living environment.
- (a) The Agency for Health Care Administration, in consultation with the department, shall develop rules for the

Page 36 of 42

licensure of transitional living facilities for individuals who have brain or spinal cord injuries.

(b) The goal of a transitional living program for individuals who have brain or spinal cord injuries is to assist each individual who has such a disability to achieve a higher level of independent functioning and to enable that person to recenter the community. The program shall be focused on preparing participants to return to community living.

(c) A transitional living facility for an individual who has a brain or spinal cord injury shall provide to such individual, in a residential setting, a goal-oriented treatment program designed to improve the individual's physical, cognitive, communicative, behavioral, psychological, and social functioning, as well as to provide necessary support and supervision. A transitional living facility shall offer at least the following therapies: physical, occupational, speech, neuropsychology, independent living skills training, behavior analysis for programs serving brain-injured individuals, health education, and recreation.

(d) All residents shall use the transitional living facility as a temporary measure and not as a permanent home or domicile. The transitional living facility shall develop an initial treatment plan for each resident within 3 days after the resident's admission. The transitional living facility shall develop a comprehensive plan of treatment and a discharge plan for each resident as soon as practical, but no later than 30

Page 37 of 42

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days after the resident's admission. Each comprehensive treatment plan and discharge plan must be reviewed and updated as necessary, but no less often than quarterly. This subsection does not require the discharge of an individual who continues to require any of the specialized services described in paragraph (c) or who is making measurable progress in accordance with that individual's comprehensive treatment plan. The transitional living facility shall discharge any individual who has an appropriate discharge site and who has achieved the goals of his or her discharge plan or who is no longer making progress toward the goals established in the comprehensive treatment plan and the discharge plan. The discharge location must be the least restrictive environment in which an individual's health, wellbeing, and safety is preserved. (7) Recipients of services, under this section, from any of the facilities referred to in this section shall pay a fee based on ability to pay. Section 7. Subsection (4) of section 381.78, Florida Statutes, is amended to read: 381.78 Advisory council on brain and spinal cord injuries.-The council shall+ (a) provide advice and expertise to the department in the preparation, implementation, and periodic review of the brain

Page 38 of 42

(b) Annually appoint a five-member committee composed of

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and spinal cord injury program.

one individual who has a brain injury or has a family member with a brain injury, one individual who has a spinal cord injury or has a family member with a spinal cord injury, and three members who shall be chosen from among these representative groups: physicians, other allied health professionals, administrators of brain and spinal cord injury programs, and representatives from support groups with expertise in areas related to the rehabilitation of individuals who have brain or spinal cord injuries, except that one and only one member of the committee shall be an administrator of a transitional living facility. Membership on the council is not a prerequisite for membership on this committee.

1. The committee shall perform onsite visits to those transitional living facilities identified by the Agency for Health Care Administration as being in possible violation of the statutes and rules regulating such facilities. The committee members have the same rights of entry and inspection granted under s. 400.805(4) to designated representatives of the agency.

2. Factual findings of the committee resulting from an onsite investigation of a facility pursuant to subparagraph 1. shall be adopted by the agency in developing its administrative response regarding enforcement of statutes and rules regulating the operation of the facility.

3. Onsite investigations by the committee shall be funded by the Health Care Trust Fund.

4. Travel expenses for committee members shall be

Page 39 of 42

HB 799 2014

1015	reimbursed in accordance with s. 112.061.
1016	5. Members of the committee shall recuse themselves from
1017	participating in any investigation that would create a conflict
1018	of interest under state law, and the council shall replace the
1019	member, either temporarily or permanently.
1020	Section 8. Subsection (5) of section 400.93, Florida
1021	Statutes, is amended to read:
1022	400.93 Licensure required; exemptions; unlawful acts;
1023	penalties
1024	(5) The following are exempt from home medical equipment
1025	provider licensure, unless they have a separate company,
1026	corporation, or division that is in the business of providing
1027	home medical equipment and services for sale or rent to
1028	consumers at their regular or temporary place of residence
1029	pursuant to the provisions of this part:
1030	(a) Providers operated by the Department of Health or
1031	Federal Government.
1032	(b) Nursing homes licensed under part II.
1033	(c) Assisted living facilities licensed under chapter 429,
1034	when serving their residents.
1035	(d) Home health agencies licensed under part III.
1036	(e) Hospices licensed under part IV.
1037	(f) Intermediate care facilities $\underline{\text{and}}_{\mathcal{T}}$ homes for special
1038	services, and transitional living facilities licensed under part
1039	77

Page 40 of 42

(g) Transitional living facilities licensed under part XI.

HB 799 2014

1041 (h) (g) Hospitals and ambulatory surgical centers licensed 1042 under chapter 395. 1043 (i) (h) Manufacturers and wholesale distributors when not 1044 selling directly to consumers. 1045 (j) (i) Licensed health care practitioners who use utilize 1046 home medical equipment in the course of their practice, but do 1047 not sell or rent home medical equipment to their patients.  $(k) \frac{(i)}{(i)}$  Pharmacies licensed under chapter 465. 1048 1049 Section 9. Subsection (21) of section 408.802, Florida Statutes, is amended to read: 1050 1051 408.802 Applicability.—The provisions of this part apply 1052 to the provision of services that require licensure as defined 1053 in this part and to the following entities licensed, registered, 1054 or certified by the agency, as described in chapters 112, 383, 1055 390, 394, 395, 400, 429, 440, 483, and 765: 1056 (21) Transitional living facilities, as provided under part XI  $\forall$  of chapter 400. 1057 1058 Section 10. Subsection (20) of section 408.820, Florida 1059 Statutes, is amended to read: 1060 408.820 Exemptions.—Except as prescribed in authorizing 1061 statutes, the following exemptions shall apply to specified 1062 requirements of this part: 1063 Transitional living facilities, as provided under 1064 part XI  $\forall$  of chapter 400, are exempt from s. 408.810(10). 1065 Section 11. Effective July 1, 2015, a transitional living 1066 facility licensed before the effective date of this act pursuant

Page 41 of 42

HB 799 2014

1067	to s. 400.805, Florida Statutes, must be licensed under part XI
1068	of chapter 400, Florida Statutes, as created by this act.
1069	Section 12. Except as otherwise expressly provided in this
1070	act, this act shall take effect July 1, 2014.

Page 42 of 42

### **HOUSE OF REPRESENTATIVES STAFF ANALYSIS**

BILL #:

HB 531

**Public Health Trusts** 

**SPONSOR(S):** Richardson TIED BILLS:

IDEN./SIM. BILLS: SB 640

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

### **SUMMARY ANALYSIS**

This bill amends s. 154.11, F.S., to authorize the board of trustees for a public health trust to lease, as lessor, office space controlled by the public trust without the approval of the board of county commissioners.

This bill has no fiscal impact on state government. However, this bill may result in additional revenues being generated by a public health trust from the lease of real property under its control.

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

This document does not reflect the intent or official position of the bill sponsor or House of Representatives. STORAGE NAME: h0531d.HHSC.DOCX

#### **FULL ANALYSIS**

### I. SUBSTANTIVE ANALYSIS

#### A. EFFECT OF PROPOSED CHANGES:

### **Present Situation**

#### **Public Health Trusts**

Each county is authorized to create a public corporate body known as a public health trust.<sup>1</sup> A public health trust may only be created if the governing body of the county of a public health trust declares that there is a need for the trust to function.<sup>2</sup> The governing body of the county must then designate health care facilities to be operated and governed by the trust and appoint a board of trustees (board).<sup>3</sup>

The purpose of a public health trust is to exercise supervisory control over the operation, maintenance, and governance of the designated health care facilities. A designated facility is any county-owned or county-operated facility used in connection with the delivery of health care.<sup>4</sup> Designated facilities include: <sup>5</sup>

- Sanatoriums;
- Clinics;
- Ambulatory care centers;
- Primary care centers;
- Hospitals;
- Rehabilitation centers;
- Health training facilities;
- Nursing homes;
- Nurses' residence buildings;
- Infirmaries:
- Outpatient clinics:
- Mental health facilities;
- Residences for the aged:
- · Rest homes;
- Health care administration buildings; and
- Parking facilities and areas serving health care facilities.

The board of each public health trust is authorized to become the operator of, and governing body for, any designated facility. The board is selected by the governing body of the county where the trust is located and consists of between 7 and 21 members. The members must be residents of the county in which the trust is located and are appointed on staggered terms which may not exceed 4 years. The members serve without compensation, but are entitled to necessary expenses incurred in the discharge of their duties.

<sup>&</sup>lt;sup>1</sup> Section 154.07, F.S.

<sup>2</sup> ld

<sup>&</sup>lt;sup>3</sup> Section 154.08, F.S., and s. 154.09, F.S.

<sup>&</sup>lt;sup>4</sup> Section 154.08, F.S.

<sup>&</sup>lt;sup>5</sup> ld.

<sup>&</sup>lt;sup>6</sup> ld.

<sup>&</sup>lt;sup>7</sup> Section 154.09, F.S.

<sup>&</sup>lt;sup>8</sup> ld.

<sup>&</sup>lt;sup>9</sup> ld.

The board of each public health trust is deemed to exercise a public and essential governmental function of both the state and the county. 10 The board is granted specific authority and powers to accomplish this function. This authority is subject to the limitation of the governing body of the county where the trust is located and includes the authority to: 11

- Sue and be sued:
- Make and adopt bylaws and rules and regulations for the board's guidance and for the operation, governance, and maintenance of designated facilities;
- Make and execute contracts;
- Appoint and remove a chief executive officer of the trust;
- Appoint, remove, or suspend employees or agents of the board;
- Cooperate with and contract with any governmental agency or instrumentality, federal, state, municipal, or county;
- Employ legal counsel; and
- Lease, either as lessee or lessor, or rent for any number of years and upon any terms and conditions real property, except that the board shall not lease or rent, as lessor, any real property except in accordance with the requirements of s. 125.35, F.S.

Section 125.35, F.S., authorizes the board of county commissioners sell and convey any real or personal property, and to lease real property, belonging to the county, whenever the board determines that it is in the best interest of the county to do so.

# Public Health Trust of Miami-Dade County

Miami-Dade County is the only county to have created a public health trust. In 1973 Miami-Dade County created the Public Health Trust of Miami-Dade County (Trust). The Trust's designated facilities include Jackson Memorial Hospital and all related facilities and real and personal property. The related facilities include: 13

- Multiple primary care and specialty care centers;
- A variety of school-based clinics serving many elementary, middle and high schools;
- Two long-term care nursing facilities;
- Six corrections health services clinics:
- A network of mental health facilities:
- Holtz Children's Hospital;
- Jackson Rehabilitation Hospital;
- Jackson Behavioral Health Hospital;
- Jackson North Medical Center; and
- Jackson South Community Hospital.

## **Effect of Proposed Changes**

Currently, s. 154.11(f), F.S., authorizes the board of trustees of a public health trust to lease, as lessor, any real property under its control. However, any such lease is subject to the approval by the board of county commissioners of the county where the public health trust is located. <sup>14</sup> The bill authorizes the board of trustees for a public health trust to lease, as lessor, office space controlled by the public health trust without the approval of the board of county commissioners.

<sup>14</sup> Section 125.35, F.S.

<sup>&</sup>lt;sup>10</sup> Section 154.11, F.S.

<sup>&#</sup>x27;' ld.

<sup>12</sup> Chapter 25A of the Miami-Dade County Code.

<sup>13</sup> About Jackson Health System: Overview, http://www.jacksonhealth.org/about.asp (last visited on March 1, 2014)

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**Section 1**: Amends s. 154.11, F.S., relating to powers of board of trustees.

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.

2. Expenditures:

None.

#### B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

This bill may result in additional revenues being generated by a public health trust from the lease of real property under its control.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

## III. COMMENTS

### A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

**B. RULE-MAKING AUTHORITY:** 

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

STORAGE NAME: h0531d.HHSC.DOCX DATE: 4/1/2014

PAGE: 4

# IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

STORAGE NAME: h0531d.HHSC.DOCX DATE: 4/1/2014

HB 531 2014

A bill to be entitled 1 2 An act relating to public health trusts; amending s. 3 154.11, F.S.; authorizing public health trusts to lease certain real property; providing an effective 4 5 date. 6 7 Be It Enacted by the Legislature of the State of Florida: 8 9 Section 1. Paragraph (f) of subsection (1) of section 154.11, Florida Statutes, is amended to read: 10 154.11 Powers of board of trustees. 11 12 The board of trustees of each public health trust shall be deemed to exercise a public and essential governmental 13 function of both the state and the county and in furtherance 14 15 thereof it shall, subject to limitation by the governing body of 16 the county in which such board is located, have all of the 17 powers necessary or convenient to carry out the operation and 18 governance of designated health care facilities, including, but 19 without limiting the generality of, the foregoing: 20 To lease, either as lessee or lessor, or rent for any 21 number of years and upon any terms and conditions real property, except that the board shall not lease or rent, as lessor, any 22 23 real property other than office space controlled by a public health trust, except in accordance with the requirements of s. 24 125.35, Florida Statutes [F. S. 1973]. 25 Section 2. This act shall take effect July 1, 2014. 26

Page 1 of 1

#### HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #:

CS/HB 1019

Pub. Rec./Location of Safe Houses

TIED BILLS: HB 1017

SPONSOR(S): Healthy Families Subcommittee; Spano and others

IDEN./SIM. BILLS: SB 1436

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Healthy Families Subcommittee	11 Y, 0 N, As CS	Entress	Brazzell
2) Government Operations Subcommittee	13 Y, 0 N	Williamson	Williamson
3) Health & Human Services Committee		Entress (	Calamas 😘

### **SUMMARY ANALYSIS**

Human trafficking is a form of modern-day slavery, which involves the exploitation of persons for commercial sex or forced labor. Safe homes and short-term safe houses provide services and residential care to victims of human trafficking.

This bill, which is linked to the passage of HB 1017, creates a public record exemption for information about the location of safe houses and safe foster homes. Specifically, the bill provides that the information regarding the location of safe houses that is held by an agency is confidential and exempt from public record requirements. However, the bill allows this information to be provided to any agency in order to maintain health and safety standards and to address emergency situations in the safe house and safe foster home.

The bill provides that the public record exemption is subject to the Open Government Sunset Review Act and stands repealed on October 2, 2019, unless reviewed and saved from repeal through reenactment by the Legislature. It also provides a statement of public necessity as required by the State Constitution.

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

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 or expanded public records exemption. The bill creates a public records exemption; thus, it requires a two-thirds vote for final passage.

#### **FULL ANALYSIS**

#### I. SUBSTANTIVE ANALYSIS

# A. EFFECT OF PROPOSED CHANGES:

#### Public Records

Article I, s. 24(a) of the State Constitution sets forth the state's public policy regarding access to government records. This section guarantees every person a right to inspect or copy any public record of the legislative, executive, and judicial branches of government. The Legislature, however, may provide by general law for the exemption of records from the requirements of Article I, s. 24(a) 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.<sup>1</sup>

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. Furthermore, the Open Government Sunset Review Act<sup>2</sup> 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.
- Protects trade or business secrets.

## **Human Trafficking**

Florida law defines human trafficking as "soliciting, recruiting, harboring, providing, enticing, maintaining, or obtaining another person for the purpose of exploitation of that person." Human trafficking is a form of modern-day slavery, which involves the exploitation of persons for commercial sex or forced labor. Trafficking subjects victims to force, fraud, or coercion. Children experiencing this type of sexual exploitation often become bonded with their exploiters and do not see themselves as victims. These children experience trauma and are exposed to danger but are often unable to leave their exploiter to seek help.

## Safe Houses

The Safe Harbor Act provided for "safe houses". Safe houses are homes for sexually exploited children who have been adjudicated dependent or delinquent and need to reside in a secure<sup>8</sup> residential facility.<sup>9</sup> Safe houses must provide a living environment that has set aside gender-specific, separate, and distinct living quarters for sexually exploited children and must have staff members who are awake on duty 24 hours a day.<sup>10</sup> Safe houses must also hold a license as a family foster home or residential

STORAGE NAME: h1019d.HHSC.DOCX DATE: 4/1/2014

<sup>&</sup>lt;sup>1</sup> Section 24(c), Art. I of the State Constitution.

<sup>&</sup>lt;sup>2</sup> See s. 119.15, F.S.

<sup>&</sup>lt;sup>3</sup> Section 787.06 (2)(d), F.S.

<sup>&</sup>lt;sup>4</sup> Section 787.06(1)(a), F.S.

<sup>&</sup>lt;sup>5</sup> Healthy Families Subcommittee Presentation by Professor Terry Coonan, FSU Human Rights Center, 1/14/14, s. 787.06(1)(a), F.S.

<sup>&</sup>lt;sup>6</sup> Testimony from the Detective McBride, Healthy Families Subcommittee, February 15, 2014.

<sup>&</sup>lt;sup>7</sup> Testimony from the Detective McBride, Healthy Families Subcommittee, February 15, 2014.

<sup>&</sup>lt;sup>8</sup> The term "secure" is defined as a facility providing services is supervised 24 hours a day by staff members who are awake while on duty.

<sup>&</sup>lt;sup>9</sup> Section 409.1678 (1)(b), F.S.

<sup>&</sup>lt;sup>10</sup> Section 409.1678 (1)(b), F.S.

child-caring agency.<sup>11</sup> Each facility must be appropriately licensed in this state as a residential child-caring agency as defined in s. 409.175, F.S., and must have applied for accreditation within 1 year after being licensed.<sup>12</sup> A safe house serving children who have been sexually exploited must have available staff or contract personnel who have the clinical expertise, credentials, and training to provide:

- Security;
- Crisis intervention services;
- General counseling and victim-witness counseling;
- A comprehensive assessment;
- Residential care:
- Transportation;
- Access to behavioral health services:
- Recreational activities:
- Food:
- Clothing;
- Supplies;
- Infant care:
- Miscellaneous expenses associated with caring for these children;
- Provide necessary arrangement for or provision of educational services, including life skills services and planning services for the successful transition of residents back to the community;
- Ensuring necessary and appropriate health care and dental care.<sup>13</sup>

The Department of Children and Families or the local community-based care organization is required to assess sexually exploited dependent children for placement in a safe house if the child is older than six. The assessment is required to incorporate and address the following:

- Current and historical information from any law enforcement reports;
- Psychological testing or evaluation that has occurred;
- Current and historical information from the guardian ad litem, if one has been assigned;
- Current and historical information from any current therapist, teacher, or other professional who has knowledge of the child and has worked with the child; and
- Any other information concerning the availability and suitability of safe-house placement.<sup>14</sup>

The child may be placed in a safe house if such placement is determined to be appropriate as a result of this assessment and if one is available, but placement is not required.<sup>15</sup>

There are currently two safe houses in Florida, with a total of 11 beds statewide. A third safe house is projected to open in 2014 with seven beds. If a trafficker learned the location of a safe house and went to the safe house, the safe house staff as well as the individuals residing in the safe house could be in danger of physical or emotional harm.

## **Effect of Proposed Changes**

The bill creates a public record exemption for information about the location of safe houses and other facilities housing victims of human trafficking, as defined in s. 787.06, F.S. Specifically, the bill provides that the information regarding the location of safe houses that is held by an agency, as defined in

<sup>&</sup>lt;sup>11</sup> Section 409.1678 (1)(b), F.S.

<sup>&</sup>lt;sup>12</sup> According to DCF, there are currently no entities that accredit safe houses and safe houses are not sure what type of accreditation they are required to have. No safe houses have applied for accreditation at this time.

<sup>&</sup>lt;sup>13</sup> Section 409.1671, F.S.

<sup>&</sup>lt;sup>14</sup> Section 39.524, F.S.

<sup>&</sup>lt;sup>15</sup> Section 39.524, F.S.

<sup>&</sup>lt;sup>16</sup> E-mail Correspondence with the Florida Department of Children and Families, 12/20/13, on file with subcommittee staff. **STORAGE NAME**: h1019d.HHSC.DOCX

119.011, F.S.,<sup>17</sup> is confidential and exempt<sup>18</sup> from s. 119.07(1), Florida Statutes, and s. 24(a), Article I of the State Constitution. However, the bill allows this information to be provided to any agency as necessary to maintain health and safety standards and to address emergency situations in the safe house and safe foster home.

The bill provides that the public record exemption is subject to the Open Sunset Review Act and stands repealed on October 2, 2019, unless reviewed and saved from repeal through reenactment by the Legislature.

The bill provides statements of public necessity as required by the State Constitution. 19

The bill provides an effective date contingent upon the passage of HB 1017 or similar legislation.

#### B. SECTION DIRECTORY:

**Section 1:** Amends s. 409.1678, F.S., relating to safe harbor for children who are victims of sexual exploitation.

**Section 2:** Creates an unnumbered section of law relating to a public necessity.

**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.

<sup>17</sup> Agency is defined in s. 119.011, F.S., as any state, county, district, authority, or municipal officer, department, division, board, bureau, commission, or other separate unit of government created or established by law including, for the purposes of chapter 119, F.S., the Commission on Ethics, the Public Service Commission, and the Office of Public Counsel, and any other public or private agency, person, partnership, corporation, or business entity acting on behalf of any public agency.

<sup>18</sup> There is a difference between records the Legislature has determined to be exempt from public records requirements and those that

<sup>19</sup> Section 24(c), Art. I of the State Constitution.

STORAGE NAME: h1019d.HHSC.DOCX

There is a difference between records the Legislature has determined to be exempt from public records requirements and those that have been determined to be confidential and exempt. If the Legislature has determined the information to be confidential and exempt then the information is not subject to inspection. Also, if the information is deemed to be confidential and exempt it may only be released to those person and entities designated in statute. However, the agency is not prohibited from disclosing the records in all circumstances where the records are only exempt from public records requirements. 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); see Attorney General Opinion 85-62 (August 1, 1985).

#### D. FISCAL COMMENTS:

None.

#### III. COMMENTS

#### A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. The bill does not appear to require counties or municipalities to take an action requiring the expenditure of funds, reduce the authority that counties or municipalities have to raise revenue in the aggregate, nor reduce the percentage of state tax shared with counties or municipalities.

### 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 or expanded public records exemption. The bill creates a public record exemption; 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 a public record exemption; thus, it includes a public necessity statement.

## Breadth of Exemption

Article I, s. 24(c) of the State Constitution requires a newly created public record or public meeting exemption to be no broader than necessary to accomplish the stated purpose of the law. The bill creates a public record exemption for information relating to the identification and location of safe houses. The exemption does not appear to be in conflict with the constitutional requirement that the exemption must be no broader than necessary to accomplish its purpose.

## **B. RULE-MAKING AUTHORITY:**

None.

### C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

#### IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 3, 2012, the Healthy Families Subcommittee adopted a strike-all amendment. The amendment made the following changes:

- Specified that the address of safe houses and safe foster homes, rather than safe houses and shortterm safe houses, are exempt and confidential from public records to conform the language with the changes made in PCB HFS 14-02;
- Consolidated the public records exemption to one chapter of law; and
- Exempted the address of safe houses and safe foster homes from all state and local agencies, rather than only the department of children and families and local government agencies.

The analysis is drafted to the committee substitute as passed by the Healthy Families Subcommittee.

STORAGE NAME: h1019d.HHSC.DOCX

CS/HB 1019 2014

1	A bill to be entitled
2	An act relating to public records; amending s.
3	409.1678, F.S.; providing an exemption from public
4	records requirements for information about the
5	location of safe houses and safe foster homes held by
6	an agency; providing for future legislative review and
7	repeal of the exemption; providing a statement of
8	public necessity; providing a contingent effective
9	date.
10	
11	Be It Enacted by the Legislature of the State of Florida:
12	
13	Section 1. Subsection (5) is added to section 409.1678,
14	Florida Statutes, to read:
15	409.1678 Safe harbor for children who are victims of
16	sexual exploitation
17	(5)(a) Information held by an agency as defined in s.
18	119.011 about the location of safe houses and safe foster homes
19	is confidential and exempt from s. 119.07(1) and s. 24(a), Art.
20	I of the State Constitution.
21	(b) Information about the location of safe houses and safe
22	foster homes may be provided to an agency, as defined in s.
23	119.011, as necessary to maintain health and safety standards
24	and to address emergency situations in the safe house and safe
25	foster home.
26	(c) This subsection is subject to the Open Government

Page 1 of 3

CS/HB 1019 2014

271 Sunset Review Act in accordance with s. 119.15 and shall stand 28 repealed on October 2, 2019, unless reviewed and saved from 29 repeal through reenactment by the Legislature. 30 Section 2. The Legislature finds that it is a public necessity that information about the location of safe houses and 31 safe foster homes held by an agency, as defined in s. 119.011, 32 33 Florida Statutes, be made confidential and exempt from s. 34 119.07(1), Florida Statutes, and s. 24(a), Article I of the 35 State Constitution. Safe houses and safe foster homes are 36 intended as refuges for sexually exploited victims from those who exploited them. If the individuals who victimized these 37 38 people were able to learn the location of such safe houses, they 39 may attempt to contact their victims, exploit their 40 vulnerabilities, and return them to the situations in which they 41 were victimized. Even without the return of these victims to 42 their former situations, additional contact with those who 43 victimized them would have the effect of continuing their 44 victimization and inhibiting their recoveries. Additionally, 45 knowledge about the location of safe houses and safe foster 46 homes could enable other individuals to locate and attempt to 47 victimize the residents. Therefore, it is the finding of the Legislature that such information must be made confidential and 48 49 exempt from public disclosure. 50 Section 3. This act shall take effect on the same date 51 that HB 1017 or similar legislation relating to human 52 trafficking takes effect, if such legislation is adopted in the

Page 2 of 3

CS/HB 1019 2014

same legislative session or an extension thereof and becomes a law.

Page 3 of 3



COMMITTEE/SUBCOMMITTEE ACTION

# COMMITTEE/SUBCOMMITTEE AMENDMENT Bill No. CS/HB 1019 (2014)

Amendment No.

ADOPTED	(Y/N)
ADOPTED AS AMENDED	(Y/N)
ADOPTED W/O OBJECTION	(Y/N)
FAILED TO ADOPT	(Y/N)
WITHDRAWN	(Y/N)
OTHER	
Committee Representative Spano of	fered the following:
Amendment (with ti	ttle amendment)
Remove everything	after the enacting clause and insert:
Section 1. Subsection	(5) is added to section 409.1678, Florida
Statutes, to read:	
400 1680 0-5-1	
409.1678 Sale nar	rbor for children who are victims of

(5) (a) Information about the location of a safe house, safe foster home, or other residential facility serving victims of sexual exploitation, as defined in section 39.01 (67)(g), which is held by an agency, as defined in s. 119.011, is confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

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sexual exploitation.-



# COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. CS/HB 1019 (2014)

Amendment No.

(b) Information about the location of a safe house, safe	<u> </u>
foster home, or other residential facility serving victims of	
sexual exploitation, as defined in section 39.01(67)(g), may k	<u>se</u>
provided to an agency, as defined in s. 119.011, as necessary	to
maintain health and safety standards and to address emergency	
situations in the safe house, safe foster home, or other	
residential facility serving victims of sexual exploitation, a	ıs
defined in section 39.01 (67)(g).	

- (c) This subsection 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. Subsection (8) is added to section 787.06,
  Florida Statutes, to read:
  - 787.06 Human trafficking.-
- (8) (a) Information about the location of a residential facility offering services for adult victims of human trafficking involving commercial sexual activity, which is held by an agency, as defined in s. 119.011, is confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.
- (b) Information about the location of a residential facility offering services for adult victims of human trafficking involving commercial sexual activity may be provided to an agency, as defined in s. 119.011, as necessary to maintain health and safety standards and to address emergency situations

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# COMMITTEE/SUBCOMMITTEE AMENDMENT Bill No. CS/HB 1019 (2014)

Amendment No.

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in the residential facility offering services for adult victims of human trafficking involving commercial sexual activity.

(c) This subsection 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 3. The Legislature finds that it is a public necessity that information about the location of safe houses, safe foster homes, and other residential facilities serving victims of sexual exploitation, as defined in section 39.01 (67) (q), Florida Statutes, or adult victims of human trafficking involving commercial sexual activity, held by an agency, as defined in s. 119.011, Florida Statutes, be made confidential and exempt from s. 119.07(1), Florida Statutes, and s. 24(a), Article I of the State Constitution. Safe houses, safe foster homes, and other residential facilities serving victims of sexual exploitation, as defined in section 39.01 (67)(g), Florida Statutes, or adult victims of human trafficking involving commercial sexual activity, are intended as refuges for sexually exploited victims from those who exploited them. If the individuals who victimized these people were able to learn the location of such facilities, they may attempt to contact their victims, exploit their vulnerabilities, and return them to the situations in which they were victimized. Even without the return of these victims to their former situations, additional contact with those who victimized them would have the effect of

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# COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. CS/HB 1019 (2014)

Amendment No.

Additionally, knowledge about the location of safe houses, safe foster homes, and other residential facilities serving victims of sexual exploitation, as defined in section 39.01 (67)(g), Florida Statutes, or adult victims of human trafficking involving commercial sexual activity, could enable other individuals to locate and attempt to victimize the residents. Therefore, it is the finding of the Legislature that such information must be made confidential and exempt from public records requirements.

Section 4. This act shall take effect on the same date that HB 1017, or HB 7041, or similar legislation relating to human trafficking, takes effect, if such legislation is adopted in the same legislative session or an extension thereof becomes a law.

## TITLE AMENDMENT

Remove everything before the enacting clause and insert:
An act relating to public records; amending s.
409.1678, F.S.; providing an exemption from public
records requirements for information about the
location of safe houses, safe foster homes, and other
residential facilities serving victims of sexual
exploitation held by an agency; providing for future

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# COMMITTEE/SUBCOMMITTEE AMENDMENT Bill No. CS/HB 1019 (2014)

## Amendment No.

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legislative review and repeal of the exemption; amending s. 787.06, F.S.; providing an exemption from public records requirements for information about the location of residential facilities serving adult victims of human trafficking involving commercial sexual activity held by an agency; providing for future legislative review and repeal of the exemption; providing a statement of public necessity; providing a contingent effective date.

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# **HOUSE OF REPRESENTATIVES STAFF ANALYSIS**

BILL #:

CS/HB 1225 HIV Testing

SPONSOR(S): Health Quality Subcommittee; Saunders and others

TIED BILLS:

IDEN./SIM. BILLS: SB 1470

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	11 Y, 0 N, As CS	Castagna	O'Callaghan
2) Health & Human Services Committee		Castagna 🔨	Calamas &

#### **SUMMARY ANALYSIS**

The bill relates to testing for Human Immunodeficiency Virus (HIV). HIV is an immune system debilitating virus that can lead to fatal acquired immunodeficiency syndrome (AIDS). Widespread testing prevents new HIV infections through awareness, and allows infected individuals to receive early treatment, which improves the lives of those living with HIV.

The bill defines "health care setting" and a "nonhealth care setting" for the purpose of differentiating HIV testing requirements. The bill updates the definition of "preliminary HIV test" to reflect advances in HIV testing.

The bill revises the HIV testing requirement for health care settings to no longer require informed consent from the HIV test subject and establishes new notification requirements. The bill retains the requirement to obtain informed consent from a test subject when HIV testing is performed in nonhealth care settings.

The bill provides that the Department of Health county health departments (CHDs) can operate as both a health care setting and a nonhealth care setting by recognizing testing programs within CHDs as nonhealth care settings.

The bill makes technical changes throughout s. 384.004, F.S., to clarify existing language and makes many conforming changes.

The bill appears to have no fiscal impact on state or local governments.

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

This document does not reflect the intent or official position of the bill sponsor or House of Representatives. STORAGE NAME: h1225b.HHSC.DOCX

#### **FULL ANALYSIS**

## I. SUBSTANTIVE ANALYSIS

## A. EFFECT OF PROPOSED CHANGES:

#### **Current Situation**

## Human Immunodeficiency Virus

Human Immunodeficiency Virus (HIV) is an immune system debilitating virus that can lead to fatal acquired immunodeficiency syndrome (AIDS). HIV affects specific cells of the immune system and over time the virus can destroy so many of these cells that the body cannot fight off infections and disease. There is no cure for HIV; yet, with proper medical care, HIV can be controlled. Untreated, HIV is almost always fatal.<sup>1</sup>

HIV is typically spread by having unprotected sex with someone who has HIV or sharing needles, syringes, or other equipment used to prepare injection drugs with someone who has HIV.<sup>2</sup>

# **HIV Testing**

Data from 2009 indicates that of the estimated 1.1 million adults in the United States who are infected with the virus, 18% were unaware of their infection.<sup>3</sup> HIV testing is essential for improving the health of people living with HIV and reducing new HIV infections. It is recommended that testing occur as part of a routine healthcare visit. This is especially important for people who may not consider themselves at risk for HIV.<sup>4</sup> HIV testing is nationally recommended for people ages 15 to 65 and pregnant women, including those in labor who have not been tested and whose HIV status is unknown.<sup>5</sup>

The most common types of HIV tests check for HIV antibodies in the body. In these tests, blood, oral fluid, or urine can be used to obtain results. Antibody tests are considered preliminary; if the result is positive, follow-up diagnostic testing is required to confirm the presence of the virus. Antigen tests are another form of testing, which are not as readily available as antibody tests. Antigen tests can be used to diagnose HIV infection 1 to 3 weeks after a person is first infected with HIV and a blood sample is required to obtain results.<sup>6</sup>

Over the past several decades there have been many advances in medical technology to increase access and utilization of HIV testing. Legal and programmatic advances have streamlined testing services to provide confidentiality, and, in some cases, anonymity to test subjects, to encourage widespread testing.

STORAGE NAME: h1225b.HHSC.DOCX

<sup>&</sup>lt;sup>1</sup> "About HIV/AIDS," Centers for Disease Control and Prevention, accessible at: <a href="http://www.cdc.gov/hiv/basics/whatishiv.html#panel0">http://www.cdc.gov/hiv/basics/whatishiv.html#panel0</a> (last accessed March 19, 2014).

<sup>&</sup>lt;sup>2</sup> There are several less common ways HIV can be spread including: being born to an infected mother; being stuck with an HIV contaminated needle (which is a risk mainly for health care workers); and receiving blood transfusions, blood products, or organ/tissue transplants that are contaminated with HIV. "HIV Transmission," Centers for Disease Control and Prevention, accessible at: <a href="http://www.cdc.gov/hiv/basics/transmission.html">http://www.cdc.gov/hiv/basics/transmission.html</a> (last accessed March 19, 2014).

<sup>&</sup>lt;sup>3</sup> "HIV in the United States: At a Glance," Centers for Disease Control and Prevention, accessible at: http://www.cdc.gov/hiv/statistics/basics/ataglance.html (last accessed March 20, 2014).

<sup>&</sup>lt;sup>4</sup> In Florida, only 48% of adults under 65 reported having ever been tested for HIV. Department of Health, Florida Charts, accessible at: <a href="http://www.floridacharts.com/charts/Brfss/DataViewer.aspx?bid=29">http://www.floridacharts.com/charts/Brfss/DataViewer.aspx?bid=29</a> (last accessed March 20, 2014).

<sup>&</sup>lt;sup>5</sup> "Screening for HIV, Current Recommendations," U.S. Preventive Services Task Force, Aril 2013, accessible at: <a href="http://www.uspreventiveservicestaskforce.org/uspstf/uspshivi.htm">http://www.uspreventiveservicestaskforce.org/uspstf/uspshivi.htm</a> (last accessed March 20, 2014).

<sup>&</sup>lt;sup>6</sup> "Types of HIV Tests," U.S. Department of Health and Human Services, accessible at: <a href="http://aids.gov/hiv-aids-basics/prevention/hiv-testing/hiv-test-types/index.html">http://aids.gov/hiv-aids-basics/prevention/hiv-testing/hiv-test-types/index.html</a> (last accessed March 20, 2014).

## Florida HIV Testing

Section 381,004, F.S., which governs HIV testing in Florida and requires certain procedures to be followed when tests are given, was enacted to create an environment in Florida in which people will agree to or seek out HIV testing because they are sufficiently informed about HIV infection and assured about the privacy of a decision to be tested. To promote informed patient decision-making, s. 381.004, F.S., prohibits HIV testing without a person's knowledge and consent, except under certain defined circumstances.8 and gives the patient special rights to control who learns of the HIV test results.9

As stated in s. 381.004(2)(a), F.S., informed consent<sup>10</sup> must be obtained by all persons receiving an HIV test. Consent must be in writing unless it is documented in the person's medical record that they have been educated about the test and given consent to be tested. The right to confidential treatment of information identifying the subject of the test and the results must then be explained to the test subject. 11 The subject of the test must be informed that a positive HIV test result will be reported to the local Department of Health county health department (CHD) with enough information to identify the test subject. 12 The test subject must also be informed about the location of local sites at which anonymous testing<sup>13</sup> is available.<sup>14</sup>

The Department of Health has developed a comprehensive program for preventing the spread of HIV/AIDS with many testing options available throughout the state in a variety of settings. CHDs<sup>15</sup> are the primary outlet for state-sponsored HIV programs and, in addition to testing services, CHDs provide prevention outreach and education free to the public.

## **Effect of Proposed Changes**

The bill provides a definition for health care setting and nonhealth care setting to differentiate between the two for the purpose of HIV testing.

Health Care Setting

"Health care setting" is defined in the bill as a setting devoted to both the diagnosis and care of persons, such as:

STORAGÉ NAME: h1225b.HHSC.DOCX

<sup>&</sup>lt;sup>7</sup> "Florida's Omnibus AIDS Act," Jack P Hartog, Department of Health, accessible at: www.floridahealth.gov/diseases.../Omnibusbooklet-update-2013.pdf (last accessed March 21, 2014).

Section 381.004(2)(h), F.S., lists the exceptions to the requirement to obtain informed consent, including: when a person is tested for sexually transmitted diseases, when blood, plasma, or other human fluids or tissues are donated, when a determination for appropriate emergency medical care or treatment is required, during an autopsy, when testing pregnant women, when a defendant is charged with sexual battery and is consented to by the defendant, pursuant to court order, or for certain research purposes.

<sup>&</sup>lt;sup>10</sup> Informed consent is a process of communication between patient and provider through which an informed patient can choose whether to undergo HIV testing or decline to do so. Elements of informed consent typically include providing oral or written information regarding HIV, the risks and benefits of testing, the implications of HIV test results, how test results will be communicated, and the opportunity to ask questions. Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings, Centers for Disease Control and Prevention, September 22, 2006, accessible at: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm (last accessed March 19, 2014).

Under limited circumstances, test results may be released to certain persons, entities, or the Agency for Health Care Administration

pursuant to s. 395.3025, F.S. <sup>12</sup> HIV is a notifiable disease and positive test results must be reported to the Department of Health to effectively monitor disease trends, assess effectiveness of prevention and control measures, identify populations at a higher risk, and develop public health policies. National Notifiable Disease Surveillance System, Centers for Disease Control and Prevention, accessible at: http://wwwn.cdc.gov/nndss/ (last accessed March 20, 2014).

<sup>&</sup>lt;sup>13</sup> Anonymous testing is available at some testing sites and does not require test subject to identify themselves. When a person takes an anonymous HIV test, they are given a unique identifier that allows only them to access their test results. Centers for Disease Control and Prevention, Testing, accessible at: http://www.cdc.gov/actagainstaids/basics/testing.html (last accessed March 20, 2014).

County Health Departments are the local sector of the Department of Health, providing public health services in all 67 Florida counties. Their core functions are infectious disease prevention and control, basic family health services, and environmental health services. County Health Departments, Department of Health, accessible at: http://www.floridahealth.gov/public-health-in-yourlife/county-health-departments/index.html (last accessed March 20, 2014).

- County health department clinics,
- · Hospital emergency departments,
- Urgent care clinics,
- · Substance abuse treatment clinics,
- Primary care settings,
- · Community clinics,
- Mobile medical clinics, and
- Correctional health care facilities.

The bill changes the current requirement for informed consent for HIV testing performed in a health care setting by requiring a health care provider to instead notify the test subject that the test is planned, and provide information to the test subject on HIV, the risks of being tested, and implications of HIV test results. The provider must also inform the test subject that they have the right to decline the test. The explanation of the right to confidential treatment of information identifying the test subject and the results of the test as provided in current law<sup>16</sup> is retained. The provider must document in the person's medical record if the test was declined.

## Nonhealth Care Setting

"Nonhealth care setting" is defined in the bill as a site that conducts HIV testing solely for diagnosis purposes, not treatment. Such settings do not provide medical treatment but may include:

- Community-based organizations,
- Outreach settings.
- · County health department HIV testing programs, and
- Mobile health vehicles.

The bill clarifies that informed consent remains a requirement for testing performed in nonhealth care settings.

## County Health Departments

For purposes of HIV testing, CHDs will operate as both health care and nonhealth care settings. If a person is to be tested at a CHD, or a CHD sponsored outreach event, for HIV testing only, the testing will be conducted following nonhealth care setting testing requirements. If a person is being seen at a CHD clinic, such as an STD or family planning clinic, the provider must meet health care setting notification requirements.

### Confidentiality

For both health care and nonhealth care settings, the test subject must be informed that a positive HIV test result will be reported to the local CHD with sufficient information to identify the test subject. The subject must also be informed of the availability of sites at which anonymous testing is performed and requires CHDs to maintain a list of those sites. The sites' locations, telephone numbers, and hours of operation must be kept on file with the CHD. All of these requirements exist in current law, but the bill ensures these requirements apply to both health care and nonhealth care settings.

The bill authorizes hospitals licensed under chapter 395, F.S., to release HIV test results, as is currently authorized, if the hospital notifies the patient of the confidentiality protections for HIV test results included in medical records. The bill conforms this requirement to the notification requirements in the bill related to health care setting HIV testing.

<sup>&</sup>lt;sup>16</sup> Section 381.004 (2)(e), F.S. **STORAGE NAME**: h1225b.HHSC.DOCX **DATE**: 4/1/2014

The bill updates the definition of "preliminary HIV tests" to reflect advances in HIV testing and deletes obsolete language.

The bill also makes conforming changes and corrects a cross-reference.

### **B. SECTION DIRECTORY:**

Section 1. Amends s. 381.004, F.S., relating to HIV testing.

Section 2. Amends s. 456.032, F.S., relating to Hepatitis B or HIV carriers.

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.

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:

C. DRAFTING ISSUES OR OTHER COMMENTS: None.

### IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 24, 2014, the Health Quality Subcommittee adopted an amendment and passed HB 1225 as a committee substitute (CS). The amendment reinstates current law which does not require informed consent when testing pregnant women for HIV.

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

STORAGE NAME: h1225b.HHSC.DOCX

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A bill to be entitled

An act relating to HIV testing; amending s. 381.004, F.S.; revising and adding definitions; differentiating between the notification and consent procedures for performing an HIV test in a health care setting and a nonhealth care setting; amending s. 456.032, F.S.; conforming a cross-reference; providing an effective date.

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

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Section 1. Subsection (1), paragraphs (a), (b), (g), and (h) of subsection (2), and paragraph (d) of subsection (4) of section 381.004, Florida Statutes, are amended, and subsection (1) of that section is reordered, to read:

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381.004 HIV testing.-

17 18 (1) DEFINITIONS.—As used in this section:

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(a) "Health care setting" means a setting devoted to both the diagnosis and care of persons, such as county health department clinics, hospital emergency departments, urgent care clinics, substance abuse treatment clinics, primary care settings, community clinics, mobile medical clinics, and

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correctional health care facilities.

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(b) (a) "HIV test" means a test ordered after July 6, 1988, to determine the presence of the antibody or antigen to human immunodeficiency virus or the presence of human immunodeficiency

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Page 1 of 16

27 virus infection.

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- (c) (b) "HIV test result" means a laboratory report of a human immunodeficiency virus test result entered into a medical record on or after July 6, 1988, or any report or notation in a medical record of a laboratory report of a human immunodeficiency virus test. As used in this section, The term "HIV test result" does not include test results reported to a health care provider by a patient.
- (d) "Nonhealth care setting" means a site that conducts
  HIV testing for the sole purpose of identifying HIV infection.
  Such setting does not provide medical treatment but may include community-based organizations, outreach settings, county health department HIV testing programs, and mobile vans.
  - (f) (c) "Significant exposure" means:
- 1. Exposure to blood or body fluids through needlestick, instruments, or sharps;
- 2. Exposure of mucous membranes to visible blood or body fluids, to which universal precautions apply according to the National Centers for Disease Control and Prevention, including, without limitations, the following body fluids:
  - a. Blood.
  - b. Semen.
  - c. Vaginal secretions.
- d. Cerebrospinal Cerebro-spinal fluid (CSF).
  - e. Synovial fluid.
  - f. Pleural fluid.

Page 2 of 16

g. Peritoneal fluid.

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- h. Pericardial fluid.
- i. Amniotic fluid.
- j. Laboratory specimens that contain HIV (e.g., suspensions of concentrated virus); or
- 3. Exposure of skin to visible blood or body fluids, especially when the exposed skin is chapped, abraded, or afflicted with dermatitis or the contact is prolonged or involving an extensive area.
- <u>(e)(d)</u> "Preliminary HIV test" means an antibody <u>or</u> antibody-antigen screening test, such as the enzyme-linked immunosorbent assays (IA), or a rapid test approved by the federal Food and Drug Administration (ELISAs) or the Single-Use Diagnostic System (SUDS).
- <u>(g)(e)</u> "Test subject" or "subject of the test" means the person upon whom an HIV test is performed, or the person who has legal authority to make health care decisions for the test subject.
- (2) HUMAN IMMUNODEFICIENCY VIRUS TESTING; INFORMED CONSENT; RESULTS; COUNSELING; CONFIDENTIALITY.—
  - (a) Before performing an HIV test:
- 1. In a health care setting, the health care provider shall notify the person to be tested that the test is planned, provide information about the test, and advise the person that he or she has the right to decline the test. The health care provider shall also explain the right to confidential treatment

Page 3 of 16

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of information identifying the subject of the test and the results of the test as provided by law. If a person declines the test, the health care provider shall note that fact in the person's medical record. No person in this state shall order a test designed to identify the human immunodeficiency virus, or its antigen or antibody, without first obtaining the informed consent of the person upon whom the test is being performed, except as specified in paragraph (h). Informed consent shall be preceded by an explanation of the right to confidential treatment of information identifying the subject of the test and the results of the test to the extent provided by law. Information shall also be provided on the fact that a positive HIV test result will be reported to the county health department with sufficient information to identify the test subject and on the availability and location of sites at which anonymous testing is performed. As required in paragraph (3)(c), each county health department shall maintain a list of sites at which anonymous testing is performed, including the locations, phone numbers, and hours of operation of the sites. Consent need not be in writing provided there is documentation in the medical record that the test has been explained and the consent has been obtained.

2. In a nonhealth care setting, a provider shall obtain the informed consent of the person upon whom the test is being performed. Informed consent shall be preceded by an explanation of the right to confidential treatment of information

Page 4 of 16

identifying the subject of the test and the results of the test
as provided by law.

- The test subject shall also be informed that a positive HIV test result will be reported to the county health department with sufficient information to identify the test subject and on the availability and location of sites at which anonymous testing is performed. As required in paragraph (3)(c), each county health department shall maintain a list of sites at which anonymous testing is performed, including the locations, telephone
- (b) Except as provided in paragraph (h), informed consent must be obtained from a legal guardian or other person authorized by law if when the person:

numbers, and hours of operation of the sites.

- 1. Is not competent, is incapacitated, or is otherwise unable to make an informed judgment; or
- 2. Has not reached the age of majority, except as provided in s. 384.30.
- (g) Human immunodeficiency virus test results contained in the medical records of a hospital licensed under chapter 395 may be released in accordance with s. 395.3025 without being subject to the requirements of subparagraph (e)2., subparagraph (e)9., or paragraph (f) if; provided the hospital has notified the patient of the limited confidentiality protections afforded HIV test results contained in hospital medical records obtained written informed consent for the HIV test in accordance with

Page 5 of 16

131 provisions of this section.

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- (h) Notwithstanding the provisions of paragraph (a), informed consent is not required:
- 1. When testing for sexually transmissible diseases is required by state or federal law, or by rule including the following situations:
- a. HIV testing pursuant to s. 796.08 of persons convicted of prostitution or of procuring another to commit prostitution.
- b. HIV testing of inmates pursuant to s. 945.355 <u>before</u> prior to their release from prison by reason of parole, accumulation of gain-time credits, or expiration of sentence.
- c. Testing for HIV by a medical examiner in accordance with s. 406.11.
  - d. HIV testing of pregnant women pursuant to s. 384.31.
- 2. Those exceptions provided for blood, plasma, organs, skin, semen, or other human tissue pursuant to s. 381.0041.
- 3. For the performance of an HIV-related test by licensed medical personnel in bona fide medical emergencies <u>if</u> when the test results are necessary for medical diagnostic purposes to provide appropriate emergency care or treatment to the person being tested and the patient is unable to consent, as supported by documentation in the medical record. Notification of test results in accordance with paragraph (c) is required.
- 4. For the performance of an HIV-related test by licensed medical personnel for medical diagnosis of acute illness where, in the opinion of the attending physician, providing

Page 6 of 16

notification obtaining informed consent would be detrimental to the patient, as supported by documentation in the medical record, and the test results are necessary for medical diagnostic purposes to provide appropriate care or treatment to the person being tested. Notification of test results in accordance with paragraph (c) is required if it would not be detrimental to the patient. This subparagraph does not authorize the routine testing of patients for HIV infection without notification informed consent.

- 5. If When HIV testing is performed as part of an autopsy for which consent was obtained pursuant to s. 872.04.
- 6. For the performance of an HIV test upon a defendant pursuant to the victim's request in a prosecution for any type of sexual battery where a blood sample is taken from the defendant voluntarily, pursuant to court order for any purpose, or pursuant to the provisions of s. 775.0877, s. 951.27, or s. 960.003; however, the results of an any HIV test performed shall be disclosed solely to the victim and the defendant, except as provided in ss. 775.0877, 951.27, and 960.003.
  - 7. If When an HIV test is mandated by court order.
- 8. For epidemiological research pursuant to s. 381.0031, for research consistent with institutional review boards created by 45 C.F.R. part 46, or for the performance of an HIV-related test for the purpose of research, if the testing is performed in a manner by which the identity of the test subject is not known and may not be retrieved by the researcher.

Page 7 of 16

9. If When human tissue is collected lawfully without the consent of the donor for corneal removal as authorized by s. 765.5185 or enucleation of the eyes as authorized by s. 765.519.

- 10. For the performance of an HIV test upon an individual who comes into contact with medical personnel in such a way that a significant exposure has occurred during the course of employment or within the scope of practice and where a blood sample is available which that was taken from that individual voluntarily by medical personnel for other purposes. The term "medical personnel" includes a licensed or certified health care professional; an employee of a health care professional or health care facility; employees of a laboratory licensed under chapter 483; personnel of a blood bank or plasma center; a medical student or other student who is receiving training as a health care professional at a health care facility; and a paramedic or emergency medical technician certified by the department to perform life-support procedures under s. 401.23.
- a. Before performing Prior to performance of an HIV test on a voluntarily obtained blood sample, the individual from whom the blood was obtained shall be requested to consent to the performance of the test and to the release of the results. If consent cannot be obtained within the time necessary to perform the HIV test and begin prophylactic treatment of the exposed medical personnel, all information concerning the performance of an HIV test and any HIV test result shall be documented only in the medical personnel's record unless the individual gives

Page 8 of 16

written consent to entering this information on the individual's medical record.

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- Reasonable attempts to locate the individual and to obtain consent shall be made, and all attempts must be documented. If the individual cannot be found or is incapable of providing consent, an HIV test may be conducted on the available blood sample. If the individual does not voluntarily consent to the performance of an HIV test, the individual shall be informed that an HIV test will be performed, and counseling shall be furnished as provided in this section. However, HIV testing shall be conducted only after appropriate medical personnel under the supervision of a licensed physician documents, in the medical record of the medical personnel, that there has been a significant exposure and that, in accordance with the written protocols based on the National Centers for Disease Control and Prevention guidelines on HIV postexposure prophylaxis and in the physician's medical judgment, the information is medically necessary to determine the course of treatment for the medical personnel.
- c. Costs of <u>an</u> any HIV test of a blood sample performed with or without the consent of the individual, as provided in this subparagraph, shall be borne by the medical personnel or the employer of the medical personnel. However, costs of testing or treatment not directly related to the initial HIV tests or costs of subsequent testing or treatment may not be borne by the medical personnel or the employer of the medical personnel.

Page 9 of 16

d. In order to <u>use utilize</u> the provisions of this subparagraph, the medical personnel must <del>either</del> be tested for HIV pursuant to this section or provide the results of an HIV test taken within 6 months <u>before</u> prior to the significant exposure if such test results are negative.

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- e. A person who receives the results of an HIV test pursuant to this subparagraph shall maintain the confidentiality of the information received and of the persons tested. Such confidential information is exempt from s. 119.07(1).
- f. If the source of the exposure will not voluntarily submit to HIV testing and a blood sample is not available, the medical personnel or the employer of such person acting on behalf of the employee may seek a court order directing the source of the exposure to submit to HIV testing. A sworn statement by a physician licensed under chapter 458 or chapter 459 that a significant exposure has occurred and that, in the physician's medical judgment, testing is medically necessary to determine the course of treatment constitutes probable cause for the issuance of an order by the court. The results of the test shall be released to the source of the exposure and to the person who experienced the exposure.
- 11. For the performance of an HIV test upon an individual who comes into contact with medical personnel in such a way that a significant exposure has occurred during the course of employment or within the scope of practice of the medical personnel while the medical personnel provides emergency medical

Page 10 of 16

treatment to the individual; or notwithstanding s. 384.287, an individual who comes into contact with nonmedical personnel in such a way that a significant exposure has occurred while the nonmedical personnel provides emergency medical assistance during a medical emergency. For the purposes of this subparagraph, a medical emergency means an emergency medical condition outside of a hospital or health care facility that provides physician care. The test may be performed only during the course of treatment for the medical emergency.

- a. An individual who is capable of providing consent shall be requested to consent to an HIV test <u>before</u> prior to the testing. If consent cannot be obtained within the time necessary to perform the HIV test and begin prophylactic treatment of the exposed medical personnel and nonmedical personnel, all information concerning the performance of an HIV test and its result, shall be documented only in the medical personnel's or nonmedical personnel's record unless the individual gives written consent to entering this information <u>in on</u> the individual's medical record.
- b. HIV testing shall be conducted only after appropriate medical personnel under the supervision of a licensed physician documents, in the medical record of the medical personnel or nonmedical personnel, that there has been a significant exposure and that, in accordance with the written protocols based on the National Centers for Disease Control and Prevention guidelines on HIV postexposure prophylaxis and in the physician's medical

Page 11 of 16

judgment, the information is medically necessary to determine the course of treatment for the medical personnel or nonmedical personnel.

- c. Costs of any HIV test performed with or without the consent of the individual, as provided in this subparagraph, shall be borne by the medical personnel or the employer of the medical personnel or nonmedical personnel. However, costs of testing or treatment not directly related to the initial HIV tests or costs of subsequent testing or treatment may not be borne by the medical personnel or the employer of the medical personnel or nonmedical personnel.
- d. In order to <u>use utilize</u> the provisions of this subparagraph, the medical personnel or nonmedical personnel shall be tested for HIV pursuant to this section or shall provide the results of an HIV test taken within 6 months <u>before prior to</u> the significant exposure if such test results are negative.
- e. A person who receives the results of an HIV test pursuant to this subparagraph shall maintain the confidentiality of the information received and of the persons tested. Such confidential information is exempt from s. 119.07(1).
- f. If the source of the exposure will not voluntarily submit to HIV testing and a blood sample was not obtained during treatment for the medical emergency, the medical personnel, the employer of the medical personnel acting on behalf of the employee, or the nonmedical personnel may seek a court order

Page 12 of 16

directing the source of the exposure to submit to HIV testing. A sworn statement by a physician licensed under chapter 458 or chapter 459 that a significant exposure has occurred and that, in the physician's medical judgment, testing is medically necessary to determine the course of treatment constitutes probable cause for the issuance of an order by the court. The results of the test shall be released to the source of the exposure and to the person who experienced the exposure.

- 12. For the performance of an HIV test by the medical examiner or attending physician upon an individual who expired or could not be resuscitated while receiving emergency medical assistance or care and who was the source of a significant exposure to medical or nonmedical personnel providing such assistance or care.
- a. HIV testing may be conducted only after appropriate medical personnel under the supervision of a licensed physician documents in the medical record of the medical personnel or nonmedical personnel that there has been a significant exposure and that, in accordance with the written protocols based on the National Centers for Disease Control and Prevention guidelines on HIV postexposure prophylaxis and in the physician's medical judgment, the information is medically necessary to determine the course of treatment for the medical personnel or nonmedical personnel.
- b. Costs of  $\underline{an}$   $\underline{any}$  HIV test performed under this subparagraph may not be charged to the deceased or to the family

Page 13 of 16

of the deceased person.

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- c. For the provisions of this subparagraph to be applicable, the medical personnel or nonmedical personnel must be tested for HIV under this section or must provide the results of an HIV test taken within 6 months before the significant exposure if such test results are negative.
- d. A person who receives the results of an HIV test pursuant to this subparagraph shall comply with paragraph (e).
- 13. For the performance of an HIV-related test medically indicated by licensed medical personnel for medical diagnosis of a hospitalized infant as necessary to provide appropriate care and treatment of the infant if when, after a reasonable attempt, a parent cannot be contacted to provide consent. The medical records of the infant must shall reflect the reason consent of the parent was not initially obtained. Test results shall be provided to the parent when the parent is located.
- 14. For the performance of HIV testing conducted to monitor the clinical progress of a patient previously diagnosed to be HIV positive.
- 15. For the performance of repeated HIV testing conducted to monitor possible conversion from a significant exposure.
- (4) HUMAN IMMUNODEFICIENCY VIRUS TESTING REQUIREMENTS;
  REGISTRATION WITH THE DEPARTMENT OF HEALTH; EXEMPTIONS FROM
  REGISTRATION.—No county health department and no other person in this state shall conduct or hold themselves out to the public as conducting a testing program for acquired immune deficiency

Page 14 of 16

syndrome or human immunodeficiency virus status without first registering with the Department of Health, reregistering each year, complying with all other applicable provisions of state law, and meeting the following requirements:

- (d) A program in a health care setting shall meet the notification criteria contained in subparagraph (2)(a)1. A program in a nonhealth care setting shall meet all informed consent criteria contained in subparagraph (2)(a)2. The program must meet all the informed consent criteria contained in subsection (2).
- Section 2. Subsection (2) of section 456.032, Florida Statutes, is amended to read:

456.032 Hepatitis B or HIV carriers.-

(2) Any person licensed by the department and any other person employed by a health care facility who contracts a blood-borne infection shall have a rebuttable presumption that the illness was contracted in the course and scope of his or her employment, provided that the person, as soon as practicable, reports to the person's supervisor or the facility's risk manager any significant exposure, as that term is defined in s. 381.004(1)(f) 381.004(1)(e), to blood or body fluids. The employer may test the blood or body fluid to determine if it is infected with the same disease contracted by the employee. The employer may rebut the presumption by the preponderance of the evidence. Except as expressly provided in this subsection, there shall be no presumption that a blood-borne infection is a job-

Page 15 of 16

related injury or illness.

Section 3. This act shall take effect July 1, 2014.

Page 16 of 16



# COMMITTEE/SUBCOMMITTEE AMENDMENT Bill No. CS/HB 1225 (2014)

Amendment No.

COMMITTE	E/SUBCOMMITTEE	ACTION
ADOPTED		(Y/N)
ADOPTED AS AM	ENDED	(Y/N)
ADOPTED W/O O	BJECTION	(Y/N)
FAILED TO ADO	PT	(Y/N)
WITHDRAWN		(Y/N)
OTHER		

Committee/Subcommittee hearing bill: Health & Human Services Committee

Representative Pigman offered the following:

#### Amendment

Remove lines 74-82 and insert:

1. In a health care setting, the person to be tested shall be provided information about the test and shall be notified that the test is planned, that he or she has the right to decline the test, and that he or she has the right to confidential treatment of information identifying the subject of the test and of the results of the test as provided by the law. If the person to be tested declines the test, such decision shall be documented in the medical record. No person in this state shall order a

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## HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #:

CS/HB 479 Substance Abuse Services

SPONSOR(S): Healthy Families Subcommittee; Hager and others

TIED BILLS:

**IDEN./SIM. BILLS:** 

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Healthy Families Subcommittee	12 Y, 0 N, As CS	McElroy	Brazzell
2) Health Care Appropriations Subcommittee	12 Y, 0 N	Fontaine	Pridgeon
3) Health & Human Services Committee		McElroy CM	Calamas 🕊

#### **SUMMARY ANALYSIS**

CS/HB 479 establishes programs for the voluntary certification of recovery residences. The bill defines "recovery residence" as a residential dwelling unit or other form of group housing that is offered or advertised through any form, including oral, written, electronic or printed means, by any person or entity to be a residence that provides a peer-supported, alcohol-free and drug-free living environment.

The bill creates s. 397.487, F.S., to establish a voluntary certification for recovery residences. It requires DCF to select a credentialing entity to issue certificates of compliance and establishes the criteria for selecting the entity. The bill requires the credentialing entity to inspect recovery residences prior to the initial certification and during every subsequent renewal period and to automatically terminate certification if it is not renewed within one year of the issuance date. The bill provides for application, inspection and renewal fees for the certification of a recovery residence. The bill requires all recovery residence staff to pass a Level II background screening. Any costs associated with these screenings are to be borne by the employer, employee or volunteer. It requires the credentialing agency to deny certification, and allows it to suspend or revoke the certification, if a recovery residence fails to meet and maintain certain criteria.

The bill creates s. 397.4871, F.S., to establish a voluntary certification for recovery residences administrators. The bill requires DCF to select a credentialing entity to develop and administer the program. The bill establishes the criteria DCF is to use when selecting a credentialing entity and creating the certification program. The bill requires that all certified recovery residence administrators pass a Level II background screening, and that the costs associated with these screenings be the responsibility of the individual seeking certification. The bill provides for application and renewal fees for the certification of the recovery residence administrator. The bill authorizes the credentialing entity to suspend or revoke certification if a certified recovery residence administrator does not meet and maintain certain criteria.

The bill creates s. 397.4872, F.S., to allow DCF to exempt an individual from the disqualifying offenses of a Level II background screening if the individual meets certain criteria and the recovery residence attests that it is in the best interest of the program. It also requires DCF to publish a list of all recovery residences and recovery residences administrators on its website but allows a recovery residence or recovery residence administrator to be excluded from the list upon written request to DCF.

The bill creates a first degree misdemeanor for any entity or person who advertises as a "certified recovery residence" or "certified recovery residence administrator", respectively, unless the entity or person has obtained certification under this section.

The bill amends s. 397.407, F.S., to require, effective October 1, 2015, a licensed service provider to refer a current or discharged patient only to a recovery residence that holds a valid certificate of compliance, is actively managed by a certified recovery residence administrator, or both, or is owned and operated by a licensed service provider.

The bill has an insignificant, negative fiscal impact on the Department of Children and Families and may also have a negative local jail bed impact.

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

This document does not reflect the intent or official position of the bill sponsor or House of Representatives. STORAGE NAME: h0479b.HHSC.DOCX

**DATE**: 4/1/2014

## **FULL ANALYSIS**

#### I. SUBSTANTIVE ANALYSIS

## A. EFFECT OF PROPOSED CHANGES:

#### **Present Situation**

## Recovery Residences

There is no universally accepted definition of "recovery residence" (also known as "sober home" or "sober living home"). One definition is that recovery residences:

- Are alcohol- and drug-free living environments for individuals in recovery who are attempting to maintain abstinence from alcohol and drugs;
- Offer no formal treatment but perhaps mandate or strongly encourage attendance at 12-step groups; and
- Are self-funded through resident fees, and residents may reside there as long as they are in compliance with the residence's rules.<sup>1</sup>

Some recovery residences voluntarily join coalitions or associations<sup>2</sup> that monitor health, safety, quality, and adherence to the membership requirements for the specific coalition or association.<sup>3</sup> The exact number of recovery residences in Florida is currently unknown.<sup>4</sup>

Multiple studies have found that individuals benefit in their recovery by residing in a recovery residence. For example, an Illinois study found regarding those residing in an Oxford House, a very specific type of recovery residence, that:

[T]hose in the Oxford Houses... had significantly lower substance use (31.3% vs. 64.8%), significantly higher monthly income (\$989.40 vs. \$440.00), and significantly lower incarceration rates (3% vs. 9%). Oxford House participants, by month 24, earned roughly \$550 more per month than participants in the usual-care group. In a single year, the income difference for the entire Oxford House sample corresponds to approximately \$494,000 in additional production. In 2002, the state of Illinois spent an average of \$23,812 per year to incarcerate each drug offender. The lower rate of incarceration among Oxford House versus usual-care participants at 24 months (3% vs. 9%) corresponds to an annual saving of roughly \$119,000 for Illinois. Together, the productivity and incarceration benefits yield an estimated \$613,000 in savings per year, or an average of \$8,173 per Oxford House member.<sup>5</sup>

STORAGE NAME: h0479b.HHSC.DOCX

regulatory entity.

<sup>&</sup>lt;sup>1</sup> A Clean and Sober Place to Live: Philosophy, Structure, and Purported Therapeutic Factors in Sober Living Houses,., J Psychoactive Drugs, Jun 2008; 40(2): 153–159, Douglas L. Polcin, Ed.D., MFT and Diane Henderson, B.A.

<sup>&</sup>lt;sup>2</sup> Id.

<sup>&</sup>lt;sup>3</sup> Id.

<sup>&</sup>lt;sup>4</sup> Recovery Residence Report, Department of Children and Families, Office of Substance Abuse and Mental Health, October 1, 2013, available at <a href="https://www.google.com/url?q=http://www.dcf.state.fl.us/programs/samh/docs/SoberHomesPR/DCFProvisoRpt-SoberHomes.pdf&sa=U&ei=Z6MkU4-nEZCqkAeFnIHoAg&ved=0CAYQFjAA&client=internal-uds-cse&usg=AFQjCNGWYVuZhTcEpRYTnWNvtqqVM3WoDg">https://www.dcf.state.fl.us/programs/samh/docs/SoberHomesPR/DCFProvisoRpt-SoberHomes.pdf&sa=U&ei=Z6MkU4-nEZCqkAeFnIHoAg&ved=0CAYQFjAA&client=internal-uds-cse&usg=AFQjCNGWYVuZhTcEpRYTnWNvtqqVM3WoDg</a> (last visited on March 15, 2014). A commonly expressed theme has been that the number is currently unknown, given that the operation of a recovery residence has not come under the purview of a

<sup>&</sup>lt;sup>5</sup> L. Jason, B. Olson, J., Ferrari, and A. Lo Sasso, *Communal Housing Settings Enhance Substance Abuse Recovery*, 96 American Journal of Public Health (10), (2006), at 1727-1729.

A cost-benefit analysis regarding residing in Oxford Houses found:

While treatment costs were roughly \$3000 higher for the OH group, benefits differed substantially between groups. Relative to usual care, OH enrollees exhibited a mean net benefit of \$29,022 per person. The result suggests that the additional costs associated with OH treatment, roughly \$3000, are returned nearly tenfold in the form of reduced criminal activity, incarceration, and drug and alcohol use as well as increases in earning from employment... even under the most conservative assumption, we find a statistically significant and economically meaningful net benefit to Oxford House of \$17,800 per enrollee over two years.<sup>6</sup>

Additionally, a study in California which focused on recovery residences in Sacramento County and Berkley found:

- Residents at six months were sixteen times more likely to report being abstinent;
- Residents at twelve months were fifteen times more likely to report being abstinent; and
- Residents at eighteen months were six times more likely to report being abstinent.

The Department of Children and Families (DCF) recently conducted a study of recovery residences in Florida. DCF sought public comment relating to community concern for recovery residences. Three common concerns for the recovery residences were the safety of the residents, safety of the neighborhoods and lack of governmental oversight.

Participants at public meetings raised the following concerns:

- Residents being evicted with little or no notice;
- Drug testing might be a necessary part of compliance monitoring;
- Unscrupulous landlords, including an alleged sexual offender who was running a woman's program:
- A recovery residence owned by a bar owner and attached to the bar;
- Residents dying in recovery residences;
- Lack of regulation and harm to neighborhoods;
- Whether state agencies have the resources to enforce regulations and adequately regulate these homes:
- Land use problems, and nuisance issues caused by visitors at recovery residences, including issues with trash, noise, fights, petty crimes, substandard maintenance, and parking:
- Mismanagement of resident moneys or medication;
- Treatment providers that will refer people to any recovery residence:
- Lack of security at recovery residences and abuse of residents:
- The need for background checks of recovery residence staff;
- The number of residents living in some recovery residences and the living conditions in these recovery residences;

<sup>9</sup> Recovery Residence Report, supra footnote 4.

STORAGE NAME: h0479b.HHSC.DOCX

**DATE**: 4/1/2014

<sup>&</sup>lt;sup>6</sup> A. Lo Sasso, E. Byro, L. Jason, J. Ferrari, and B. Olson, *Benefits and Costs Associated with Mutual-Help Community-Based Recovery Homes: The Oxford House Model*, 35 Evaluation and Program Planning (1), (2012).

<sup>&</sup>lt;sup>7</sup> D. Polcin, R. Korcha, J. Bond, and G. Galloway, *Sober Living Houses for Alcohol and Drug Dependence: 18-Month Outcome*, 38 Journal of Substance Abuse Treatment, 356-365 (2010).

<sup>&</sup>lt;sup>8</sup> Ch. 2013-040, L.O.F. The 2013-2014 General Appropriations Act directed DCF to determine whether to establish a licensure/registration process for recovery residences and to provide the Governor and Legislature with a report on its findings. In its report, DCF was required to identify the number of recovery residences operating in Florida, identify benefits and concerns in connection with the operation of recovery residences, and the impact of recovery residences on effective treatment of alcoholism and on recovery residence residents and surrounding neighborhoods. DCF was also required to include the feasibility, cost, and consequences of licensing, regulating, registering, or certifying recovery residences and their operators. DCF submitted its report to the Governor and Legislature on October 1, 2013.

- Activities going on in recovery residences that require adherence to medical standards and that treatment services may be provided to clients in recovery residences. This included acupuncture and urine tests;
- Houses being advertised as treatment facilities and marketed as the entry point for treatment rather than as a supportive service for individuals who are exiting treatment;
- False advertising;
- Medical tourism;
- The allegation that medical providers capable of ordering medical tests, and billing insurance companies were doing so unlawfully;
- Lack of uniformity in standards; and
- Alleged patient brokering, in violation of Florida Statutes.<sup>10</sup>

## Federal Law

#### Americans with Disabilities Act

The Americans with Disabilities Act (ADA) prohibits discrimination against individuals with disabilities.<sup>11</sup> The ADA requires broad interpretation of the term "disability" so as to include as many individuals as possible under the definition.<sup>12</sup> The ADA defines disability as a physical or mental impairment that substantially limits one or more major life activities.<sup>13</sup> Disability also includes individuals who have a record of such impairment, or are regarded as having such impairment.<sup>14</sup> The phrase "physical or mental impairment" includes, among others<sup>15</sup>, drug addiction and alcoholism.<sup>16</sup> However, this only applies to individuals in recovery as ADA protections are not extended to individuals who are actively abusing substances.<sup>17</sup>

# Fair Housing Amendment Act

The Fair Housing Amendment Acts of 1988 (FHA) prohibits housing discrimination based upon an individual's handicap. <sup>18</sup> A person is considered to have a handicap if he or she has a physical or mental impairment which substantially limits one or more of his or her major life activities. <sup>19</sup> This includes individuals who have a record of such impairment, or are regarded as having such impairment. <sup>20</sup> Drug or alcohol addiction are considered to be handicaps under the FHA. <sup>21</sup> However, current users of illegal controlled substances and persons convicted for illegal manufacture or distribution of a controlled substance are not considered handicapped under the FHA.

<sup>&</sup>lt;sup>10</sup> Id.

<sup>&</sup>lt;sup>11</sup> 42 U.S.C. s. 12101. This includes prohibition against discrimination in employment, State and local government services, public accommodations, commercial facilities, and transportation. U.S. Department of Justice, *Information and Technical Assistance on the Americans with Disabilities Act*, available at <a href="http://www.ada.gov/2010">http://www.ada.gov/2010</a> regs.htm (last visited March 14, 2014).

<sup>12</sup> 42 U.S.C. s. 12102.

<sup>&</sup>lt;sup>13</sup> Id.

<sup>&</sup>lt;sup>14</sup> Id.

<sup>&</sup>lt;sup>15</sup> 28 C.F.R. s. 35.104(4)(1)(B)(ii). The phrase physical or mental impairment includes, but is not limited to, such contagious and noncontagious diseases and conditions as orthopedic, visual, speech and hearing impairments, cerebral palsy, epilepsy, muscular dystrophy, multiple sclerosis, cancer, heart disease, diabetes, mental retardation, emotional illness, specific learning disabilities, HIV disease (whether symptomatic or asymptomatic) and tuberculosis.

<sup>&</sup>lt;sup>16</sup> 28 C.F.R. s. 35.104(4)(1)(B)(ii).

<sup>&</sup>lt;sup>17</sup> 28 C.F.R. s. 35.131.

<sup>&</sup>lt;sup>18</sup> 42 U.S.C. § 3604. Similar protections are also afforded under the Florida Fair Housing Act, s. 760.23, F.S., which provides that it is unlawful to discriminate in the sale or rental of, or to otherwise make unavailable or deny, a dwelling to any buyer or renter because of a handicap of a person residing in or intending to reside in that dwelling after it is sold, rented, or made available. The statute provides that "discrimination" is defined to include a refusal to make reasonable accommodations in rules, policies, practices, or services, when such accommodations may be necessary to afford such person equal opportunity to use and enjoy a dwelling.

<sup>&</sup>lt;sup>19</sup> 42 U.S.C. § 3602(h).

<sup>&</sup>lt;sup>20</sup> Id.

<sup>&</sup>lt;sup>21</sup> Oxford House, Inc. v. Town of Babylon, 819 F. Supp. 1179, 1182 (E.D.N.Y. 1993).
STORAGE NAME: h0479b.HHSC.DOCX

#### Case Law

An individual in recovery from a drug addiction or alcoholism is provided protection from discrimination under the ADA and FHA. As a protected class, federal courts have held that mandatory conditions placed on housing for people in recovery from either state or sub-state entities, such as ordinances, licenses or conditional use permits, may in application be overbroad and result in violations of the FHA and ADA.<sup>22</sup> Additionally, regulations which require registry of housing for protected classes, including recovery residences, have been invalidated by federal courts.<sup>23</sup> Further, federal courts have enjoined state action that is predicated on discriminatory local government decisions.<sup>24</sup>

State and local governments have the authority to enact regulations, including housing restrictions, which serve to protect the health and safety of the community. 25 However, this authority may not be used as a guise to impose additional restrictions on protected classes under the FHA.26 Further, these

<sup>22</sup> Recovery Residence Report, supra footnote 4. Jeffrey O. v. City of Boca Raton, 511 F. Supp. 2d 1339, (Court invalidated local zoning and density restrictions as being discriminatory to individuals in recovery); Oxford House, Inc. v. Town of Babylon, 819 F. Supp. 1179 (Court held that city singled out plaintiffs for zoning enforcement and inspections, on the basis of disability, plaintiff demonstrated city was ignoring zoning violations from people without disabilities); Marbrunak v. City of Stow, OH., 947 F. 2d 43, (6th Cir. 1992) (Court held conditional use permit requiring health and safety protections was an onerous burden); U.S. v. City of Baltimore, MD, 845 F. Supp. 2d. 640 (D. Md. 2012) (Court held that conditional ordinance was overbroad and discriminatory); Children's Alliance v. City of Bellevue, 950 F. Supp. 1491, (W.D. Wash, 1997) (Court held zoning scheme establishing classes of facilities was overbroad, and created an undue burden on a protected class); Oxford House-Evergreen, 769 F. Supp. 1329, (Court held that refusal to issue permit was based on opposition of neighbors, not on protection of health and safety as claimed); Potomac Group Home, Inc., 823 F. Supp. 1285, (Court held that county requirement for evaluation of program offered at facility at public board. At review board, decisions were based on non-programmatic factors, such as neighbor concerns. Further to this, the court held that the requirement to notify neighboring property and enumerated civic organizations violated the FHA).

**DATE**: 4/1/2014

<sup>&</sup>lt;sup>23</sup> Recovery Residence Report, supra footnote 4. Nevada Fair Housing Center, Inc., v. Clark County, et. al., 565 F. Supp. 2d 1178, (D. Nev. 2008) (Invalidating state statute requiring Nevada State Health Department to operate a registry of group homes); See, Human Resource Research and Management Group, 687 F. Supp. 2d 237, (Court held that defendant-city failed to show that the requirement of registration, inspection and background checks was narrowly tailored to support a legitimate government interest); Community Housing Trust et. al., v. Department of Consumer and Regulatory Affairs et. al., 257 F. Supp. 2d 208, (D.C. Cir. 2003) (Court held that the zoning administrators classification of plaintiff-facility, requiring a certificate of occupancy rose to discriminatory practice under FHA). See, e.g., City of Edmonds v. Oxford House et. al., 574 U.S. 725 (1995) (City's restriction on composition of family violated FHAA); Safe Haven Sober Houses LLC, et. al., v. City of Boston, et. al., 517 F. Supp. 2d 557, (D. Mass. 2007); United States v. City of Chicago Heights, 161 F. Supp. 2d 819, (N.D. Ill. 2001) (City violated FHA by requiring inspection for protected class housing that was not narrowly tailored to the protection of disabled); Human Resource Research and Management Group, 687 F. Supp. 2d 237, (Court held that the city's purported interest in the number of facilities, in relation to the zoning plan, was not a legitimate government interest. Further to this, the court found that there was insufficient evidence to justify action by the city in relation to the protection of this class. The city also failed to justify the requirement for a 24 hour staff member, certified by the New York State Office of Alcoholism and Substance Abuse Services).

<sup>&</sup>lt;sup>24</sup> Recovery Residence Report, supra footnote 4. See e.g., Larkin v. State of Mich. 883 F. Supp. 172, (E.D. Mich. 1994), judgment aff'd 89 F. 3 d 285, (6th Cir. 1996) (Court held there was no rational basis for denial of license on the basis of dispersal requirement, and local government's refusal to permit. The court did find, however, that the city was not a party to the law suit because the state statute did not mandate a variance); Arc of New Jersey, Inc., v. State of N.J. 950 F. Supp. 637, D.N.J. 1996) (Court held that municipal land use law, including conditional use, spacing and ceiling quotas violated FHA); North Shore-Chicago Rehabilitation Inc. v. Village of Skokie, 827 F. Supp. 497, (N.D. Ill. 1993) (Court held that municipalities could not rely on the absence of a state licensing scheme to deny an occupancy permit); Easter Seal Soc. of New Jersey, Inc. v. Township of North Bergen, 798 F. Supp. 228 (D.N.J. 1992) (Court held that city denial of permit on the basis of failure to obtain state license was due to the city's discriminatory enforcement of zoning enforcement); Ardmore, Inc. v. City of Akron, Ohio, 1990 WL 385236 (N.D. Ohio 1990) (Court held granted a preliminary injunction against the enforcement of an ordinance requiring conditional use permit, even though it was applied to everyone, because Congress intended to protect the rights of disabled individuals to obtain housing). <sup>25</sup> 42 U.S.C. s. 3604(f)(9).

<sup>&</sup>lt;sup>26</sup> Recovery Residence Report, supra footnote 4. Bangerter v. Orem City Corp., 46 F.3d 1491, (10th Cir. 1995) (Any requirements placed on housing for a protected class based on the protection of the class must be tailored to needs or abilities associated with particular kinds of disabilities, and must have a necessary correlation to the actual abilities of the persons upon whom they are imposed); Association for Advancement of the Mentally Handicapped, Inc. v. City of Elizabeth, 876 F. Supp. 614, (D.N.J. 1994) (Court held state and local governments have the authority to protect safety and health, but that authority may be used to restrict the STORAGE NAME: h0479b.HHSC.DOCX

regulations must not single out housing for disabled individuals and place requirements which are different and unique from the requirements for housing for the general population.<sup>27</sup> Instead, the FHA and ADA require that a reasonable accommodation be made when necessary to allow a person with a qualifying disability equal opportunity to use and enjoy a dwelling.<sup>28</sup> The governmental entity bears the burden of proving through objective evidence that a regulation serves to protect the health and safety of the community and is not based upon stereotypes or unsubstantiated inferences.<sup>29</sup>

## **Effect of Proposed Changes**

The bill defines "recovery residence" as a residential dwelling unit or other form of group housing that is offered or advertised through any form, including oral, written, electronic or printed means, by any person or entity to be a residence that provides a peer-supported, alcohol-free and drug-free living environment.

The bill defines "recovery residence administrator" as the person responsible for overall management of the recovery residence, including the supervision of residents and of staff employed by, or volunteering for, the residence.

The bill defines "certified recovery residence" as a recovery residence that holds a valid certificate of compliance or that is actively managed by a certified recovery residence administrator.

The bill creates s. 397.487, F.S., to establish a voluntary certification of recovery residences program. The bill requires DCF to select a credentialing entity to develop and administer the program, and provides for an initial application and subsequent renewal fee of the recovery residence to the credentialing entity. The bill establishes the criteria DCF is to use when selecting a credentialing entity. The bill requires a recovery residence to provide the following documents to the credentialing entity:

- Policy and Procedures Manual;
- Rules for residents:
- Copies of all forms provided to residents;
- Intake procedures;
- Relapse policy;
- Fee schedule;
- Refund policy;
- Eviction procedures and policy;

ability of protected classes to live in the community); *Pulcinella v. Ridley Tp.*, 822 F. Supp. 204,822 F. Supp. 204, (Special conditions may not be imposed under the pretext of health and safety concerns).

STORAGE NAME: h0479b.HHSC.DOCX

DATE: 4/1/2014

<sup>&</sup>lt;sup>27</sup> Bangerter v. Orem City Corp., 46 F.3d 1491, (10th Cir. 1995) (Invalidating and act and ordinance that facially singles out the handicapped, and applies different and unique rules to them); Human Resource Research and Management Group, Inc. v. County of Suffolk, 687 F. Supp. 2d 237 (E.D. N.Y. 2010), (It is undisputed that [the ordinance] is discriminatory on its face, in that it imposes restrictions and limitations solely upon a class of disabled individuals); Potomac Group Home Corp. v. Montgomery County, Md., 823 F. Supp. 1285,, (No other county law or regulation imposed any similar requirement on a residence to be occupied by adult persons who do not have disabilities).

<sup>&</sup>lt;sup>28</sup> Recovery Residence Report, supra footnote 4. 42 U.S.C. s. 3604(f)(3)(B); 42 U.S.C. s. 12131, et. seq., 28 C.F.R. s. 35.130(b)(7). To comply with the reasonable accommodation provisions of the ADA, regulations have been promulgated for public entities (defined by 28 C.F.R. s. 35.104). This includes a self-evaluation plan of current policies and procedures and modify as needed (28 C.F.R. s. 35.105). This is subject to the exclusions of 28 C.F.R. s. 35.150. For interpretation by the judiciary, see, Jeffrey O. v. City of Boca Raton, 511 F. Supp. 2d 1339, (Court invalidated local ordinance because city failed to make reasonable accommodations for individuals with disabilities); Oxford House Inc., v. Township of Cherry Hill, 799 F. Supp. 450, (D.N.J. 1992) (Court held that a reasonable accommodation means changing some rule that is generally applicable to everyone so as to make it less burdensome for a protected class).

<sup>&</sup>lt;sup>29</sup> Oconomowoc Residential Programs, Inc., v. City of Milwaukee, 300 F. 3d 775, (7th Cir. 2002) (Denial for a variance due to purported health and safety concerns for the disabled adults could not be based on blanket stereotypes); Oxford House-Evergreen v. City of Plainfield, 769 F. Supp. 1329 (D.N.J. 1991) (Generalized assumptions, subjective fears and speculation are insufficient to prove direct threat to others), Cason v. Rochester Housing Authority, 748 F. Supp. 1002, (W.D.N.Y. 1990).

- Code of ethics:
- Proof of insurance:
- · Background screening; and
- Proof of satisfactory fire, safety, and health inspections.

The bill requires the credentialing agency to conduct an on-site inspection of the recovery residence prior to the initial certification and then at least once a year for every subsequent renewal period. The bill requires that all employed and volunteer staff of a recovery residence pass a Level II background screening, and that the costs associated with such screenings be the responsibility of the credentialing agency. The bill establishes the requirements for the submission and evaluation of the background screening. The bill requires the credentialing agency to deny certification, and authorizes suspension and revocation of the certification, if the recovery residence:

- Is not in compliance with any provision of this section;
- Has failed to remedy any deficiency identified by the credentialing entity within the time period specified;
- · Provided false, misleading or incomplete information to the credentialing entity; and
- Has employed or volunteer staff who are subject to the disqualifying offenses set forth in the Level II background screening statute, unless an exemption has been provided.

The bill establishes that certification automatically terminates if not renewed within one year of the date of issuance. The bill also creates a first degree misdemeanor for any person or entity who advertises that any recovery residence is a "certified recovery residence," unless that recovery residence has obtained certification under this section.

The bill creates s. 397.4871, F.S., to establish a voluntary certification for recovery residence administrators. The bill requires DCF to select a credentialing entity to develop and administer the program. The bill establishes the criteria DCF is to use when selecting a credentialing entity and creating the certification program, and provides for an initial application and subsequent renewal fee of the recovery residence to the credentialing entity. The bill requires that all certified recovery residence administrators pass a Level II background screening, and that costs associated with such screenings be the responsibility of the credentialing entity. The bill establishes the requirements for the submission and evaluation of the background screening. The bill authorizes the credentialing entity to suspend or revoke certification if a certified recovery resident administrator:

- Fails to adhere to the continuing education requirements; or
- Becomes subject to the disqualifying offenses set forth in the Level II background screening statute, unless an exemption has been provided.

The bill creates a first degree misdemeanor for any person or entity who advertises that he or she is a "certified recovery residence administrator," unless he or she has obtained certification under this section.

The bill creates s. 397.4872, F.S., to provide an exemption for disqualifying offenses and create a publication requirement for DCF. The bill authorizes DCF to exempt an individual from disqualifying offenses if it has been at least three years since the individual has completed or been lawfully released from confinement, supervision, or sanction for the disqualifying offense. The exemption is not available to any individual who is a:

- Sexual predator as designated pursuant to s. 775.21, F.S.;
- Career offender pursuant to s. 775.261, F.S.; or
- Sexual offender pursuant to s. 943.0435, F.S., unless the requirement to register as a sexual offender has been removed pursuant to s. 943.04354, F.S.

The bill requires credentialing entities to provide a list to DCF no later than April 1, 2015, of all recovery residences or recovery residence administrators which it has certified and hold valid certificates of compliance. DCF in turn must publish these lists on its website. The bill allows a recovery residence or recovery residence administrator to be excluded from the list upon written request to DCF.

The bill amends s. 397.407, F.S., to require, effective October 1, 2015, that a licensed service provider refer a current or discharged patient only to a recovery residence that holds a valid certificate of compliance, is actively managed by a certified recovery residence administrator, or both, or is owned and operated by a licensed service provider.

## **B. SECTION DIRECTORY:**

**Section 1**: Amends s. 397.311, F.S., relating to definitions for substance abuse services.

Section 2: Creates s. 397.487, F.S., relating to voluntary certification of recovery residences.

Section 3: Creates s. 397.4871, F.S., relating to recovery residence administrator certification.

Section 4: Creates s. 397.4872, F.S., relating to exemption from disqualification and publication.

Section 5: 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 requires DCF to review results for the employed and volunteer staff of recovery residences as a condition of certification, as well as requests for exemption from disqualifying offenses. The department performs similar reviews for providers of substance abuse services. Given the infrastructure for such reviews is currently part of the department's prescribed regulatory procedures, the costs of the bill are anticipated to be insignificant and can be absorbed within existing resources.

## B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

## 2. Expenditures:

The bill could result in a negative local jail bed impact because it creates a new misdemeanor for any entity or person who advertises as a "certified recovery residence" or "certified recovery residence administrator", respectively, unless the entity or person has obtained certification under the provisions of the bill.

## C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The fiscal impact to the certification boards and recovery residences or administrators is indeterminate as it is dependent upon the number of individuals and entities that elect to participate in the voluntary certification program. Application fees and renewal fees may not exceed \$100 for certification of a recovery residence. Recovery residence certification also requires inspection fees which are to be charged at cost. Application fees for a recovery residence administrator cannot exceed \$225 and renewal fees cannot exceed \$100.

The bill requires fingerprints to be submitted to the FDLE and FBI as part of the required background screening and provides these costs be covered by the prospective employee or volunteer of the credentialing entity (the cost for a Level II background screen ranges from \$38 to \$75 depending upon the selected vendor).<sup>30</sup>

D. FISCAL COMMENTS:

None.

#### **III. COMMENTS**

## A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill appears to be exempt from the requirements of Article VII, Section 18 of the Florida Constitution because it is a criminal law.

2. Other:

None.

**B. RULE-MAKING AUTHORITY:** 

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

# IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 18, 2014, the Healthy Families Subcommittee adopted two amendments to the PCS for HB 479. The amendments set forth the requirements for the submission and evaluation of a Level II background screening for individuals participating in the voluntary certification of recovery residence program and the voluntary certification of recovery residence administrator program. The amendments:

- Require fingerprints to be submitted by DCF or an authorized entity or vendor;
- Require DCF to forward the fingerprints to the Department of Law Enforcement (FDLE) for state processing;
- Require FDLE to forward the fingerprints to the Federal Bureau of Investigation for national processing;
- Establish that the individual is responsible for state and national fingerprint processing fees; and
- Require DCF to determine if the individual meets the certification requirements for background screening.

The bill was reported favorably as a Committee Substitute. This analysis is drafted to the Committee Substitute.

STORAGE NAME: h0479b.HHSC.DOCX

**DATE: 4/1/2014** 

<sup>&</sup>lt;sup>30</sup> http://www.dcf.state.fl.us/programs/backgroundscreening/map.asp, Department of Children and Families' website, accessed 3/26/2014.

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A bill to be entitled An act relating to substance abuse services; amending s. 397.311, F.S.; providing definitions; conforming a cross-reference; creating s. 397.487, F.S.; providing legislative findings; requiring the Department of Children and Families to create a voluntary certification program for recovery residences; requiring the department to approve credentialing entities to develop and administer the certification program; requiring an approved credentialing entity to establish a process for certifying recovery residences that meet certain qualifications; requiring an approved credentialing entity to establish certain fees; requiring a credentialing entity to conduct onsite inspections of a recovery residence; requiring background screening of employees and volunteers of a recovery residence; providing for denial, suspension, or revocation of certification; providing a criminal penalty for advertising a recovery residence as a "certified recovery residence" unless certified; creating s. 397.4871, F.S.; providing legislative intent; requiring the department to create a voluntary certification program for recovery residence administrators; authorizing the department to approve credentialing entities to develop and administer the certification program; requiring an approved

Page 1 of 22

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credentialing entity to establish a process for certifying recovery residence administrators who meet certain qualifications; requiring an approved credentialing entity to establish certain fees; requiring background screening of applicants for recovery residence administrator certification; providing for suspension or revocation of certification; providing a criminal penalty for advertising oneself as a "certified recovery residence administrator" unless certified; creating s. 397.4872, F.S.; providing exemptions from disqualifying offenses; requiring credentialing entities to provide the department with a list of all certified recovery residences and recovery residence administrators by a date certain; requiring the department to publish the list on its website; allowing recovery residences and recovery residence administrators to be excluded from the list; amending s. 397.407, F.S.; authorizing licensed service providers to refer patients to certified recovery residences or recovery residences owned and operated by licensed service providers; defining the term "refer"; amending ss. 212.055, 394.9085, 397.405, 397.416, and 440.102, F.S.; conforming cross-references; providing an effective date.

Page 2 of 22

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

Section 1. Present subsection (32) of section 397.311, Florida Statutes, is amended, subsection (4), subsections (5) through (28), and subsections (29) through (39) are renumbered as subsection (7), subsections (9) through (32), and subsections (35) through (45), respectively, and new subsections (4), (5).

- (6), (8), (33), and (34) are added to that section, to read:
- 397.311 Definitions.—As used in this chapter, except part VIII, the term:
  - (4) "Certificate of compliance" means a certificate that is issued by a credentialing entity to a recovery residence or a recovery residence administrator.
  - (5) "Certified recovery residence" means a recovery residence that holds a valid certificate of compliance or that is actively managed by a certified recovery residence administrator.
  - (6) "Certified recovery residence administrator" means a recovery residence administrator who holds a valid certificate of compliance.
  - (8) "Credentialing entity" means a nonprofit organization that develops and administers professional certification programs according to nationally recognized certification and psychometric standards.
  - (33) "Recovery residence" means a residential dwelling unit, or other form of group housing, that is offered or

Page 3 of 22

advertised through any means, including oral, written, electronic, or printed means, by any person or entity as a residence that provides a peer-supported, alcohol-free, and drug-free living environment.

- responsible for overall management of the recovery residence, including the supervision of residents and staff employed by, or volunteering for, the residence.
- (38) (32) "Service component" or "component" means a discrete operational entity within a service provider which is subject to licensing as defined by rule. Service components include prevention, intervention, and clinical treatment described in subsection (22) (18).
- Section 2. Section 397.487, Florida Statutes, is created to read:
  - 397.487 Voluntary certification of recovery residences.-
- (1) The Legislature finds that a person suffering from addiction has a higher success rate of achieving long-lasting sobriety when given the opportunity to build a stronger foundation by living in a recovery residence after completing treatment. The Legislature further finds that this state and its subdivisions have a legitimate state interest in protecting these persons, who represent a vulnerable consumer population in need of adequate housing. It is the intent of the Legislature to protect persons who reside in a recovery residence.

Page 4 of 22

104	(2) The department shall approve one or more credentialing
105	entities for the purpose of developing and administering a
106	voluntary certification program for recovery residences. The
107	approved credentialing entity shall:
108	(a) Establish recovery residence certification
109	requirements.
110	(b) Establish processes to:
111	1. Administer the application, certification,
112	recertification, and disciplinary processes.
113	2. Monitor and inspect a recovery residence and its staff
114	to ensure compliance with certification requirements.
115	3. Interview and evaluate residents, employees, and
116	volunteer staff on their knowledge and application of
117	certification requirements.
118	(c) Provide training for owners, managers, and staff.
119	(d) Develop a code of ethics.
120	(e) Establish application, inspection, and annual
121	certification renewal fees. The application fee may not exceed
122	\$100. The inspection fee shall reflect actual costs for
123	inspections. The annual certification renewal fee may not exceed
124	<u>\$100.</u>
125	(3) A credentialing entity shall require the recovery
126	residence to submit the following documents with the completed
127	application and fee:
128	(a) A policy and procedures manual containing:
129	1. Job descriptions for all staff positions.

Page 5 of 22

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130	2. Drug testing procedures and requirements.
131	3. A prohibition on the premises against alcohol, illegal
132	drugs, and the use of prescribed medications by an individual
133	other than the individual for whom the medication is prescribed.
134	4. Policies to support a resident's recovery efforts.
135	5. A good neighbor policy to address neighborhood concerns
136	and complaints.
137	(b) Rules for residents.
138	(c) Copies of all forms provided to residents.
139	(d) Intake procedures.
140	(e) Relapse policy.
141	(f) Fee schedule.
142	(g) Refund policy.
143	(h) Eviction procedures and policy.
144	(i) Code of ethics.
145	(j) Proof of insurance requirements.
146	(k) Background screening requirements.
147	(1) Requirements for proof of satisfactory fire, safety,
148	and health inspections.
149	(4) A credentialing entity shall conduct an onsite
150	inspection of the recovery residence before issuing a
151	certificate of compliance. Onsite followup monitoring of any
152	certified recovery residence may be conducted by the
153	credentialing entity to determine continuing compliance with
154	certification requirements. Each certified recovery residence

Page 6 of 22

shall be inspected at least once during each certification renewal period to ensure compliance.

- employees and volunteer staff of a recovery residence pass a level 2 background screening as provided in s. 435.04. The employee's and volunteer's fingerprints must be submitted by the department, an entity, or a vendor as authorized by s. 943.053(13)(a). The fingerprints shall be forwarded to the Department of Law Enforcement for state processing, and the Department of Law Enforcement shall forward them to the Federal Bureau of Investigation for national processing. Fees for state and national fingerprint processing shall be borne by the employer, employee, or volunteer. The department shall screen background results to determine whether an employee or volunteer meets certification requirements.
- (6) A credentialing entity shall issue a certificate of compliance upon approval of the recovery residence's application and inspection. The certification shall automatically terminate if not renewed within 1 year after the date of issuance.
- (7) A credentialing entity shall deny a recovery residence's application for certification, and may suspend or revoke a certification, if the recovery residence:
- (a) Is not in compliance with any provision of this section;
- (b) Has failed to remedy any deficiency identified by the credentialing entity within the time period specified;

Page 7 of 22

(c) Provided false, misleading, or incomplete information 181 182 to the credentialing entity; or 183 (d) Has employees or volunteer staff who are subject to 184 the disqualifying offenses set forth in s. 435.04(2), unless an 185 exemption has been provided under s. 397.4872. 186 (8) It is unlawful for a person to advertise to the 187 public, in any way or by any medium whatsoever, any recovery 188 residence as a "certified recovery residence" unless such 189 recovery residence has first secured a certificate of compliance 190 under this section. A person who violates this subsection 191 commits a misdemeanor of the first degree, punishable as 192 provided in s. 775.082 or s. 775.083. 193 Section 3. Section 397.4871, Florida Statutes, is created 194 to read: 195 397.4871 Recovery residence administrator certification.-196 (1) It is the intent of the Legislature that a recovery 197 residence administrator voluntarily earn and maintain 198 certification from a credentialing entity approved by the 199 Department of Children and Families. The Legislature further 200 intends that certification ensure that an administrator has the 201 competencies necessary to appropriately respond to the needs of 202 residents, to maintain residence standards, and to meet 203 residence certification requirements. 204 The department shall approve one or more credentialing

Page 8 of 22

entities for the purpose of developing and administering a

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206	volunteer credentialing program for administrators. The approved
207	credentialing entity shall:
208	(a) Establish recovery residence administrator core
209	competencies, certification requirements, testing instruments,
210	and recertification requirements according to nationally
211	recognized certification and psychometric standards.
212	(b) Establish a process to administer the certification
213	application, award, and maintenance processes.
214	(c) Demonstrate ability to administer:
215	1. A code of ethics and disciplinary process.
216	2. Biennial continuing education requirements and annual
217	certification renewal requirements.
218	3. An education provider program to approve training
219	entities that are qualified to provide precertification training
220	to applicants and continuing education opportunities to
221	certified persons.
222	(3) A credentialing entity shall establish a certification
223	<pre>program that:</pre>
224	(a) Is established according to nationally recognized
225	certification and psychometric standards.
226	(b) Is directly related to the core competencies.
227	(c) Establishes minimum requirements in each of the
228	following categories:
229	1. Training.
230	2. On-the-job work experience.
231	3. Supervision.

Page 9 of 22

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232 Testing. 4. 233 5. Biennial continuing education. (d) Requires adherence to a code of ethics and provides 234 235 for a disciplinary process that applies to certified persons. 236 Approves qualified training entities that provide 237 precertification training to applicants and continuing education to certified recovery residence administrators. To avoid a 238 239 conflict of interest, a credentialing entity or its affiliate 240 may not deliver training to an applicant or continuing education 241 to a certificateholder. (4) A credentialing entity shall require each applicant to 242 243 pass a level 2 background screening as provided in s. 435.04. 244 The applicant's fingerprints must be submitted by the department, an entity, or a vendor as authorized by s. 245 246 943.053(13)(a). The fingerprints shall be forwarded to the 247 Department of Law Enforcement for state processing, and the 248 Department of Law Enforcement shall forward them to the Federal 249 Bureau of Investigation for national processing. Fees for state 250 and national fingerprint processing shall be borne by the 251 applicant. The department shall screen background results to 252 determine whether an applicant meets certification requirements. 253 (5) A credentialing entity shall establish application, 254 examination, and certification fees and an annual certification 255 renewal fee. The application, examination, and certification fee

Page 10 of 22

may not exceed \$225. The annual certification renewal fee may

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not exceed \$100.

258 The credentialing entity shall issue a certificate of 259 compliance upon approval of a person's application. The 260 certification shall automatically terminate if not renewed 261 within 1 year after the date of issuance. 262 (7) A person who is subject to the disqualifying offenses 263 set forth in s. 435.04(2) is ineligible to become a certified 264 recovery residency administrator. 265 (8) A credentialing entity may suspend or revoke the 266 recovery residence administrator's certificate of compliance if 267 the recovery residence administrator: 268 (a) Fails to adhere to the continuing education 269 requirements; or 270 (b) Becomes subject to the disqualifying offenses set 271 forth in s. 435.04(2), unless an exemption has been provided 272 under s. 397.4872. 273 It is unlawful for a person to advertise himself or 274 herself to the public, in any way or by any medium whatsoever, as a "certified recovery residence administrator" unless he or 275 276 she has first secured a certificate of compliance under this 277 section. A person who violates this subsection commits a 278 misdemeanor of the first degree, punishable as provided in s. 279 775.082 or s. 775.083. Section 4. Section 397.4872, Florida Statutes, is created 280 281 to read:

Page 11 of 22

397.4872 Exemption from disqualification; publication.-

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(1) Individual exemptions to staff disqualification or administrator ineligibility may be requested if a recovery residence deems the decision will benefit the program. Requests for exemptions shall be submitted in writing to the department and include a justification for the exemption.

- (2) The department may exempt a person from ss.

  397.487(7)(d) and 397.4871(7) if it has been at least 3 years

  since the person has completed or been lawfully released from

  confinement, supervision, or sanction for the disqualifying

  offense. An exemption from the disqualifying offenses may not be

  given under any circumstances for any person who is a:
  - (a) Sexual predator pursuant to s. 775.21;
  - (b) Career offender pursuant to s. 775.261; or
- (c) Sexual offender pursuant to s. 943.0435, unless the requirement to register as a sexual offender has been removed pursuant to s. 943.04354.
- (3) A credentialing entity shall submit a list to the department, no later than April 1, 2015, of all recovery residences or recovery residence administrators whom it has certified and who hold valid certificates of compliance.

  Thereafter, a credentialing entity shall notify the department within 3 business days when any new recovery residence administrator receives a certificate or when a recovery residence administrator's certificate expires or is terminated. The department shall publish on its website a list of each recovery residence and recovery residence administrator who

Page 12 of 22

holds a valid certificate of compliance. A recovery residence or recovery residence administrator shall be excluded from the list upon written request to the department.

Section 5. Subsections (1) and (5) of section 397.407, Florida Statutes, are amended, and subsection (11) is added to that section, to read:

397.407 Licensure process; fees.-

- (1) The department shall establish by rule the licensure process to include fees and categories of licenses. The rule must prescribe a fee range that is based, at least in part, on the number and complexity of programs listed in s. 397.311(22) 397.311(18) which are operated by a licensee. The fees from the licensure of service components are sufficient to cover at least 50 percent of the costs of regulating the service components. The department shall specify by rule a fee range for public and privately funded licensed service providers. Fees for privately funded licensed service providers. During adoption of the rule governing the licensure process and fees, the department shall carefully consider the potential adverse impact on small, not-for-profit service providers.
- (5) The department may issue probationary, regular, and interim licenses. After adopting the rule governing the licensure process and fees, the department shall issue one license for each service component that is operated by a service provider and defined in rule pursuant to s. 397.311(22)

Page 13 of 22

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397.311(18). The license is valid only for the specific service components listed for each specific location identified on the license. The licensed service provider shall apply for a new license at least 60 days before the addition of any service components or 30 days before the relocation of any of its service sites. Provision of service components or delivery of services at a location not identified on the license may be considered an unlicensed operation that authorizes the department to seek an injunction against operation as provided in s. 397.401, in addition to other sanctions authorized by s. 397.415. Probationary and regular licenses may be issued only after all required information has been submitted. A license may not be transferred. As used in this subsection, the term "transfer" includes, but is not limited to, the transfer of a majority of the ownership interest in the licensed entity or transfer of responsibilities under the license to another entity by contractual arrangement.

(11) Effective October 1, 2015, a service provider licensed under this part may refer a current or discharged patient only to a recovery residence that holds a valid certificate of compliance as provided in s. 397.487, is actively managed by a certified recovery residence administrator as provided in s. 397.4871, or both, or is owned and operated by a licensed service provider. For purposes of this subsection, the term "refer" means to inform a patient by any means about the name, address, or other details about the recovery residence.

Page 14 of 22

However, this section does not require a licensed service provider to refer any patient to a recovery residence.

Section 6. Paragraph (e) of subsection (5) of section 212.055, Florida Statutes, is amended to read:

212.055 Discretionary sales surtaxes; legislative intent; authorization and use of proceeds.—It is the legislative intent that any authorization for imposition of a discretionary sales surtax shall be published in the Florida Statutes as a subsection of this section, irrespective of the duration of the levy. Each enactment shall specify the types of counties authorized to levy; the rate or rates which may be imposed; the maximum length of time the surtax may be imposed, if any; the procedure which must be followed to secure voter approval, if required; the purpose for which the proceeds may be expended; and such other requirements as the Legislature may provide. Taxable transactions and administrative procedures shall be as provided in s. 212.054.

(5) COUNTY PUBLIC HOSPITAL SURTAX.—Any county as defined in s. 125.011(1) may levy the surtax authorized in this subsection pursuant to an ordinance either approved by extraordinary vote of the county commission or conditioned to take effect only upon approval by a majority vote of the electors of the county voting in a referendum. In a county as defined in s. 125.011(1), for the purposes of this subsection, "county public general hospital" means a general hospital as defined in s. 395.002 which is owned, operated, maintained, or

Page 15 of 22

governed by the county or its agency, authority, or public health trust.

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A governing board, agency, or authority shall be chartered by the county commission upon this act becoming law. The governing board, agency, or authority shall adopt and implement a health care plan for indigent health care services. The governing board, agency, or authority shall consist of no more than seven and no fewer than five members appointed by the county commission. The members of the governing board, agency, or authority shall be at least 18 years of age and residents of the county. No member may be employed by or affiliated with a health care provider or the public health trust, agency, or authority responsible for the county public general hospital. The following community organizations shall each appoint a representative to a nominating committee: the South Florida Hospital and Healthcare Association, the Miami-Dade County Public Health Trust, the Dade County Medical Association, the Miami-Dade County Homeless Trust, and the Mayor of Miami-Dade County. This committee shall nominate between 10 and 14 county citizens for the governing board, agency, or authority. The slate shall be presented to the county commission and the county commission shall confirm the top five to seven nominees, depending on the size of the governing board. Until such time as the governing board, agency, or authority is created, the funds provided for in subparagraph (d)2. shall be placed in a restricted account set aside from other county funds and not

Page 16 of 22

disbursed by the county for any other purpose.

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- 1. The plan shall divide the county into a minimum of four and maximum of six service areas, with no more than one participant hospital per service area. The county public general hospital shall be designated as the provider for one of the service areas. Services shall be provided through participants' primary acute care facilities.
- The plan and subsequent amendments to it shall fund a defined range of health care services for both indigent persons and the medically poor, including primary care, preventive care, hospital emergency room care, and hospital care necessary to stabilize the patient. For the purposes of this section, "stabilization" means stabilization as defined in s. 397.311(41) 397.311(35). Where consistent with these objectives, the plan may include services rendered by physicians, clinics, community hospitals, and alternative delivery sites, as well as at least one regional referral hospital per service area. The plan shall provide that agreements negotiated between the governing board, agency, or authority and providers shall recognize hospitals that render a disproportionate share of indigent care, provide other incentives to promote the delivery of charity care to draw down federal funds where appropriate, and require cost containment, including, but not limited to, case management. From the funds specified in subparagraphs (d)1. and 2. for indigent health care services, service providers shall receive reimbursement at a Medicaid rate to be determined by the

Page 17 of 22

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governing board, agency, or authority created pursuant to this paragraph for the initial emergency room visit, and a per-member per-month fee or capitation for those members enrolled in their service area, as compensation for the services rendered following the initial emergency visit. Except for provisions of emergency services, upon determination of eligibility, enrollment shall be deemed to have occurred at the time services were rendered. The provisions for specific reimbursement of emergency services shall be repealed on July 1, 2001, unless otherwise reenacted by the Legislature. The capitation amount or rate shall be determined prior to program implementation by an independent actuarial consultant. In no event shall such reimbursement rates exceed the Medicaid rate. The plan must also provide that any hospitals owned and operated by government entities on or after the effective date of this act must, as a condition of receiving funds under this subsection, afford public access equal to that provided under s. 286.011 as to any meeting of the governing board, agency, or authority the subject of which is budgeting resources for the retention of charity care, as that term is defined in the rules of the Agency for Health Care Administration. The plan shall also include innovative health care programs that provide cost-effective alternatives to traditional methods of service and delivery funding.

3. The plan's benefits shall be made available to all county residents currently eligible to receive health care

Page 18 of 22

services as indigents or medically poor as defined in paragraph (4)(d).

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- 4. Eligible residents who participate in the health care plan shall receive coverage for a period of 12 months or the period extending from the time of enrollment to the end of the current fiscal year, per enrollment period, whichever is less.
- 5. At the end of each fiscal year, the governing board, agency, or authority shall prepare an audit that reviews the budget of the plan, delivery of services, and quality of services, and makes recommendations to increase the plan's efficiency. The audit shall take into account participant hospital satisfaction with the plan and assess the amount of poststabilization patient transfers requested, and accepted or denied, by the county public general hospital.

Section 7. 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 "detoxification services," "addictions receiving facility," and "receiving facility" have the same meanings as those provided in ss. 397.311(22)(a)4. 397.311(18)(a)4., 397.311(22)(a)1. 397.311(18)(a)1., and 394.455(26), respectively.
- Section 8. Subsection (8) of section 397.405, Florida Statutes, is amended to read:
- 489 397.405 Exemptions from licensure.—The following are exempt from the licensing provisions of this chapter:

Page 19 of 22

(8) A legally cognizable church or nonprofit religious organization or denomination providing substance abuse services, including prevention services, which are solely religious, spiritual, or ecclesiastical in nature. A church or nonprofit religious organization or denomination providing any of the licensed service components itemized under s. 397.311(22) 397.311(18) is not exempt from substance abuse licensure but retains its exemption with respect to all services which are solely religious, spiritual, or ecclesiastical in nature.

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The exemptions from licensure in this section do not apply to any service provider that receives an appropriation, grant, or contract from the state to operate as a service provider as defined in this chapter or to any substance abuse program regulated pursuant to s. 397.406. Furthermore, this chapter may not be construed to limit the practice of a physician or physician assistant licensed under chapter 458 or chapter 459, a psychologist licensed under chapter 490, a psychotherapist licensed under chapter 491, or an advanced registered nurse practitioner licensed under part I of chapter 464, who provides substance abuse treatment, so long as the physician, physician assistant, psychologist, psychotherapist, or advanced registered nurse practitioner does not represent to the public that he or she is a licensed service provider and does not provide services to individuals pursuant to part V of this chapter. Failure to comply with any requirement necessary to maintain an exempt

Page 20 of 22

2014 CS/HB 479

517 status under this section is a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

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Section 9. Section 397.416, Florida Statutes, is amended to read:

397.416 Substance abuse treatment services; qualified professional.-Notwithstanding any other provision of law, a person who was certified through a certification process recognized by the former Department of Health and Rehabilitative Services before January 1, 1995, may perform the duties of a qualified professional with respect to substance abuse treatment services as defined in this chapter, and need not meet the certification requirements contained in s. 397.311(30) 397.311(26).

Section 10. Paragraphs (d) and (g) of subsection (1) of section 440.102, Florida Statutes, are 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:

- DEFINITIONS.—Except where the context otherwise requires, as used in this act:
- "Drug rehabilitation program" means a service provider, established pursuant to s.  $397.311(39) \frac{397.311(33)}{}$ , that provides confidential, timely, and expert identification, assessment, and resolution of employee drug abuse.
  - "Employee assistance program" means an established Page 21 of 22

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program capable of providing expert assessment of employee personal concerns; confidential and timely identification services with regard to employee drug abuse; referrals of employees for appropriate diagnosis, treatment, and assistance; and followup services for employees who participate in the program or require monitoring after returning to work. If, in addition to the above activities, an employee assistance program provides diagnostic and treatment services, these services shall in all cases be provided by service providers pursuant to s. 397.311(39) 397.311(33).

Section 11. This act shall take effect July 1, 2014.

Page 22 of 22



COMMITTEE/SUBCOMMITTEE ACTION

### COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. CS/HB 479 (2014)

Amendment No.

· · · · · · · · · · · · · · · · · · ·						
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 Hager off	ered the following:					
Amendment						
Remove lines 352-35	8 and insert:					
(11) Effective Jul	ly 1, 2015, a service provider licensed					

under this part may not refer a current or discharged patient to a recovery residence, unless the recovery residence holds a valid certificate of compliance as provided in s. 397.487, is actively managed by a certified recovery residence administrator as provided in s. 397.4871, or both, or is owned and operated by a licensed service provider or a licensed service provider's wholly owned subsidiary. For purposes of this subsection, the

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### HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #:

CS/HB 1275

Physician Assistants

SPONSOR(S): Select Committee on Health Care Workforce Innovation; Ahern and others

TIED BILLS:

IDEN./SIM. BILLS:

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
Select Committee on Health Care Workforce     Innovation	16 Y, 0 N, As CS	Dunn	Calamas
2) Health & Human Services Committee		Dunn 🕠	Calamas OF

### **SUMMARY ANALYSIS**

A physician assistant (PA) is a person licensed to perform health care services, in the specialty areas in which he or she has been trained, delegated by a supervising physician. PAs are governed by the respective physician practice acts for medical doctors (MDs) and doctors of osteopathic medicine (DOs), because PAs may only practice under the supervision of a MD or DO.

A PA practices under the delegated authority of a supervising physician, who may supervise up to four PAs. A physician supervising a PA must be qualified in the medical area(s) in which the PA is to perform health care tasks, and is responsible and liable for the performance and acts and omissions of the PA.

A supervising physician may delegate to a PA the authority to prescribe or dispense any medicinal drug used in the supervisory physician's practice. To delegate prescribing authority, the supervising physician must notify the Department of Health of intent to delegate prescribing authority to a PA, and the PA must file with the department a signed affidavit that he or she has completed a minimum of 10 continuing medical education hours in the specialty practice area each renewal period.

This bill amends chapters 458 and 459, F.S., to streamline administrative procedures for PAs seeking prescribing authority and for PA applicants seeking licensure. Instead of requiring PAs to submit a signed affidavit to attest to the completion of required continuing education in order to obtain prescribing privileges, the bill requires PAs to certify to the completion of the continuing education. The requirement for PA applicants to give a sworn statement of prior felony convictions or previous license denials or revocations when applying for licensure is changed to require a statement of such actions. The bill removes the requirement that PA applicants submit two letters of recommendation to be eligible for licensure.

The bill also increases the number of physician assistants a physician may supervise from four to eight.

The bill has an insignificant negative fiscal impact on the DOH. The bill has no fiscal impact on local governments.

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

This document does not reflect the intent or official position of the bill sponsor or House of Representatives. STORAGE NAME: h1275b.HHSC.DOCX

**DATE: 4/1/2014** 

#### **FULL ANALYSIS**

### I. SUBSTANTIVE ANALYSIS

### A. EFFECT OF PROPOSED CHANGES:

### **Background**

### Physician Assistants

A physician assistant (PA) is a person licensed to perform health care services, in the specialty areas in which he or she has been trained, delegated by a supervising physician. Currently, there are 5,874 instate, and 713 out-of-state, active licensed PAs in Florida.<sup>2</sup>

Prior to becoming a licensed PA in Florida, an applicant must pass the Physician Assistant National Certifying Exam.<sup>3</sup> Eligibility to take the exam requires graduation from an accredited PA program.<sup>4</sup> Earning a degree from an accredited PA program usually takes at least two years of full-time postgraduate study.<sup>5</sup> Most applicants to physician assistant education programs already have a bachelor's degree and some healthcare-related work experience.<sup>6</sup>

PAs are governed by the respective physician practice acts for medical doctors (MDs) and doctors of osteopathic medicine (DOs), because PAs may only practice under the supervision of a MD or DO. Specifically, sections 458.347(7) and 459.022(7), F.S., govern the licensure of PAs. PAs are regulated by the Florida Council on Physician Assistants (Council) in conjunction with either the Board of Medicine for PAs licensed under ch. 458, F.S., or the Board of Osteopathic Medicine for PAs licensed under ch. 459, F.S.

An applicant for a PA license must apply to the Department of Health (department). The department must issue a license to a person certified by the Council as having met all of the following requirements:<sup>8</sup>

- Is at least 18 years of age;
- Has satisfactorily passed a proficiency examination by an acceptable score established by the National Commission on Certification of Physician Assistants;<sup>9</sup>
- Has completed an application form and remitted an application fee not to exceed \$300 as set by the boards;
- Holds a certificate of completion of a PA training program, including certain course descriptions relating to pharmacotherapy if the PA applicant seeks prescribing authority:
- Pass a criminal background screening: 10

<sup>2</sup> E-mail from Florida Department of Health to the Health and Human Services Committee (Nov. 7, 2013) (on file with committee staff).

STORAGE NAME: h1275b.HHSC.DOCX

**DATE: 4/1/2014** 

<sup>&</sup>lt;sup>1</sup> Section 458.347(1), F.S.

<sup>&</sup>lt;sup>3</sup> National Commission on Certification of Physician Assistants, *PANCE*, available at <a href="https://www.nccpa.net/pance">https://www.nccpa.net/pance</a> (last visited Mar. 31, 2014).

<sup>&</sup>lt;sup>4</sup> Programs are accredited by the Accreditation Review Commission on Education for the Physician Assistant (ARC-PA).

<sup>&</sup>lt;sup>5</sup> Bureau of Labor Statistics, *Physician Assistants*, *available at* <a href="http://www.bls.gov/ooh/healthcare/physician-assistants.htm">http://www.bls.gov/ooh/healthcare/physician-assistants.htm</a> (last visited Mar. 31, 2014).

<sup>&</sup>lt;sup>7</sup> Chapters 458 and 459, F.S.

<sup>&</sup>lt;sup>8</sup> Section 458.347(7), F.S.; section 459.022(7), F.S.

<sup>&</sup>lt;sup>9</sup> The proficiency measure for the exam is a scaled score; therefore, what is considered a passing score fluctuates with each administration. National Commission on Certification of Physician Assistants, *Exam Development and Scoring*, available at http://www.nccpa.net/Scoring (last visited Mar. 31, 2014)

<sup>&</sup>lt;sup>10</sup> Background screening is conducted by fingerprint by the Department of Law Enforcement and the Federal Bureau of Investigation. Section 456.0135, F.S.

- Provides a sworn statement of any prior felony convictions;
- Provides a sworn statement of any previous revocation or denial of licensure or certification in any state; and
- Provides two letters of recommendation.

A PA's license must be renewed biennially. Each renewal must include:

- A renewal fee not to exceed \$500 as set by the boards;<sup>11</sup>
- A sworn statement of no felony convictions in the previous 2 years; and
- Proof of completion of 100 hours of continuing medical education within the biennial period or a current certificate issued by the National Commission on Certification of Physician Assistants.

### Council on Physician Assistants

The Council was created in 1995 to recommend the licensure requirements (including educational and training requirements) for PAs, establish a formulary of drugs that PAs are prohibited to prescribe, and develop rules to ensure that the continuity of a physician's supervision over a PA is maintained in each practice setting throughout the state. <sup>12</sup> The Council does not discipline PAs. Disciplinary action is the responsibility of either the Board of Medicine or the Board of Osteopathic Medicine (boards).

### Supervising Physician

A PA practices under the delegated authority of a supervising physician. A physician supervising a PA must be qualified in the medical area(s) in which the PA is to perform health care tasks and is responsible and liable for the performance and acts and omissions of the PA.<sup>13</sup> A physician is not allowed to supervise more than four PAs at any one time.<sup>14</sup>

Supervision is defined as responsible supervision and control that requires the easy availability or physical presence of the physician for consultation and direction of actions performed by a PA.<sup>15</sup> Easy availability includes the ability to use telecommunication.

The respective board is delegated the authority to establish by rule what constitutes responsible supervision. Responsible supervision, defined by rule, is the ability of the supervising physician to responsibly exercise control and provide direction over the services or tasks performed by the PA. In providing supervision, the supervising physician is required to periodically review the PA's performance. In determining whether supervision is adequate, the following factors must be considered:<sup>17</sup>

- The complexity of the task;
- The risk to the patient;
- The background, training and skill of the PA;
- The adequacy of the direction in terms of its form:
- The setting in which the tasks are performed;
- The availability of the supervising physician;
- The necessity for immediate attention; and
- The number of other persons that the supervising physician must supervise.

<sup>&</sup>lt;sup>11</sup> The fee is currently set at \$275. Fla. Admin. Code Ann. r. 64B8-30.019.

<sup>&</sup>lt;sup>12</sup> Section 458.347(9); section 459.022(9), F.S.

<sup>&</sup>lt;sup>13</sup> Section 458.347(3), F.S.; Fla. Admin. Code Ann. r. 64B8-30.012.

<sup>&</sup>lt;sup>14</sup> *Id*.

<sup>&</sup>lt;sup>15</sup> Section 458.347(1)(f), F.S.

<sup>&</sup>lt;sup>16</sup> Fla. Admin. Code Ann. r. 64B8-30.001.

<sup>&</sup>lt;sup>17</sup> Id

The boards are authorized to adopt by rule the general principles that supervising physicians must use in developing the scope of practice of a PA under direct and indirect supervision. <sup>18</sup> Direct supervision refers to the physical presence of the supervising physician on the premises so that the supervising physician is immediately available to the PA when needed; whereas, indirect supervision refers to the easy availability of the supervising physician, such that the supervising physician must be within reasonable physical proximity. 19

Under current regulations, the decision to allow the PA to perform a task or procedure under direct or indirect supervision is made by the supervising physician based on reasonable medical judgment regarding the probability of morbidity and mortality to the patient.<sup>20</sup> An example of unreasonable medical judgment is a PA providing emergency room medical services to patients when the supervising physician is located 500 miles away. 21 Additionally, it is the responsibility of the supervising physician to be certain that the PA is knowledgeable and skilled in performing the tasks and procedures assigned. Physicians supervising dermatologist physician assistants are required by statute to have a primary place of practice within 75 miles.<sup>22</sup>

The number of PAs a supervising physician may supervise varies by state.<sup>23</sup> According to the American Academy of Physician Assistants, eleven states place no restriction on the number of PAs that may be supervised.<sup>24</sup> Sixteen states, including Florida, and the District of Columbia limit the amount to four.<sup>25</sup> Sixteen states have a limit of two or three. 26 and seven states have a limit of five or six. 27

### Delegable Tasks

A supervisory physician may delegate to a PA the authority to:

- Prescribe or dispense any medicinal drug used in the supervisory physician's practice.<sup>28</sup>
- Order medicinal drugs for a hospitalized patient of the supervising physician.<sup>29</sup>
- Administer a medicinal drug under the direction and supervision of the physician.<sup>30</sup>

**DATE: 4/1/2014** 

<sup>&</sup>lt;sup>18</sup> Section 458.347(4)(a); section 459.022(4)(a), F.S.

<sup>&</sup>lt;sup>19</sup> Fla. Admin. Code Ann. r. 64B8-30.012; Fla. Admin. Code Ann. r. 64B15-6.010.

<sup>&</sup>lt;sup>21</sup> See Department of Health, Board of Medicine v. Arnaldo Carmouze, P.A., Case No. 98-4993 (DOAH September 24,

<sup>&</sup>lt;sup>22</sup> Section 458.348, F.S.

<sup>&</sup>lt;sup>23</sup> The authority of Boards charged with regulating PAs also varies by state. In some states with a defined limit on PA supervision, the regulatory Board may be given rulemaking authority to increase or decrease the limit. See DEL. CODE ANN. tit. 24, § 1771(f). In other states, the Board may be granted discretionary authority to pierce the limit on a case by case basis. See Or. Rev. Stat. § 677.510. Some statutes also contain exceptions to PA supervision limits based on the type of health care facility in which the supervision occurs. See KAN. STAT. ANN. § 65-28a10.

Alaska, Arkansas, Maine, Massachusetts, Montana, New Mexico (ODs may only supervise two PAs), North Carolina, North Dakota, Rhode Island, Tennessee, and Vermont. American Academy of Physician Assistants, State Laws and Regulations Governing the Number of Physician Assistants that One Physician may Supervise, materials on file with committee staff.

<sup>&</sup>lt;sup>5</sup> Arizona, California, Colorado, Delaware, D.C., Florida, Georgia, Maryland, Michigan, Nebraska, New Hampshire, New Jersey, New York, Oregon, Pennsylvania, South Dakota, and Utah. Id.

<sup>&</sup>lt;sup>26</sup> Alabama (full time equivalent PAs), Hawaii, Idaho, Indiana, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Nevada, Ohio, Oklahoma, South Carolina, West Virginia, Wisconsin, and Wyoming. Id.

Connecticut, Illinois, Iowa, Minnesota, Texas, Virginia, and Washington. Id.

<sup>&</sup>lt;sup>28</sup> Section 458.347(4)(e), F.S.; section 459.022(4)(e), F.S. The supervising physician must notify the department of intent to delegate prescribing authority, and the PA must file with the department a signed affidavit that he or she has completed a minimum of 10 continuing medical education hours in the specialty practice area each renewal period. Id. The PA must identify to the patient as a PA and inform the patient of the right to see the physician. Id. The PA must note the prescription or dispensing of medication in the appropriate medical record. *Id.* 

Section 458.347(4)(f); section 459.022(4)(f), F.S.

<sup>&</sup>lt;sup>30</sup> Fla. Admin. Code Ann. r. 64B8-30.008; Fla. Admin. Code Ann. r. 64B15-6.0038.

Currently, PAs are prohibited from prescribing controlled substances (Schedules I-V under s. 893.03, F.S.); general, spinal, or epidural anesthetics; and radiographic contrast materials.<sup>31</sup> However, physicians may delegate to PAs the authority to order controlled substances in facilities licensed under ch. 395, F.S. (hospitals, ambulatory surgical centers, or mobile surgical facilities).

Determination of the final diagnosis must be performed by the supervising physician, and may not be delegated to a PA.<sup>32</sup> Per rule, the following tasks are not permitted to be performed under indirect supervision:<sup>33</sup>

- Routine insertion of chest tubes and removal of pacer wires or left atrial monitoring lines;
- Performance of cardiac stress testing;
- Routine insertion of central venous catheters:
- Injection of intrathecal medication without prior approval of the supervising physician;
- Interpretation of laboratory tests, X-ray studies and EKG's without the supervising physician interpretation and final review; and
- Administration of general, spinal, and epidural anesthetics; this may be performed under direct supervision only by PA who graduated from a board-approved anesthesiology assistants program.

### **Effect of Proposed Changes**

This bill amends chapters 458 and 459, F.S., to streamline administrative procedures for PAs seeking prescribing authority and for PA applicants seeking licensure. Instead of requiring PAs to submit a signed affidavit to attest to the completion of required continuing education in order to obtain prescribing privileges, the bill requires PAs to certify to the completion of the continuing education. The requirement for PA applicants to give a sworn statement of prior felony convictions or previous license denials or revocations when applying for licensure is changed to require a statement of such actions. The bill removes the requirement that PA applicants submit two letters of recommendation to be eligible for licensure.

The bill also increases the number of physician assistants a physician may supervise from four to eight.

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

### **B. SECTION DIRECTORY:**

**Section 1.** Amends s. 458.347, F.S., relating to physician assistants.

**Section 2.** Amends s. 459.022, F.S., relating to physician assistants.

Section 3. Provides an effective date of July 1, 2014.

### II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

### A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

### 2. Expenditures:

The bill has an insignificant negative fiscal impact on the DOH associated with non-recurring costs for rulemaking, which current budget authority is adequate to absorb.<sup>34</sup>

<sup>&</sup>lt;sup>31</sup> *Id*.

<sup>&</sup>lt;sup>32</sup> *Id.* 

<sup>&</sup>lt;sup>33</sup> *Id*.

None.
D. FISCAL COMMENTS:
None.
III. COMMENTS
A. CONSTITUTIONAL ISSUES:
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
On March 19, 2014, the Select Committee on Health Care Workforce Innovation adopted an amendment to HB 1275 and reported the bill favorably as a committee substitute. The amendment increases the number

**B. FISCAL IMPACT ON LOCAL GOVERNMENTS:** 

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

1. Revenues: None.

2. Expenditures:

None.

Committee Substitute.

<sup>34</sup> Department of Health Bill Analysis of HB 1275, March 28, 2014, on file with committee staff. **STORAGE NAME**: h1275b.HHSC.DOCX

PAGE: 6 **DATE: 4/1/2014** 

of physician assistants a physician may supervise from four to eight. This analysis is drafted to the

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A bill to be entitled

An act relating to physician assistants; amending ss. 458.347 and 459.022, F.S.; increasing the number of licensed physician assistants that a physician may supervise at any one time; revising circumstances under which a physician assistant is authorized to prescribe or dispense medication; revising application requirements for licensure as a physician assistant and license renewal; providing an effective date.

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

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Section 1. Subsection (3), paragraph (e) of subsection (4), and paragraphs (a) and (c) of subsection (7) of section 458.347, Florida Statutes, are amended to read:

16 17 458.347 Physician assistants.-

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or group of physicians supervising a licensed physician assistant must be qualified in the medical areas in which the physician assistant is to perform and shall be individually or collectively responsible and liable for the performance and the acts and omissions of the physician assistant. A physician may not supervise more than <a href="eight four">eight four</a> currently licensed physician assistants at any one time. A physician supervising a physician assistant pursuant to this section may not be required to review and cosign charts or medical records prepared by such physician

Page 1 of 8

27 assistant.

- (4) PERFORMANCE OF PHYSICIAN ASSISTANTS.-
- (e) A supervisory physician may delegate to a fully licensed physician assistant the authority to prescribe or dispense any medication used in the supervisory physician's practice unless such medication is listed on the formulary created pursuant to paragraph (f). A fully licensed physician assistant may only prescribe or dispense such medication under the following circumstances:
- 1. A physician assistant must clearly identify to the patient that he or she is a physician assistant. Furthermore, the physician assistant must inform the patient that the patient has the right to see the physician prior to any prescription being prescribed or dispensed by the physician assistant.
- 2. The supervisory physician must notify the department of his or her intent to delegate, on a department-approved form, before delegating such authority and notify the department of any change in prescriptive privileges of the physician assistant. Authority to dispense may be delegated only by a supervising physician who is registered as a dispensing practitioner in compliance with s. 465.0276.
- 3. The physician assistant must certify to file with the department a signed affidavit that he or she has completed a minimum of 10 continuing medical education hours in the specialty practice in which the physician assistant has prescriptive privileges with each licensure renewal application.

Page 2 of 8

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

- 5. The prescription must be written in a form that complies with chapter 499 and must contain, in addition to the supervisory physician's name, address, and telephone number, the physician assistant's prescriber number. Unless it is a drug or drug sample dispensed by the physician assistant, the prescription must be filled in a pharmacy permitted under chapter 465 and must be dispensed in that pharmacy by a pharmacist licensed under chapter 465. The appearance of the prescriber number creates a presumption that the physician assistant is authorized to prescribe the medicinal drug and the prescription is valid.
- 6. The physician assistant must note the prescription or dispensing of medication in the appropriate medical record.
  - (7) PHYSICIAN ASSISTANT LICENSURE.-
- (a) Any person desiring to be licensed as a physician assistant must apply to the department. The department shall issue a license to any person certified by the council as having met the following requirements:
  - 1. Is at least 18 years of age.
- 2. Has satisfactorily passed a proficiency examination by an acceptable score established by the National Commission on

Page 3 of 8

Certification of Physician Assistants. If an applicant does not hold a current certificate issued by the National Commission on Certification of Physician Assistants and has not actively practiced as a physician assistant within the immediately preceding 4 years, the applicant must retake and successfully complete the entry-level examination of the National Commission on Certification of Physician Assistants to be eligible for licensure.

- 3. Has completed the application form and remitted an application fee not to exceed \$300 as set by the boards. An application for licensure made by a physician assistant must include:
- a. A certificate of completion of a physician assistant training program specified in subsection (6).
  - b. A sworn statement of any prior felony convictions.
- c. A sworn statement of any previous revocation or denial of licensure or certification in any state.

#### d. Two letters of recommendation.

- description from a physician assistant training program describing course content in pharmacotherapy, if the applicant wishes to apply for prescribing authority. These documents must meet the evidence requirements for prescribing authority.
- (c) The license must be renewed biennially. Each renewal must include:
  - 1. A renewal fee not to exceed \$500 as set by the boards.

Page 4 of 8

2. A sworn statement of no felony convictions in the previous 2 years.

Section 2. Subsection (3), paragraph (e) of subsection (4), and paragraphs (a) and (b) of subsection (7) of section 459.022, Florida Statutes, are amended to read:

459.022 Physician assistants.-

- or group of physicians supervising a licensed physician assistant must be qualified in the medical areas in which the physician assistant is to perform and shall be individually or collectively responsible and liable for the performance and the acts and omissions of the physician assistant. A physician may not supervise more than <a href="eight four">eight four</a> currently licensed physician assistants at any one time. A physician supervising a physician assistant pursuant to this section may not be required to review and cosign charts or medical records prepared by such physician assistant.
  - (4) PERFORMANCE OF PHYSICIAN ASSISTANTS.-
- (e) A supervisory physician may delegate to a fully licensed physician assistant the authority to prescribe or dispense any medication used in the supervisory physician's practice unless such medication is listed on the formulary created pursuant to s. 458.347. A fully licensed physician assistant may only prescribe or dispense such medication under the following circumstances:
  - 1. A physician assistant must clearly identify to the

Page 5 of 8

patient that she or he is a physician assistant. Furthermore, the physician assistant must inform the patient that the patient has the right to see the physician prior to any prescription being prescribed or dispensed by the physician assistant.

- 2. The supervisory physician must notify the department of her or his intent to delegate, on a department-approved form, before delegating such authority and notify the department of any change in prescriptive privileges of the physician assistant. Authority to dispense may be delegated only by a supervisory physician who is registered as a dispensing practitioner in compliance with s. 465.0276.
- 3. The physician assistant must certify to file with the department a signed affidavit that she or he has completed a minimum of 10 continuing medical education hours in the specialty practice in which the physician assistant has prescriptive privileges with each licensure renewal application.
- 4. The department may issue a prescriber number to the physician assistant granting authority for the prescribing of medicinal drugs authorized within this paragraph upon completion of the foregoing requirements. The physician assistant shall not be required to independently register pursuant to s. 465.0276.
- 5. The prescription must be written in a form that complies with chapter 499 and must contain, in addition to the supervisory physician's name, address, and telephone number, the physician assistant's prescriber number. Unless it is a drug or drug sample dispensed by the physician assistant, the

Page 6 of 8

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

- 6. The physician assistant must note the prescription or dispensing of medication in the appropriate medical record.
  - (7) PHYSICIAN ASSISTANT LICENSURE.-

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- (a) Any person desiring to be licensed as a physician assistant must apply to the department. The department shall issue a license to any person certified by the council as having met the following requirements:
  - 1. Is at least 18 years of age.
- 2. Has satisfactorily passed a proficiency examination by an acceptable score established by the National Commission on Certification of Physician Assistants. If an applicant does not hold a current certificate issued by the National Commission on Certification of Physician Assistants and has not actively practiced as a physician assistant within the immediately preceding 4 years, the applicant must retake and successfully complete the entry-level examination of the National Commission on Certification of Physician Assistants to be eligible for licensure.
- 3. Has completed the application form and remitted an application fee not to exceed \$300 as set by the boards. An

Page 7 of 8

application for licensure made by a physician assistant must include:

- a. A certificate of completion of a physician assistant training program specified in subsection (6).
  - b. A sworn statement of any prior felony convictions.
- c. A sworn statement of any previous revocation or denial of licensure or certification in any state.
  - d. Two letters of recommendation.

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- description from a physician assistant training program describing course content in pharmacotherapy, if the applicant wishes to apply for prescribing authority. These documents must meet the evidence requirements for prescribing authority.
- (b) The licensure must be renewed biennially. Each renewal must include:
  - 1. A renewal fee not to exceed \$500 as set by the boards.
- 2. A sworn statement of no felony convictions in the previous 2 years.
  - Section 3. This act shall take effect July 1, 2014.

Page 8 of 8



Amendment No. 1

	COMMITTEE/SUBCOMMITTEE ACTION							
	ADOPTED (Y/N)							
	ADOPTED AS AMENDED (Y/N)							
	ADOPTED W/O OBJECTION (Y/N)							
	FAILED TO ADOPT (Y/N)							
	WITHDRAWN (Y/N)							
	OTHER							
1	Committee/Subcommittee hearing bill: Health & Human Services							
2	Committee							
3	Representative Ahern offered the following:							
4								
5	Amendment (with title amendment)							
6	Remove line 27 and insert:							
7	assistant. Notwithstanding the foregoing, a physician may only							
8	supervise up to four physician assistants in offices regulated							
9	pursuant to s. 458.348(4)(c).							
10								
11	Remove line 121 and insert:							
	assistant. Notwithstanding the foregoing, a physician may only							
12	assistant. Notwithstanding the foregoing, a physician may only							
12 13	assistant. Notwithstanding the foregoing, a physician may only supervise up to four physician assistants in offices regulated							
13	supervise up to four physician assistants in offices regulated							
13 14	supervise up to four physician assistants in offices regulated							

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Amendment No. 1

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19	TITLE AMENDMENT
20	Remove line 5 and insert:
21	supervise at any one time; providing an exception; revising
22	circumstances
23	

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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						
1	Committee/Subcommittee hearing bill: Health & Human Services						
2	Committee						
3	Representative Ahern offered the following:						
4							
5	Amendment (with title amendment)						
6	Remove lines 58-59 and insert:						
7	5. The prescription may must be written or electronic, but						
8	must be in a form that complies with ss. 456.0392(1) and						
9	456.42(1), chapter $499$ and must contain, in addition to the						
10							
11	Remove lines 152-153 and insert:						
12	5. The prescription <u>may</u> must be written <u>or electronic</u> , but						
13	must be in a form that complies with ss. 456.0392(1) and						
14	456.42(1), chapter $499$ and must contain, in addition to the						
15							
16							
17							

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Amendment No. 2

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19	TITLE AMENDMENT

20 Remove line 7 and insert:

prescribe or dispense medication; specifying that a prescription may be in written or electronic form and must meet certain requirements;

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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						
1	Committee/Subcommittee hearing bill: Health & Human Services						
2	Committee						
3	Representative Ahern offered the following:						
4							
5	Amendment						
6	Between lines 101 and 102, insert:						
7	e. Physician assistants seeking initial licensure on or						
8	after January 1, 2015, shall submit fingerprints pursuant to the						
9	procedures established in s. 456.0135.						
10							
11	Between lines 195 and 196, insert:						
12	e. Physician assistants seeking initial licensure on or						
13	after January 1, 2015, shall submit fingerprints pursuant to the						
14	procedures established in s. 456.0135.						
15							

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Amendment No. 4

COMMITTEE/SUBCOMMI	TTEE 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 Ahern offered the following:

### Amendment

Between lines 106 and 107, insert:

(e) Upon employment as a physician assistant, a licensed physician assistant must notify the department in writing within 30 days after such employment and provide or after any subsequent changes in the supervising physician. The notification must include the full name, Florida medical license number, specialty, and address of the a designated supervising physician. Any subsequent changes in the designated supervising physician shall be reported to the department within 30 days after the change. Assignment of a designated supervising physician does not preclude a physician assistant from practicing under multiple supervising physicians.

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Amendment No. 4

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Between lines 200 and 201, insert:

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Upon employment as a physician assistant, a licensed physician assistant must notify the department in writing within 30 days after such employment and provide or after any subsequent changes in the supervising physician. The notification must include the full name, Florida medical license number, specialty, and address of the a designated supervising physician. Any subsequent changes in the designated supervising physician shall be reported to the department within 30 days after the change. Assignment of a designated supervising physician does not preclude a physician assistant from practicing under multiple supervising physicians.

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Published On: 4/2/2014 7:22:12 PM



Amendment No. 5

COMMITTEE/SUBCOMMIT	TEE 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 Pigman offered the following:

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Between lines 106 and 107, insert:

Amendment (with title amendment)

Section 2. Paragraph (c) of subsection (4) of section 458.348, Florida Statutes, is amended to read:

458.348 Formal supervisory relationships, standing orders, and established protocols; notice; standards.—

(4) SUPERVISORY RELATIONSHIPS IN MEDICAL OFFICE SETTINGS.—A physician who supervises an advanced registered nurse practitioner or physician assistant at a medical office other than the physician's primary practice location, where the advanced registered nurse practitioner or physician assistant is not under the onsite supervision of a supervising physician, must comply with the standards set forth in this subsection. For

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Amendment No. 5

the purpose of this subsection, a physician's "primary practice location" means the address reflected on the physician's profile published pursuant to s. 456.041.

- (c) A physician who supervises an advanced registered nurse practitioner or physician assistant at a medical office other than the physician's primary practice location, where the advanced registered nurse practitioner or physician assistant is not under the onsite supervision of a supervising physician and the services offered at the office are primarily dermatologic or skin care services, which include aesthetic skin care services other than plastic surgery, must comply with the standards listed in subparagraphs 1.-4. Notwithstanding s. 458.347(4)(e)6., a physician supervising a physician assistant pursuant to this paragraph may not be required to review and cosign charts or medical records prepared by such physician assistant.
- 1. The physician shall submit to the board the addresses of all offices where he or she is supervising an advanced registered nurse practitioner or a physician's assistant which are not the physician's primary practice location.
- 2. The physician must be board certified or board eligible in dermatology or plastic surgery as recognized by the board pursuant to s. 458.3312.
- 3. All such offices that are not the physician's primary place of practice must be within 25 miles of the physician's primary place of practice or in a county that is contiguous to

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Amendment No. 5

the county of the physician's primary place of practice.

However, the distance between any of the offices may not exceed
75 miles.

- 4. The physician may supervise only one office other than the physician's primary place of practice except that until July 1, 2011, the physician may supervise up to two medical offices other than the physician's primary place of practice if the addresses of the offices are submitted to the board before July 1, 2006. Effective July 1, 2011, the physician may supervise only one office other than the physician's primary place of practice, regardless of when the addresses of the offices were submitted to the board.
- 5. As used in this subparagraph, the term "nonablative aesthetic skin care services" includes, but is not limited to, services provided using intense pulsed light, lasers, radio frequency, ultrasound, injectables, and fillers.
- a. Subparagraph 2. does not apply to offices at which nonablative aesthetic skin care services are performed by a physician assistant under the supervision of a physician if the physician assistant has successfully completed at least:
- (I) Forty hours of postlicensure education and clinical training on physiology of the skin, skin conditions, skin disorders, skin diseases, preprocedure and postprocedure skin care, and infection control.
- (II) Forty hours of postlicensure education and clinical training on laser and light technologies and skin applications.

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Amendment No. 5

(II)	I) Thirty	y-two	hours	of	postl	Licensure	education	and
clinical	training	on i	njectak	oles	and	fillers.		

- b. The physician assistant shall submit to the board documentation evidencing successful completion of the education and training required under this subparagraph.
- c. For purposes of compliance with s. 458.347(3), a physician who has completed 24 hours of education and clinical training on nonablative aesthetic skin care services, the curriculum of which has been preapproved by the Florida Board of Medicine, is qualified to supervise a physician assistant performing nonablative aesthetic skin care services pursuant to this subparagraph.

#### TITLE AMENDMENT

Remove line 9 and insert:

and license renewal; amending s. 458.348, F.S.; defining the

term "nonablative aesthetic skin care services"; authorizing a

physician assistant who has completed specified education and

clinical training requirements to perform nonablative aesthetic

skin care services under the supervision of a physician;

providing that a physician must complete a specified number of

education and clinical training hours to be qualified to

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Amendment No. 5

supervise physician assistants performing certain services;

providing an effective date.

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Amendment No. 6

COMMITTEE/SUBCOMMI	TTEE 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 Pigman offered the following:

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## Amendment (with title amendment)

Between lines 200 and 201, insert:

Section 3. Paragraph (c) of subsection (3) of section 459.025, Florida Statutes, is amended to read:

459.025 Formal supervisory relationships, standing orders, and established protocols; notice; standards.—

(3) SUPERVISORY RELATIONSHIPS IN MEDICAL OFFICE SETTINGS.—An osteopathic physician who supervises an advanced registered nurse practitioner or physician assistant at a medical office other than the osteopathic physician's primary practice location, where the advanced registered nurse practitioner or physician assistant is not under the onsite supervision of a supervising osteopathic physician, must comply with the

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Amendment No. 6

standards set forth in this subsection. For the purpose of this subsection, an osteopathic physician's "primary practice location" means the address reflected on the physician's profile published pursuant to s. 456.041.

- c) An osteopathic physician who supervises an advanced registered nurse practitioner or physician assistant at a medical office other than the osteopathic physician's primary practice location, where the advanced registered nurse practitioner or physician assistant is not under the onsite supervision of a supervising osteopathic physician and the services offered at the office are primarily dermatologic or skin care services, which include aesthetic skin care services other than plastic surgery, must comply with the standards listed in subparagraphs 1.-4. Notwithstanding s. 459.022(4)(e)6., an osteopathic physician supervising a physician assistant pursuant to this paragraph may not be required to review and cosign charts or medical records prepared by such physician assistant.
- 1. The osteopathic physician shall submit to the Board of Osteopathic Medicine the addresses of all offices where he or she is supervising or has a protocol with an advanced registered nurse practitioner or a physician's assistant which are not the osteopathic physician's primary practice location.
- 2. The osteopathic physician must be board certified or board eligible in dermatology or plastic surgery as recognized by the Board of Osteopathic Medicine pursuant to s. 459.0152.

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Amendment No. 6

- 3. All such offices that are not the osteopathic physician's primary place of practice must be within 25 miles of the osteopathic physician's primary place of practice or in a county that is contiguous to the county of the osteopathic physician's primary place of practice. However, the distance between any of the offices may not exceed 75 miles.
- 4. The osteopathic physician may supervise only one office other than the osteopathic physician's primary place of practice except that until July 1, 2011, the osteopathic physician may supervise up to two medical offices other than the osteopathic physician's primary place of practice if the addresses of the offices are submitted to the Board of Osteopathic Medicine before July 1, 2006. Effective July 1, 2011, the osteopathic physician may supervise only one office other than the osteopathic physician's primary place of practice, regardless of when the addresses of the offices were submitted to the Board of Osteopathic Medicine.
- 5. As used in this subparagraph, the term "nonablative aesthetic skin care services" includes, but is not limited to, services provided using intense pulsed light, lasers, radio frequency, ultrasound, injectables, and fillers.
- a. Subparagraph 2. does not apply to offices at which nonablative aesthetic skin care services are performed by a physician assistant under the supervision of a physician if the physician assistant has successfully completed at least:

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#### Amendment No. 6

<u>(I)</u>	Forty	hours	of ]	post.	licens	ure	educ	cation	and	clir	nical
training	on phys	siology	of	the	skin,	ski	in co	onditi	ons,	skir	<u>1</u>
disorders	s, skin	diseas	es,	prep	proced	ure	and	postp	roce	dure	skin
care, and	d infect	cion co	ntr	ol.							

- (II) Forty hours of postlicensure education and clinical training on laser and light technologies and skin applications.
- (III) Thirty-two hours of postlicensure education and clinical training on injectables and fillers.
- b. The physician assistant shall submit to the board documentation evidencing successful completion of the education and training required under this subparagraph.
- c. For purposes of compliance with s. 459.022(3), a physician who has completed 24 hours of education and clinical training on nonablative aesthetic skin care services, the curriculum of which has been preapproved by the Board of Osteopathic Medicine, is qualified to supervise a physician assistant performing nonablative aesthetic skin care services pursuant to this subparagraph.

## Remove line 9 and insert:

and license renewal; amending s. 459.025, F.S.; defining the term "nonablative aesthetic skin care services"; authorizing a physician assistant who has completed specified education and

TITLE AMENDMENT

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Amendment No. 6

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clinical training requirements to perform nonablative aestheti
skin care services under the supervision of a physician;
providing that a physician must complete a specified number of
education and clinical training hours to be qualified to
supervise physician assistants performing certain services;
providing an effective date.

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#### HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #:

HB 457

Pub. Rec./Dental Workforce Surveys

SPONSOR(S): Harrell

TIED BILLS:

IDEN./SIM. BILLS:

SB 520

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	11 Y, 0 N	Guzzo	O'Callaghan
2) Government Operations Subcommittee	11 Y, 0 N	Williamson	Williamson
3) Health & Human Services Committee		Guzzo	Calamas 🚳

## **SUMMARY ANALYSIS**

The bill creates a public record exemption for personal identifying information that is contained in a record provided by a dentist or dental hygienist in response to a dental workforce survey and held by the Department of Health.

The bill provides exceptions to the public record exemption under certain circumstances. Specifically, the bill provides that personal identifying information contained in such a record:

- Must be disclosed with the express written consent of the individual, to whom the information pertains, or the individual's legally authorized representative;
- Must be disclosed by court order upon a showing of good cause; and
- May be disclosed to a research entity, provided certain requirements are met.

The bill provides for repeal of the exemption on October 2, 2019, unless reviewed and saved from repeal by the Legislature. In addition, the bill provides a statement of public necessity as required by the State Constitution.

The bill does not appear to have a fiscal impact.

The bill provides an effective date of upon becoming a law.

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 or expanded public record or public meeting exemption. The bill creates a new public record exemption; thus, it requires a two-thirds vote for final passage.

This document does not reflect the intent or official position of the bill sponsor or House of Representatives. STORAGE NAME: h0457d.HHSC.DOCX

#### **FULL ANALYSIS**

#### I. SUBSTANTIVE ANALYSIS

#### A. EFFECT OF PROPOSED CHANGES:

#### **Current Situation**

#### **Public Records**

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. The Legislature, however, may provide by general law for the exemption of records from the requirements of Article I, s. 24(a) 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.<sup>1</sup>

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. Furthermore, the Open Government Sunset Review Act<sup>2</sup> 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.
- Protects trade or business secrets.

#### Workforce Surveys

In 2009, the Department of Health (DOH) developed a workforce survey for dentists and dental hygienists to complete on a voluntary basis in conjunction with the biennial renewal of dental licenses.<sup>3</sup> Of the 11,272 dentists who renewed an active license by June 23, 2010, 89 percent responded to the voluntary survey.<sup>4</sup>

Responses to the survey are self-reported. The survey was designed to obtain information unavailable elsewhere on key workforce characteristics in order to better inform and shape public healthcare policy. Specifically, the survey consists of 25 core questions on demographics, education and training, practice characteristics and status, specialties, retention, and access to oral healthcare in Florida.<sup>5</sup>

Unlike dentists and dental hygienists, physicians are statutorily required to respond to physician workforce surveys as a condition of license renewal.<sup>6</sup> All personal identifying information contained in records provided by physicians in response to these workforce surveys is confidential and exempt

<sup>&</sup>lt;sup>1</sup> Section 24(c), Art. I of the State Constitution.

<sup>&</sup>lt;sup>2</sup> Section 119.15, F.S.

<sup>&</sup>lt;sup>3</sup> Section 466.013(2), F.S., authorizes DOH to adopt rules for the biennial renewal of licenses.

<sup>&</sup>lt;sup>4</sup> Florida Department of Health , *Report on the 2009-2010 Workforce Survey of Dentists*, March 2011, at 11, http://www.doh.state.fl.us/Family/dental/OralHealthcareWorkforce/2009\_2010\_Workforce\_Survey\_Dentists\_Report.pdf (last visited February 14, 2014).

<sup>5</sup> Id

<sup>&</sup>lt;sup>6</sup> Section 381.4018, F.S. Language requiring the submission of physician workforce surveys for license renewal can be found in s. 458.3191, F.S., for allopathic physicians, and s. 459.0081, F.S., for osteopathic physicians.
STORAGE NAME: h0457d.HHSC.DOCX
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under s. 458.3193, F.S., concerning allopathic physicians, and s. 459.0083, F.S., concerning osteopathic physicians.

#### **Effect of Proposed Changes**

The bill provides that personal identifying information that is contained in a record provided by a dentist or dental hygienist licensed under ch. 466, F.S., in response to a dental workforce survey and held by DOH is confidential and exempt<sup>7</sup> from public records requirements.

The bill provides exceptions to the exemption under certain circumstances. Specifically, the bill provides that personal identifying information contained in such a record:

- Must be disclosed with the express written consent of the individual, to whom the information pertains, or the individual's legally authorized representative;
- Must be disclosed by court order upon a showing of good cause; and
- May be disclosed to a research entity, if the entity seeks the record or data pursuant to a research protocol approved by DOH.

The research entity must maintain the records or data in accordance with the approved research protocol, and enter into a purchase and data-use agreement with DOH. The purchase and data-use agreement is required to:

- Prohibit the release of information by the research entity which would identify individuals;
- Limit the use of records or data to the approved research protocol; and
- Prohibit any other use of the records or data.

The bill provides that copies of records or data remain the property of DOH.

DOH is authorized to deny a research entity's request if the protocol provides for intrusive follow-back contacts, does not plan for the destruction of the confidential records after the research is concluded, is administratively burdensome, or does not have scientific merit.

The bill provides for repeal of the exemption on October 2, 2019, unless reviewed and saved from repeal by the Legislature. It also provides a statement of public necessity as required by the State Constitution.<sup>8</sup> The public necessity statement declares the public record exemption necessary to foster candid and honest responses to the workforce survey and to ensure DOH has accurate information on dentists and dental hygienists.

#### **B. SECTION DIRECTORY:**

**Section 1:** Creates s. 466.051, F.S., relating to confidentiality of certain information contained in dental workforce surveys.

Section 2: Provides a public necessity statement.

Section 3: Provides an effective date of upon becoming a law.

## II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

8 Section 24(c), Art. I of the State Constitution.

STORAGE NAME: h0457d.HHSC.DOCX

<sup>&</sup>lt;sup>7</sup> 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).

#### A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

#### 2. Expenditures:

The bill could create a minimal fiscal impact on DOH, because staff responsible for complying with public record requests could require training related to creation of the new public record exemption. In addition, DOH 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 department.

#### **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:

#### 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 or expanded public record or public meeting exemption. The bill creates a public record exemption; 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 a public record exemption and it includes a public necessity statement.

#### Breadth of Exemption

Article I, s. 24(c) of the State Constitution requires a newly created public record or public meeting exemption to be no broader than necessary to accomplish the stated purpose of the law. The bill creates a public record exemption limited to the personal identifying information of dentists and dental hygienists who respond to dental workforce surveys. The exemption does not appear to be in

STORAGE NAME: h0457d.HHSC.DOCX

conflict with the constitutional requirement that the exemption be no broader than necessary to accomplish its purpose.

#### **B. RULE-MAKING AUTHORITY:**

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

## C. DRAFTING ISSUES OR OTHER COMMENTS:

## Other Comments: Voluntary Survey

DOH developed a workforce survey for dentists and dental hygienists to complete on a voluntary basis in conjunction with the biennial renewal of dental licenses. However, it is unclear if there is any statutory authority for the creation of such survey.

## Other Comments: Retroactive Application

The Supreme Court of Florida ruled that a public record exemption is not to be applied retroactively unless the legislation clearly expresses intent that such exemption is to be applied retroactively. The bill does not contain a provision requiring retroactive application. As such, the public record exemption would only apply prospectively.

#### IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

None.

<sup>9</sup> Memorial Hospital-West Volusia, Inc. v. News-Journal Corporation, 729 So.2d. 373 (Fla. 2001). STORAGE NAME: h0457d.HHSC.DOCX DATE: 4/1/2014 HB 457 2014

1	A bill to be entitled
2	An act relating to public records; creating s.
3	466.051, F.S.; providing an exemption from public
4	records requirements for information contained in
5	dental workforce surveys submitted by dentists or
6	dental hygienists to the Department of Health;
7	providing exceptions to the exemption; providing for
8	future legislative review and repeal of the exemption
9	under the Open Government Sunset Review Act; providing
10	a statement of public necessity; providing an
11	effective date.
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13	Be It Enacted by the Legislature of the State of Florida:
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15	Section 1. Section 466.051, Florida Statutes, is created
16	to read:
17	466.051 Confidentiality of certain information contained
18	<u>in dental workforce surveys.—</u>
19	(1) Personal identifying information that is contained in
20	a record provided by a dentist or dental hygienist licensed
21	under this chapter in response to a dental workforce survey and
22	held by the Department of Health is confidential and exempt from
23	s. 119.07(1) and s. 24(a), Art. I of the State Constitution.
24	Personal identifying information in such a record:
25	(a) Shall be disclosed with the express written consent of
26	the individual to whom the information pertains or the

Page 1 of 3

HB 457 2014

individual's legally authorized representative.

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- (b) Shall be disclosed by court order upon a showing of good cause.
- (c) May be disclosed to a research entity, if the entity seeks the records or data pursuant to a research protocol approved by the Department of Health, maintains the records or data in accordance with the approved protocol, and enters into a purchase and data-use agreement with the department, the fee provisions of which are consistent with s. 119.07(4). The department may deny a request for records or data if the protocol provides for intrusive follow-back contacts, does not plan for the destruction of the confidential records after the research is concluded, is administratively burdensome, or does not have scientific merit. The agreement must prohibit the release of information by the research entity which would identify individuals, limit the use of records or data to the approved research protocol, and prohibit any other use of the records or data. Copies of records or data issued pursuant to this paragraph remain the property of the department.
- (2) This section 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 personal identifying information that is contained in a record provided by a dentist or dental hygienist

Page 2 of 3

HB 457 2014

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licensed under chapter 466, Florida Statutes, who responds to a dental workforce survey be made confidential and exempt from disclosure. Candid and honest responses by licensed dentists or dental hygienists to the workforce survey will ensure that timely and accurate information is available to the Department of Health. The Legislature finds that the failure to maintain the confidentiality of such personal identifying information would prevent the resolution of important state interests to ensure the availability of dentists or dental hygienists in this state.

Section 3. This act shall take effect upon becoming a law.

Page 3 of 3

#### HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 7077 PCB HQS 14-01 Sterile Compounding

**SPONSOR(S):** Health Quality Subcommittee; Patronis **TIED BILLS: IDEN./SIM. BILLS:** SB 662

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
Orig. Comm.: Health Quality Subcommittee	13 Y, 0 N	Poche	O'Callaghan
1) Health Care Appropriations Subcommittee	12 Y, 0 N	Rodriguez	Pridgeon
2) Health & Human Services Committee		Poche	Calamas

#### **SUMMARY ANALYSIS**

House Bill 7077 requires any nonresident pharmacy registered with the state and any outsourcing facility, as defined in federal law, to obtain a nonresident sterile compounding permit in order to ship, mail, deliver, or dispense a compounded sterile product into this state. The bill outlines the requirements for the permit application and the standards that applicants must meet in order to obtain the permit.

The bill grants authority to the Department of Health and the Board of Pharmacy to enforce the laws and rules governing sterile compounding, including the authority to conduct onsite inspections of out-of-state applicants and permittees and the authority to administratively discipline applicants and permittees for failing to comply with Florida law.

The bill has an indeterminate fiscal impact on state government. However, additional revenues generated from initial permit fees, biennial renewal fees, fines and penalties along with the utilization of existing department resources will offset any fiscal impact related to state government expenditures. The bill also requires costs associated with the inspection of nonresident pharmacies and nonresident sterile compounding permittees to be borne by such pharmacy or permittee.

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

This document does not reflect the intent or official position of the bill sponsor or House of Representatives. STORAGE NAME: h7077b.HHSC

#### **FULL ANALYSIS**

#### I. SUBSTANTIVE ANALYSIS

#### A. EFFECT OF PROPOSED CHANGES:

## **Background**

#### Pharmacy Regulation

Chapter 465, F.S., regulates the practice of pharmacy in Florida and contains the minimum requirements for safe practice.<sup>1</sup> The Board of Pharmacy (Board) is tasked with adopting rules to implement the provisions of the chapter and with setting standards of practice within the state.<sup>2</sup> In order to be a licensed pharmacist, a person must meet certain educational and other requirements and pass an examination.<sup>3</sup> A licensed pharmacist must renew her or his license every two years by paying a fee and meeting continuing professional pharmaceutical education requirements.<sup>4</sup>

Any person who wants to operate a pharmacy in Florida must have a permit. The following permits are issued by the Department of Health (DOH):

- Community pharmacy A permit is required for each location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis.<sup>5</sup>
- Institutional pharmacy A permit is required for every location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility where medicinal drugs are compounded, dispensed, stored, or sold.<sup>6</sup>
- Nuclear pharmacy A permit is required for every location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold. The term "nuclear pharmacy" does not include hospitals licensed under chapter 395 or the nuclear medicine facilities of such hospitals.
- Special pharmacy A permit is required for every location where medicinal drugs are compounded, dispensed, stored, or sold if the location does not otherwise meet an applicable pharmacy definition in s. 465.003, F.S.<sup>8</sup>
- Internet pharmacy A permit is required for a location not otherwise licensed or issued a permit
  under this chapter, within or outside this state, which uses the Internet to communicate with or
  obtain information from consumers in this state to fill or refill prescriptions or to dispense,
  distribute, or otherwise practice pharmacy in this state.<sup>9</sup>

A pharmacy located outside of the state and ships, mails, or delivers, in any manner, a dispensed medicinal drug into the state must be registered as a nonresident pharmacy with the Board.<sup>10</sup> Registration requires application to the Board and payment of an initial registration fee.<sup>11</sup> Renewal of the registration is required every two years with payment of a fee.<sup>12</sup> Further, a registered nonresident pharmacy is required to provide services at a high level of competence and patient protection.<sup>13</sup> Lastly, a nonresident pharmacy must disclose to the Board the following information:

STORAGE NAME: h7077b.HHSC

<sup>&</sup>lt;sup>1</sup> S. 465.002, F.S.

<sup>&</sup>lt;sup>2</sup> SS. 465.005, F.S., 465.0155, F.S., and 465.022, F.S.

<sup>&</sup>lt;sup>3</sup> S. 465.007, F.S.

<sup>&</sup>lt;sup>4</sup> SS. 465.008, F.S., and 465.009, F.S.

<sup>&</sup>lt;sup>5</sup> SS. 465.003(11)(a)1. and 465.018, F.S.

<sup>&</sup>lt;sup>6</sup> SS. 465.003(11)(a)2. and 465.019, F.S.

<sup>&</sup>lt;sup>7</sup> SS. 465.003(11)(a)3. and 465.0193, F.S.

<sup>&</sup>lt;sup>8</sup> SS. 465.003(11)(a)4. and 465.0196, F.S.

<sup>&</sup>lt;sup>9</sup> SS. 465.003(11)(a)5. and 465.0197, F.S.

<sup>&</sup>lt;sup>10</sup> S. 465.0156, F.S.

<sup>&</sup>lt;sup>11</sup> S. 465.0156(2) and (3), F.S.

<sup>&</sup>lt;sup>12</sup> ld.

<sup>&</sup>lt;sup>13</sup> S. 465.0156(1), F.S.

- That it maintains at all times a valid, unexpired license, permit, or registration to operate the pharmacy in compliance with the laws of the state where it is located;<sup>14</sup>
- The location, names, and titles of all principal corporate officers and the pharmacist who serves as the prescription department manager for dispensing medicinal drugs to residents of this state;<sup>15</sup>
- That it complies with all lawful directions and requests for information from the regulatory or licensing agency of all states in which it is licensed as well as with all requests for information made by the Board;<sup>16</sup>
- That it maintains its records of medicinal drugs dispensed to patients in this state so that the records are readily retrievable;<sup>17</sup> and
- That during its regular hours of operation but not less than 6 days per week, for a minimum of 40 hours per week, a toll-free telephone service is provided to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records.<sup>18</sup>

The Board may deny, revoke, or suspend registration of, or fine or reprimand, a nonresident pharmacy for failure to comply with s. 465.025, F.S., regarding the substitution of drugs, or with any requirement of the statute. In addition, the Board may deny, revoke, or suspend registration of, or fine or reprimand, a nonresident pharmacy for conduct which causes serious bodily injury or serious psychological injury to a resident of this state. In Board must refer conduct that caused an injury to the regulatory or licensing agency in the state where the pharmacy is located. If the regulatory or licensing agency fails to investigate such conduct within 180 days of the referral, the Board may take appropriate action.

## Compounding

In general, compounding is a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient.<sup>23</sup> Compounding has been an integral part of the practice of pharmacy in the United States since the early 20<sup>th</sup> century.<sup>24</sup> Commonly compounded products include lotions, ointments, suppositories, and intravenous medications.

There are two types of compounding: sterile and non-sterile. Sterile compounding is the preparation of a custom medication or product in a sterile environment to prevent contamination and protect patient safety. Sterile compounded products are used to treat a variety of diseases and conditions and are categorized as low, medium, or high risk, depending upon the preparation and administration of the product. Products intended to be injected, infused, or applied to the eye must be compounded in a sterile environment to provide special safeguards to prevent injury or death to the people receiving those products.

Non-sterile compounding is similarly categorized depending upon the difficulty of compounding and the danger posed by the individual ingredients combined, mixed, or altered in a non-sterile environment.

STORAGE NAME: h7077b.HHSC DATE: 4/1/2014

<sup>&</sup>lt;sup>14</sup> S. 465.0156(1)(a), F.S.

<sup>&</sup>lt;sup>15</sup> S. 465.0156(1)(b), F.S.

<sup>&</sup>lt;sup>16</sup> S. 465.0156(1)(c), F.S.

<sup>&</sup>lt;sup>17</sup> S. 465.0156(1)(d), F.S.

<sup>&</sup>lt;sup>18</sup> S. 465.0156(1)(e), F.S.

<sup>&</sup>lt;sup>19</sup> S. 465.0156(4), F.S.

<sup>&</sup>lt;sup>20</sup> S. 465.0156(5), F.S.

<sup>&</sup>lt;sup>21</sup> Id.

<sup>&</sup>lt;sup>22</sup> ld.

<sup>&</sup>lt;sup>23</sup> U.S. Dept. of Health and Human Services, U.S. Food and Drug Administration, *Compounding and the FDA: Questions and Answers*, available at <a href="http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm">http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm</a> (last viewed on March 30, 2014).

<sup>&</sup>lt;sup>24</sup> Allen, Loyd V., *The Art, Science, and Technology of Pharmaceutical Compounding*, 4<sup>th</sup> Ed., Chapter 1, pages 3-4 (Washington, D.C.: American Pharmacists Association; 2012).

Simple non-sterile compounding involves mixing medications according to established formulas and creating liquid versions of drugs normally sold in tablet or capsule form. Moderate non-sterile compounding involves making preparations with harmful medications that require special handling. Complex non-sterile compounding requires advanced training and special equipment to make products such as extended-release capsules and transdermal patches.

According to the Board, there are 301 registered nonresident pharmacies engaged in sterile compounding that ship, mail, deliver, or dispense compounded sterile products into the state.<sup>25</sup>

## Special Sterile Compounding Permit

Effective September 23, 2013, most pharmacies that engage or intend to engage in the preparation of compounded sterile products in Florida must obtain a Special Sterile Compounding Permit (SSCP). Pharmacies required to obtain this permit must compound sterile products in strict compliance with standards set forth in Rule 64B16-27.797, F.A.C., which contains specific standards for compounding sterile preparations, and Rule 64B16-27.700, F.A.C., which contains standards that must be met for office use compounding. The following entities are not required to obtain the SSCP:

- Stand-alone special parenteral/enteral pharmacies;
- Special parenteral/enteral extended scope pharmacies;
- Pharmacies that only perform non-sterile compounding; and
- Non-resident pharmacies.<sup>28</sup>

All pharmacies engaged in sterile compounding in the state were required to obtain the SSCP by March 21, 2104. No fee was required for existing licensees.<sup>29</sup> New establishments were required to submit \$255 with the application for the SSCP, in addition to the \$255 fee for the primary pharmacy permit.<sup>30</sup>

#### Drug Quality and Security Act

On November 27, 2013, President Barack Obama signed the Drug Quality and Security Act (DQSA), which contains provisions relating to the oversight of compounding. Title I of the DQSA, titled the "Compounding Quality Act," describes the conditions<sup>31</sup> under which certain compounded human drug products are entitled to exemptions from three sections of the Food, Drug, and Cosmetic Act (FDCA) requiring:

- Compliance with current good manufacturing practices (cGMP);<sup>32</sup>
- Labeling with adequate directions for use;<sup>33</sup> and
- Food and Drug Administration (FDA) approval prior to marketing of the drug.<sup>34</sup>

In addition, the new law permits a pharmacy or non-pharmacy engaged in compounding to voluntarily register as an "outsourcing facility." An outsourcing facility may qualify for exemptions from the FDA

STORAGE NAME: h7077b.HHSC

<sup>&</sup>lt;sup>25</sup> Florida Dept. of Health, Division of Medical Quality Assurance, *Florida Board of Pharmacy Compounding Survey Report*, January 23, 2013, page 15 (on file with Health and Human Services Committee staff).

<sup>&</sup>lt;sup>26</sup> Rule 64B16-28.100(8), F.A.C.

<sup>&</sup>lt;sup>27</sup> Rule 64B16-28.802, F.A.C.; "Office use compounding" is the provision and administration of a compounded drug to a patient by a health care practitioner in her or his office or by the practitioner in a health care facility or treatment setting, including a hospital, ambulatory surgical center, or pharmacy.

<sup>&</sup>lt;sup>28</sup> Florida Board of Pharmacy, *Special Sterile Compounding Permit*, available at <u>www.floridaspharmacy.gov/latest-news/special-sterile-compounding-permit</u>/ (last viewed on March 30, 2014).

compounding-permit/ (last viewed on March 30, 2014).

<sup>29</sup> Florida Board of Pharmacy, *Sterile Compounding Permit*, available at <a href="https://www.floridaspharmacy.gov/licensing/sterile-compounding-permit/">www.floridaspharmacy.gov/licensing/sterile-compounding-permit/</a> (last viewed on March 30, 2014).

<sup>30</sup> Id.

<sup>&</sup>lt;sup>31</sup> FDCA, s. 503(A)

<sup>&</sup>lt;sup>32</sup> FDCA, s. 501(a)(2)(B)

<sup>&</sup>lt;sup>33</sup> FDCA, s. 502(f)(1)

<sup>&</sup>lt;sup>34</sup> FDCA, s. 505

<sup>&</sup>lt;sup>35</sup> FDCA, s. 503(B)

approval requirements and the requirement to label products with adequate directions for use, but not the exemption from cGMP requirements. Outsourcing facilities:

- Must comply with cGMP requirements;
- Will be inspected by FDA according to a risk-based schedule; and
- Must meet certain other conditions, such as reporting adverse events and providing FDA with certain information about the products they compound.

The FDA anticipates that state boards of pharmacy will continue their oversight and regulation of the practice of pharmacy, including traditional pharmacy compounding. The FDA has indicated its intention to continue to cooperate with state authorities to address pharmacy compounding activities that may violate the FDCA.

According to the FDA, there are currently 37 registered outsourcing facilities in the U.S., three of which are located in Florida.<sup>36</sup>

## New England Compounding Center

On September 18, 2012, the Tennessee Department of Health (TDOH) was alerted by a clinician regarding a patient with culture-confirmed fungal meningitis diagnosed 46 days after an epidural steroid injection at a Tennessee ambulatory surgical center.<sup>37</sup> By September 27, 2012, the initial investigation, carried out by the TDOH in collaboration with the Centers for Disease Control and Prevention (CDC) and the North Carolina Department of Health and Human Services, had identified an additional eight patients with clinically diagnosed meningitis: seven in Tennessee and one in North Carolina. All nine patients had received an epidural steroid injection with preservative-free methylprednisolone acetate solution (MPA), compounded at New England Compounding Center (NECC) in Framingham, Massachusetts. Subsequent testing revealed fungal contamination of the MPA vials. After an in-depth investigation of NECC, it was determined that the MPA vials, and other products made by NECC, were compounded in violation of the laws and rules of Massachusetts governing sterile compounding. The investigation found that NECC's sterile compounding processes were not sterile and violated many provisions of the U.S. Pharmacopeia Chapter 797.<sup>38</sup>

The infections identified as part of this investigation include fungal meningitis, spinal or paraspinal infections, and infections associated with injections in a knee, shoulder, or ankle. The majority of infections reported to the CDC were in patients with localized spinal or paraspinal infections.

The following map illustrates the number of cases of fungal meningitis and other infections in each state resulting from the contaminated MPA from NECC:<sup>39</sup>

STORAGE NAME: h7077b.HHSC DATE: 4/1/2014

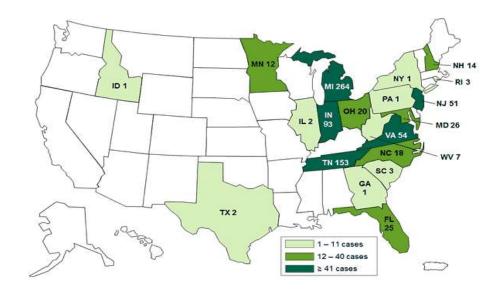
<sup>&</sup>lt;sup>36</sup> U.S. Dept. of Health and Human Services, U.S. Food and Drug Administration, *Registered Outsourcing Facilities* (updated as of March 21, 2014), available at <a href="https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm378645.htm">www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm378645.htm</a> (last viewed on March 30, 2014). The Florida-based registered outsourcing facilities are KRS Global Biotechnology, Inc., in Boca Raton, and Lowlite Investments, Inc., and OPS International, Inc., in Orlando, both doing business under the name Olympia Pharmacy.

<sup>37</sup> Kainer, M, and Wiese, A., Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report-Multistate Outbreak of Fungal Infection Associated with Injection of Methylprednisolone Acetate Solution from a Single Compounding Pharmacy -United States, 2012, 61(41);839-842, October 19, 2012, available at

www.dcd.gov/mmwr/preview/mmwrhtml/mm614a4.htm?s\_cid=mm614a4\_w (last viewed on March 30, 2014).

38 See infra, *U.S. Pharmacopeia and USP 797*, page 6.

<sup>&</sup>lt;sup>39</sup> Centers for Disease Control and Prevention, *Multistate Outbreak of Fungal Meningitis & Other Infections-Case Count*, October 23, 2013, available at <a href="https://www.cdc.gov/hai/outbreaks/meningitis-map-large.html">www.cdc.gov/hai/outbreaks/meningitis-map-large.html</a> (last viewed on March 30, 2014)(according to the CDC, no further case count updates were expected following the Oct. 23, 2013 update).



In total, 751 people in 20 states were sickened by the contaminated MPA injections, including 25 Floridians.<sup>40</sup> Of the 751 people infected, 64 people died and 7 of those deaths were in Florida.

#### U.S. Pharmacopeia and USP 797

The U.S. Pharmacopeia (USP) is a non-profit agency that develops and publishes standards for drug substances, drug products, excipients, and dietary supplements in the U.S. Pharmacopeia–National Formulary (USP–NF). USP–NF standards play a role in the adulteration and misbranding provisions of the FDCA. USP has no role in enforcement of these or other provisions that recognize USP–NF standards, which is the responsibility of the FDA.

USP 797 refers to chapter 797, "Pharmaceutical Compounding – Sterile Preparations," in the USP-NF. It is the first set of enforceable sterile compounding standards issued by the USP. USP 797 describes the guidelines, procedures and compliance requirements for compounding sterile preparations and sets the standards that apply to all settings in which sterile preparations are compounded. Standards in USP–NF for compounded preparations may be enforced by both the states and the FDA.

The Board requires compliance with USP 797. At least 24 other states have practice rules which incorporate all, most, or some of the USP 797 standards.<sup>41</sup> Three states consider the USP 797 to be a standard of practice: Hawaii, Oklahoma, and South Carolina.<sup>42</sup>

## **Effect of Proposed Changes**

To ensure the safety and quality of sterile products compounded outside of the state and dispensed to Floridians, House Bill 7077 requires any registered nonresident pharmacy and any non-pharmacy outsourcing facility to obtain a nonresident sterile compounding permit in order to ship, mail, deliver, or dispense a compounded sterile product in this state. To obtain the permit, a registered nonresident pharmacy or an outsourcing facility must submit an application and fee to DOH. The application must include the following information:

STORAGE NAME: h7077b.HHSC

<sup>&</sup>lt;sup>40</sup> Centers for Disease Control and Prevention, Cases and Deaths with Fungal Infections Linked to Steroid Injections, available at <a href="https://www.cdc.gov/hai/outbreaks/meningitis-map-large.html#casecount\_table">www.cdc.gov/hai/outbreaks/meningitis-map-large.html#casecount\_table</a> (last viewed on March 30, 2014).

<sup>&</sup>lt;sup>41</sup> These states are Arkansas, Colorado, Delaware, Georgia, Indiana, Iowa, Kentucky, Louisiana, Maryland, Minnesota, Missouri, Nevada, New Jersey, New Mexico, Ohio, Oregon, Rhode Island, South Dakota, Texas, Utah, Virginia, West Virginia, Wisconsin, and Wyoming. Jessen, L., *Compounding: What is Manufacturing? What is Compounding?*, National Association of Boards of Pharmacy 2012 Triathlon, Interactive Executive Officer Forum, PowerPoint presentation, November 13-14, 2012, slide 9 (on file with Health and Human Services Committee staff).

- Proof of registration as an outsourcing facility, if eligible pursuant to the DQSA;
- Proof of registration as a nonresident pharmacy under s. 465.0156, F.S., or, if the applicant is
  not a pharmacy, proof of an active and unencumbered license, registration, or permit issued by
  the state, territory, or district where the applicant is located, which is required to compound
  sterile products in that jurisdiction;
- Attestation by an owner or officer and the prescription department manager or the pharmacist in charge that:
  - o They have read and understand Florida law and rules governing sterile compounding;
  - Any sterile compounded product shipped or otherwise introduced into this state will meet or exceed Florida law and rules governing sterile compounding; and
  - Any sterile compounded product shipped or otherwise introduced has not been, and will
    not be, compounded in violation of laws and rules governing sterile compounding where
    the applicant is located.
- Copies of existing policies and procedures governing sterile compounding that meet certain standards; and
- A current inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state, territory or district where the applicant is located.

The bill establishes a timeframe within which an inspection report will be considered current. The inspection report must be dated no later than six months from the application for an initial permit and no later than twelve months from the application for renewal of the permit. The bill takes into account unforeseen circumstances that prevent an applicant from submitting a current inspection report, and authorizes the Board to define what is considered unforeseen or acceptable circumstances. If an applicant claims that unforeseen or acceptable circumstances prevent it from including a current inspection report with the application, or if the applicant has never undergone an inspection by a regulatory or licensing agency, the bill authorizes DOH to:

- Conduct an onsite inspection of the applicant, or contract with a third party to conduct the onsite inspection;
- Accept a satisfactory inspection report, as determined by rule, from an entity approved by the Board: or
- Accept an inspection report from the FDA, conducted pursuant to the provisions of the DQSA.

A permittee may not ship or otherwise introduce a compounded sterile product into Florida that was compounded in violation of the laws and rules of the place where it is located and does not meet or exceed the standards governing sterile compounding in this state.

A registered nonresident pharmacy which is shipping or otherwise introducing a compounded sterile product into the state may continue to do so as long as the product is compounded in accordance with all laws and rules in its home state and in Florida and it obtains a permit by February 28, 2015, which is the expiration date of all pharmacy permits in Florida. However, an applicant seeking to register as a nonresident pharmacy on or after the effective date of the bill is required to obtain a permit before it may ship, mail, deliver, or dispense a compounded sterile product into Florida.

The bill grants the Board authority to administratively discipline a nonresident sterile compounding permittee for failing to comply with the requirements of s. 465.0158, F.S., violating statutes that outline acts and omissions which are grounds for discipline, violating health care fraud provisions, and violating the provisions of s. 465.0156, F.S. The bill specifies that the Board may impose fines on violators.

The bill gives the Board the authority to administratively discipline a registered nonresident pharmacy for failing to comply with s. 465.017, F.S., which allows the Board to inspect a nonresident pharmacy to ensure compliance with applicable laws and rules, or failing to comply with s. 465.0158, F.S. In

addition, the bill subjects a registered nonresident pharmacy to the health care fraud provisions and penalties in s. 456.0635, F.S. 43

The bill gives DOH the authority to inspect a nonresident pharmacy or a nonresident sterile compounding permittee to ensure compliance with applicable laws and rules. The pharmacy or permittee is required to bear all costs of such an inspection.

Lastly, the bill adds the definitions of "compounding" and "outsourcing facility" to chapter 465, F.S.

#### **B. SECTION DIRECTORY:**

**Section 1:** Amends s. 465.003, F.S., relating to definitions.

**Section 2:** Amends s. 465.0156, F.S., relating to registration of nonresident pharmacies.

Section 3: Creates s. 465.0158, F.S., relating to nonresident sterile compounding permit.

**Section 4:** Amends s. 465.017, F.S., relating to authority to inspect; disposal.

**Section 5:** Provides an effective date of October 1, 2014.

#### II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

#### A. FISCAL IMPACT ON STATE GOVERNMENT:

#### 1. Revenues:

This bill will have a positive impact on state revenues. DOH will collect new fees associated with applications for initial permits and biennial renewal of permits. DOH estimates that approximately 350 applications for nonresident sterile compounding permits will be received.<sup>44</sup> Initial permit fee and renewal fees are \$250 plus \$5 for an Unlicensed Activity fee. In total, \$255 times the estimated number of nonresident permittees (350) equals \$89,250. Less the 8% surcharge to General Revenue, the anticipated additional revenue would be approximately \$82,110 annually. Revenues collected from initial permit fees and biennial renewal fees are deposited into the Medical Quality Assurance Trust Fund.

DOH or the Board may impose fines or penalties on either nonresident pharmacies or nonresident sterile compounding permittees found in violation of laws or rules associated with this bill. Revenues collected from fines and penalties are deposited into the Medical Quality Assurance Trust Fund.

## 2. Expenditures:

DOH has reported that the following nonrecurring costs will be borne by the department as a result of the passage of this bill:45

- Rulemaking:
- Mail notifications to non-resident permittees; and
- Updating the existing licensure system to accommodate the new nonresident sterile compounding permit.

ld.

STORAGE NAME: h7077b.HHSC

PAGE: 8

<sup>&</sup>lt;sup>43</sup> Pursuant to s. 456.0635, F.S., each board shall refuse to admit a candidate to any examination and refuse to issue a license, certificate, or registration to any applicant if the candidate or applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant has, for example, been convicted of a felony in conjunction with participation in the Medicaid program or been terminated for cause from the Medicaid program. The statute lists several other crimes or activities that disqualify an applicant or candidate from consideration for a license, certificate, or registration issued by a board.

<sup>&</sup>lt;sup>44</sup> Florida Department of Health, 2014 Agency Legislative Bill Analysis for HB 7077, pages 5-6 (on file with Health and Human Services Committee staff).

DOH has reported that these nonrecurring costs may be absorbed within the department's current resources.46

DOH has reported that the recurring increases in workload associated with the permitting of nonresident sterile compounding permittees and the enforcement of provisions of this bill may be absorbed within the department's current resources.<sup>47</sup>

This bill gives DOH the authority to conduct an onsite inspection of an applicant for an initial nonresident sterile compounding permit or renewal of a permit which is located outside of Florida. DOH has estimated the cost of conducting an onsite inspection of an out-of-state applicant to range, depending on the location of the applicant in the U.S., from \$1,786 to \$2,371. The average cost of an inspection is estimated to be \$2,100.

	B.	FISCAL	IMPACT	ON LOCAL	GOVERNMENT	S
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	None.
2.	Expenditures:

None.

1. Revenues:

#### C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

In addition to the initial permit fee and renewal fees of \$255, a nonresident pharmacy or outsourcing facility is required to pay all costs associated with an inspection conducted in conjunction with an application for a nonresident sterile compounding permit. Also, a nonresident pharmacy and a nonresident sterile compounding permittee are required to pay all costs associated with an inspection pursuant to s. 465.017.

The cost for registration as an outsourcing facility is \$15,000, adjusted for inflation and for small businesses as detailed in the federal law. 48 The cost for registration as an outsourcing facility charged to a small business, defined as a business with gross annual sales of \$1,000,000 or less, is one-third of the establishment fee. The cost of reinspection of an outsourcing facility required by the FDA is \$15,000.<sup>49</sup>

#### 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.

<sup>46</sup> ld.

STORAGE NAME: h7077b.HHSC

<sup>&</sup>lt;sup>47</sup> Id.

<sup>&</sup>lt;sup>48</sup> DQSA, Pub. L. No. 113-54, s. 744K

## B. RULEMAKING AUTHORITY:

The bill provides sufficient rulemaking authority to DOH to implement the provisions of the act.

## C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

## IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

STORAGE NAME: h7077b.HHSC

A bill to be entitled 1 2 An act relating to sterile compounding; amending s. 3 465.003, F.S.; defining the terms "compounding" and "outsourcing facility" as used in the Florida Pharmacy 4 Act; amending s. 465.0156, F.S.; providing additional 5 grounds for administrative discipline of a nonresident 6 7 pharmacy, to which penalties apply; authorizing the Board of Pharmacy to administratively discipline a 8 9 nonresident pharmacy for certain conduct; deleting a 10 requirement that the board first refer such conduct to 11 a certain regulatory or licensing agency; providing that a nonresident pharmacy is subject to certain 12 health care fraud provisions; creating s. 465.0158, 13 F.S.; requiring a nonresident pharmacy and an 14 outsourcing facility to hold a nonresident sterile 15 compounding permit to ship, mail, deliver, or dispense 16 a compounded sterile product into this state; 17 providing permit application requirements; requiring 18 19 the Department of Health to conduct an onsite 20 inspection of a nonresident pharmacy or contract with 21 a third party to conduct such inspection; requiring the department to accept a satisfactory inspection 22 23 report from specified entities; providing restrictions on the shipment, mailing, delivery, or dispensation of 24 25 a compounded sterile product by permittees, nonresident pharmacies, and applicants for 26

Page 1 of 9

27	registration as a nonresident pharmacy; authorizing
28	the board to administratively discipline a permittee
29	for failing to comply with or violating certain
30	provisions; providing rulemaking authority; amending
31	s. 465.017, F.S.; authorizing the department to
32	inspect a registered nonresident pharmacy or
33	permittee; requiring such pharmacy or permittee to
34	bear the cost of the inspection; providing an
35	effective date.
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37	Be It Enacted by the Legislature of the State of Florida:
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39	Section 1. Subsections (18) and (19) are added to section
40	465.003, Florida Statutes, to read:
41	465.003 Definitions.—As used in this chapter, the term:
42	(18) "Compounding" means a practice in which a licensed
43	pharmacist or, in the case of an outsourcing facility, a person
44	acting under the supervision of a licensed pharmacist, combines,
45	mixes, or alters ingredients of a drug or product to create
46	another drug or product.
47	(19) "Outsourcing facility" means a single physical
48	location registered as an outsourcing facility under the federal
49	Drug Quality and Security Act, Pub. L. No. 113-54, at which
50	sterile compounding of a product is conducted.
51	Section 2. Subsections (4) and (5) of section 465.0156,
52	Florida Statutes, are amended, and subsection (6) is added to

Page 2 of 9

that section, to read:

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465.0156 Registration of nonresident pharmacies.-

- (4) The board may deny, revoke, or suspend registration of, or fine or reprimand, a nonresident pharmacy for failure to comply with s. 465.025, s. 465.017(2), s. 465.0158, or with any requirement of this section in accordance with the provisions of this chapter.
- (5) In addition to the prohibitions of subsection (4) the board may deny, revoke, or suspend registration of, or fine or reprimand, a nonresident pharmacy in accordance with the provisions of this chapter for conduct which causes or could cause serious bodily injury or serious psychological injury to a human or serious bodily injury to a nonhuman animal in resident of this state if the board has referred the matter to the regulatory or licensing agency in the state in which the pharmacy is located and the regulatory or licensing agency fails to investigate within 180 days of the referral.
- (6) A nonresident pharmacy is subject to the provisions of s. 456.0635.
- Section 3. Section 465.0158, Florida Statutes, is created to read:
  - 465.0158 Nonresident sterile compounding permit.
- (1) In order to ship, mail, deliver, or dispense, in any manner, a compounded sterile product into this state, a nonresident pharmacy registered under s. 465.0156, or an outsourcing facility as defined in s. 465.003, must hold a

Page 3 of 9

nonresident sterile compounding permit. For purposes of this section, an outsourcing facility is a nonresident facility that is not a pharmacy.

- (2) An application for a nonresident sterile compounding permit shall be submitted on a form furnished by the board. The board may require such information as it deems reasonably necessary to carry out the purposes of this section. The fee for an initial permit and biennial renewal of the permit shall be set by the board pursuant to s. 465.022(14).
- (3) An applicant must submit to the board to obtain an initial permit, or to the department to renew a permit, the following:
- (a) Proof of registration as an outsourcing facility with the Secretary of the United States Department of Health and Human Services if the applicant is eligible for such registration pursuant to the federal Drug Quality and Security Act, Pub. L. No. 113-54.
- (b) Proof of registration as a nonresident pharmacy, pursuant to s. 465.0156, unless the applicant is an outsourcing facility, in which case the application must include proof of the active and unencumbered license, permit, or registration issued by the state, territory, or district in which the outsourcing facility is physically located which allows the outsourcing facility to engage in compounding and ship, mail, deliver, or dispense a compounded sterile product into this state.

Page 4 of 9

(c) Written attestation by an owner or officer of the applicant, and by the applicant's prescription department manager or pharmacist in charge, that:

- 1. The applicant has read and understands the laws and rules governing sterile compounding in this state.
- 2. A compounded sterile product shipped, mailed, delivered, or dispensed into this state will meet or exceed this state's standards for sterile compounding.
  - 3. A compounded sterile product shipped, mailed, delivered, or dispensed into this state must not have been, and may not be, compounded in violation of the laws and rules of the state in which the applicant is located.
  - (d) The applicant's existing policies and procedures for sterile compounding, which must comply with pharmacy standards in United States Pharmacopoeia chapter 797, to the extent required by board rule, or current good manufacturing practices for an outsourcing facility.
- (e) A current inspection report from an inspection conducted by the regulatory or licensing agency of the state, territory, or district in which the applicant is located. The inspection report must reflect compliance with the requirements of this chapter. An inspection report is current if the inspection was conducted no more than 6 months before the date of submission of the application for the initial permit or no more than 1 year before the date of submission of the application for renewal of the permit. If an applicant is unable

Page 5 of 9

to submit a current inspection report due to unforeseeable or 131 other acceptable circumstances, as established by rule, or if an 132 133 inspection has not been performed, the department shall: 1. Conduct, or contract with an entity approved by the 134 board to conduct, an onsite inspection, for which all costs 135 136 shall be borne by the applicant; 2. Accept a satisfactory inspection report in lieu of an 137 onsite inspection, as determined by rule, from an entity 138 139 approved by the board; or 140 3. Accept an inspection report from the United States Food 141 and Drug Administration conducted pursuant to the federal Drug 142 Quality and Security Act, Pub. L. No. 113-54, in lieu of an 143 onsite inspection. (4) A permittee may not ship, mail, deliver, or dispense a 144 145 compounded sterile product into this state if the product was 146 compounded in violation of the laws or rules of the state in 147 which the permittee is located or does not meet or exceed this state's sterile compounding standards. 148 149 (5) In accordance with this chapter, the board may deny, 150 revoke, or suspend the permit of, fine, or reprimand a permittee 151 for: (a) Failure to comply with the requirements of this 152 153 section; (b) A violation listed under s. 456.0635, s. 456.065, or 154 155 s. 456.072; 156 (c) A violation under s. 465.0156(5); or

Page 6 of 9

157	(d)	Α	violation	listed	under	s.	465.03	16.
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- (6) A nonresident pharmacy registered under s. 465.0156 which ships, mails, delivers, or dispenses a compounded sterile product into this state may continue to do so if the product meets or exceeds the standards for sterile compounding in this state, the product is not compounded in violation of any law or rule of the state where the pharmacy is located, and the pharmacy applies for and is issued a permit under this section on or before February 28, 2015.
- (7) An applicant registering on or after October 1, 2014, as a nonresident pharmacy under s. 465.0156 may not ship, mail, deliver, or dispense a compounded sterile product into this state until the applicant is registered as a nonresident pharmacy and is issued a permit under this section.
- (8) The board shall adopt rules as necessary to administer this section, including rules for:
- (a) Developing an application for the permit required by this section.
- (b) Determining how, when, and under what circumstances an inspection of a nonresident sterile compounding permittee shall be conducted.
- (c) Evaluating and approving entities from which a satisfactory inspection report will be accepted in lieu of an onsite inspection by the department or an inspection by the licensing or regulatory agency of the state, territory, or district where the applicant is located.

Page 7 of 9

Section 4. Section 465.017, Florida Statutes, is amended to read:

465.017 Authority to inspect; disposal.-

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- (1) Duly authorized agents and employees of the department shall have the power to inspect in a lawful manner at all reasonable hours any pharmacy, hospital, clinic, wholesale establishment, manufacturer, physician's office, or any other place in the state in which drugs and medical supplies are compounded, manufactured, packed, packaged, made, stored, sold, offered for sale, exposed for sale, or kept for sale for the purpose of:
- (a) Determining if any of the provisions of this chapter or any rule adopted promulgated under its authority is being violated;
- (b) Securing samples or specimens of any drug or medical supply after paying or offering to pay for such sample or specimen; or
- (c) Securing such other evidence as may be needed for prosecution under this chapter.
- (2) Duly authorized agents and employees of the department may inspect a nonresident pharmacy registered under s. 465.0156 or a nonresident sterile compounding permittee under s. 465.0158 pursuant to this section. The costs of such inspections shall be borne by such pharmacy or permittee.
- (3) (2) (a) Except as permitted by this chapter, and chapters 406, 409, 456, 499, and 893, records maintained in a

Page 8 of 9

pharmacy relating to the filling of prescriptions and the dispensing of medicinal drugs shall not be furnished to any person other than to the patient for whom the drugs were dispensed, or her or his legal representative, or to the department pursuant to existing law, or, in the event that the patient is incapacitated or unable to request said records, her or his spouse except upon the written authorization of such patient. Such records may be furnished in any civil or criminal proceeding, upon the issuance of a subpoena from a court of competent jurisdiction and proper notice to the patient or her or his legal representative by the party seeking such records.

- (b) The board shall adopt rules <u>establishing to establish</u> practice guidelines for pharmacies to dispose of records maintained in a pharmacy relating to the filling of prescriptions and the dispensing of medicinal drugs. Such rules shall be consistent with the duty to preserve the confidentiality of such records in accordance with applicable state and federal law.
  - Section 5. This act shall take effect October 1, 2014.

Page 9 of 9



## COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. HB 7077 (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
1	Committee/Subcommittee hearing bill: Health & Human Services
2	Committee
3	Representative Patronis offered the following:
4	•
5	Amendment (with title amendment)
6	Remove everything after the enacting clause and insert:
7	
8	Section 1. Subsections (18) and (19) are added to section
9	465.003, Florida Statutes, to read:
10	465.003 Definitions.—As used in this chapter, the term:
11	(18) "Compounding" means combining, mixing, or altering
12	the ingredients of one or more drugs or products to create
13	another drug or product.
14	(19) "Outsourcing facility" means a single physical
15	location registered as an outsourcing facility under the federal
16	Drug Quality and Security Act, Pub. L. No. 113-54, at which
17	sterile compounding of a drug or product is conducted.

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## COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. HB 7077 (2014)

Amendment No.

 Section 2. Subsections (4) and (5) of section 465.0156, Florida Statutes, are amended, present subsections (6) through (8) of that section are redesignated as subsections (7) through (9), respectively, and a new subsection (6) is added to that section, to read:

465.0156 Registration of nonresident pharmacies.

- (4) The board may deny, revoke, or suspend registration of, or fine or reprimand, a nonresident pharmacy for failure to comply with <u>s. 465.0158</u>, <u>s. 465.017(2)</u>, or <u>s. 465.025</u>, or with any requirement of this section in accordance with <del>the</del> <del>provisions of</del> this chapter.
- (5) In addition to the prohibitions of subsection (4) the board may deny, revoke, or suspend registration of, or fine or reprimand, a nonresident pharmacy in accordance with the provisions of this chapter for conduct which causes or could cause serious bodily injury or serious psychological injury to a human or serious bodily injury to a nonhuman animal in resident of this state if the board has referred the matter to the regulatory or licensing agency in the state in which the pharmacy is located and the regulatory or licensing agency fails to investigate within 180 days of the referral.
- (6) A nonresident pharmacy is subject to s. 456.0635.

  Section 3. Section 465.0158, Florida Statutes, is created to read:
  - 465.0158 Nonresident sterile compounding permit.-

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Published On: 4/2/2014 7:06:38 PM



Bill No. HB 7077 (2014)

Amendment No.

- (1) In order to ship, mail, deliver, or dispense, in any manner, a compounded sterile product into this state, a nonresident pharmacy registered under s. 465.0156, or an outsourcing facility, must hold a nonresident sterile compounding permit. For purposes of this section, an outsourcing facility, as defined under s. 465.003, is a nonresident facility that is not a pharmacy.
- (2) An application for a nonresident sterile compounding permit shall be submitted on a form furnished by the board. The board may require such information as it deems reasonably necessary to carry out the purposes of this section. The fee for an initial permit and biennial renewal of the permit shall be set by the board pursuant to s. 465.022(14).
- (3) An applicant must submit the following to the board to obtain an initial permit, or to the department to renew a permit:
- (a) Proof of registration as an outsourcing facility with the Secretary of the United States Department of Health and Human Services if the applicant is eligible for such registration pursuant to the federal Drug Quality and Security Act, Pub. L. No. 113-54.
- (b) Proof of registration as a nonresident pharmacy, pursuant to s. 465.0156, unless the applicant is an outsourcing facility, in which case the application must include proof of an active and unencumbered license, permit, or registration issued by the state, territory, or district in which the outsourcing

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Bill No. HB 7077 (2014)

Amendment No.

facility is physically located which allows the outsourcing facility to engage in compounding and to ship, mail, deliver, or dispense a compounded sterile product into this state.

- (c) Written attestation by an owner or officer of the applicant, and by the applicant's prescription department manager or pharmacist in charge, that:
- 1. The attestor has read and understands the laws and rules governing sterile compounding in this state.
- 2. A compounded sterile product shipped, mailed, delivered, or dispensed into this state meets or exceeds this state's standards for sterile compounding.
- 3. A compounded sterile product shipped, mailed, delivered, or dispensed into this state must not have been, and may not be, compounded in violation of the laws and rules of the state, territory, or district in which the applicant is located.
- (d) The applicant's existing policies and procedures for sterile compounding, which must comply with pharmaceutical standards in chapter 797 of the United States Pharmacopoeia and any standards for sterile compounding required by board rule or current good manufacturing practices for an outsourcing facility.
- (e) A current inspection report from an inspection conducted by the regulatory or licensing agency of the state, territory, or district in which the applicant is located. The inspection report must reflect compliance with this section. An inspection report is current if the inspection was conducted

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Bill No. HB 7077 (2014)

Amendment No.

within 6 months before the date of submitting the application
for the initial permit or within 1 year before the date of
submitting an application for permit renewal. If the applicant
is unable to submit a current inspection report conducted by the
regulatory or licensing agency of the state, territory, or
district in which the applicant is located due to acceptable
circumstances, as established by rule, or if an inspection has
not been performed, the department shall:

- 1. Conduct, or contract with an entity to conduct, an onsite inspection for which all costs shall be borne by the applicant;
- 2. Accept a current and satisfactory inspection report, as determined by rule, from an entity approved by the board; or
- 3. Accept a current inspection report from the United

  States Food and Drug Administration conducted pursuant to the

  federal Drug Quality and Security Act, Pub. L. No. 113-54.
- (4) A permittee may not ship, mail, deliver, or dispense a compounded sterile product into this state if the product was compounded in violation of the laws or rules of the state, territory, or district in which the permittee is located or does not meet or exceed this state's sterile compounding standards.
- (5) In accordance with this chapter, the board may deny, revoke, or suspend the permit of, fine, or reprimand a permittee for:
  - (a) Failure to comply with this section;

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Bill No. HB 7077 (2014)

Amendment No.

120	(b)	A violation	listed under	s. 456.0635,	s.	456.065,	or
121	s. 456.072	2, except s.	456.072(1)(s)	or (1)(u);			

- (c) A violation under s. 465.0156(5); or
- (d) A violation listed under s. 465.016.
- (6) A nonresident pharmacy registered under s. 465.0156 which ships, mails, delivers, or dispenses a compounded sterile product into this state may continue to do so if the product meets or exceeds the standards for sterile compounding in this state, the product is not compounded in violation of any law or rule of the state, territory, or district where the pharmacy is located, and the pharmacy is issued a permit under this section on or before March 1, 2015.
- (7) An applicant registering on or after October 1, 2014, as a nonresident pharmacy under s. 465.0156 may not ship, mail, deliver, or dispense a compounded sterile product into this state until the applicant is registered as a nonresident pharmacy and is issued a permit under this section.
- (8) The board shall adopt rules as necessary to administer this section, including rules for:
- (a) Submitting an application for the permit required by this section.
- (b) Determining how, when, and under what circumstances an inspection of a nonresident sterile compounding permittee must be conducted.
- (c) Evaluating and approving entities from which a satisfactory inspection report will be accepted in lieu of an

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Bill No. HB 7077 (2014)

Amendment No.

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distri	ct w	vhere	the	appli	cant	is l	ocate	ed.				

Section 4. Section 465.017, Florida Statutes, is amended to read:

465.017 Authority to inspect; disposal.-

- (1) Duly authorized agents and employees of the department may shall have the power to inspect in a lawful manner at all reasonable hours any pharmacy, hospital, clinic, wholesale establishment, manufacturer, physician's office, or any other place in the state in which drugs and medical supplies are compounded, manufactured, packed, packaged, made, stored, sold, offered for sale, exposed for sale, or kept for sale for the purpose of:
- (a) Determining if any provision of the provisions of this chapter or any rule adopted promulgated under its authority is being violated;
- (b) Securing samples or specimens of any drug or medical supply after paying or offering to pay for such sample or specimen; or
- (c) Securing such other evidence as may be needed for prosecution under this chapter.
- (2) Duly authorized agents and employees of the department may inspect a nonresident pharmacy registered under s. 465.0156 or a nonresident sterile compounding permittee under s. 465.0158

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Bill No. HB 7077 (2014)

Amendment No.

pursuant to this section. The costs of such inspections shall be borne by such pharmacy or permittee.

- (3)(2)(a) Except as permitted by this chapter, and chapters 406, 409, 456, 499, and 893, records maintained in a pharmacy relating to the filling of prescriptions and the dispensing of medicinal drugs may shall not be furnished only to any person other than to the patient for whom the drugs were dispensed, or her or his legal representative, or to the department pursuant to existing law, or, if in the event that the patient is incapacitated or unable to request such said records, her or his spouse except upon the written authorization of such patient.
- (a) Such records may be furnished in any civil or criminal proceeding, upon the issuance of a subpoena from a court of competent jurisdiction and proper notice to the patient or her or his legal representative by the party seeking such records.
- (b) The board shall adopt rules <u>establishing</u> to <u>establish</u> practice guidelines for pharmacies to dispose of records maintained in a pharmacy relating to the filling of prescriptions and the dispensing of medicinal drugs. Such rules <u>must shall</u> be consistent with the duty to preserve the confidentiality of such records in accordance with applicable state and federal law.

Section 5. This act shall take effect October 1, 2014.

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## COMMITTEE/SUBCOMMITTEE AMENDMENT Bill No. HB 7077 (2014)

Amendment No.

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## TITLE AMENDMENT

Remove everything before the enacting clause and insert: An act relating to nonresident sterile compounding permits; amending s. 465.003, F.S.; defining the terms "compounding" and "outsourcing facility"; amending s. 465.0156, F.S.; conforming provisions to changes made by the act; expanding penalties to apply to injury to a nonhuman animal; deleting a requirement that the Board of Pharmacy refer regulatory issues affecting a nonresident pharmacy to the state where the pharmacy is located; creating s. 465.0158, F.S.; requiring registered nonresident pharmacies and outsourcing facilities to obtain a permit in order to ship, mail, deliver, or dispense compounded sterile products into this state; requiring submission of an application and a nonrefundable fee; specifying requirements; authorizing the board to deny, revoke, or suspend a permit, or impose a fine or reprimand for certain actions; providing dates by which certain nonresident pharmacies must obtain a permit; authorizing the board to adopt rules; amending s. 465.017, F.S.; authorizing the department to inspect nonresident pharmacies and nonresident sterile compounding permittees; requiring such pharmacies and permittees to pay for the costs of such inspections; providing an effective date.

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## **HOUSE OF REPRESENTATIVES STAFF ANALYSIS**

BILL #:

CS/CS/HB 819 Department of Health

SPONSOR(S): Health Care Appropriations Subcommittee; Health Quality Subcommittee; Pigman

TIED BILLS:

IDEN./SIM. BILLS: SB 1066

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

#### **SUMMARY ANALYSIS**

This bill makes various changes to laws governing health care practitioners regulated by the Department of Health (Department).

This bill removes the requirement that medical doctors complete certain continuing education requirements, but authorizes the Board of Medicine (Board), through rulemaking, to mandate specific continuing medical education requirements. Also, the Board may, by rule, allow the fulfillment of continuing education requirements, for:

- Continuing medical education courses approved by the American Medical Association;
- · Attendance at board meetings in which a licensee is being disciplined;
- Service as a volunteer expert witness in a disciplinary proceeding or service as a member of a probable cause panel
- Pro bono services to indigent and underserved populations or patients in critical need areas;
- · Performing research in critical need areas; or
- Training for advanced professional certification.

This bill allows a board, or the Department when there is no board, to adopt rules (under certain circumstances) to waive initial application and licensure fees, and licensure renewal fees, for health care practitioners licensed under ch. 456, F.S. The waiver of renewal fees may not exceed 2 years.

This bill allows the Department to enter into an interagency agreement with the Department of Highway and Safety Motor Vehicles to access current digital photographic images of licensed health care practitioners to assist the Department with practitioner or unlicensed practice investigations. It also updates the law to authorize the Department, instead of the Agency for Health Care Administration, to access patient records for such investigations.

In addition, the bill makes practitioner-specific changes. It:

- Removes the option of apprenticeship as a pathway to licensure for massage therapists.
- Aligns continuing training requirements for certified nursing assistants' certification renewals with their biennial renewal cycles and abolishes the Council on Certified Nursing Assistants.
- Removes the requirement that the Department send a notification by registered mail to each registered dental laboratory operator within 30 days following the expiration date of the dental laboratory operator's registration.
- Updates the names of certain accrediting bodies for midwifery programs and registered dieticians.
- Revises the membership structure for the Board of Nursing Home Administrators and allows for those with a
  master's degree in health care services or an equivalent field to take the examination to be a licensed nursing home
  administrator regardless of the type of bachelor's degree earned.

The bill has an insignificant positive fiscal impact on the Department of Health.

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

This document does not reflect the intent or official position of the bill sponsor or House of Representatives. STORAGE NAME: h0819d.HHSC.DOCX

#### **FULL ANALYSIS**

#### I. SUBSTANTIVE ANALYSIS

#### A. EFFECT OF PROPOSED CHANGES:

## **Background**

## Department of Health, Division of Medical Quality Assurance

Currently, the Division of Medical Quality Assurance (MQA) within the Department of Health (Department) licenses and regulates health care practitioners to preserve the health, safety, and welfare of the public. Working in conjunction with 22 boards and 6 councils, the MQA licenses and regulates 7 types of facilities and 200-plus license types in more than 40 health care professions.<sup>1</sup>

A board is a statutorily created entity that is authorized to exercise regulatory or rulemaking functions within the MQA.<sup>2</sup> Boards are responsible for approving or denying applications for licensure, establishing continuing medical education requirements, and are involved in disciplinary hearings. Sections 456.072, 456.073, and 456.074 F.S., provide the authority for a board to take disciplinary action against a licensee. The board can take action for any legally sufficient, written, and signed complaint that is filed before it.<sup>3</sup> Not every profession is governed by a board.

#### Department Investigations

The Department has the authority to investigate a complaint against a health care professional. Further, the Department may initiate an investigation if it has reasonable cause to believe that a licensee has violated a Florida Statute, or an administrative rule of either a board or the Department. However, patient and personnel records may only be issued to the Agency for Health Care Administration (AHCA) for purposes of investigation, prosecution, and disciplinary proceedings against a health care practitioner. A Records used to form the basis of an investigation against a health care practitioner, must be made available, upon written request, to the practitioner who is under investigation or prosecution. Otherwise, the patient records are currently protected from public access under s. 456.057(9)(a), F.S.

#### Licenses and Fees

A regulatory board issues a license to a health care practitioner after certain statutory and administrative criteria are met. Two licenses are issued to health care practitioners, 1 wallet-sized, and one wall certificate<sup>5</sup> measuring 6 ½ inches by 5 inches.<sup>6</sup> If a provider's license is revoked or issued in error, the licensee must surrender both of these to the Department. Photos of each licensee are kept on file with the Department.

Typical fees associated with obtaining an initial license for a profession within the jurisdiction of the Department include:

An initial licensing fee;

<sup>&</sup>lt;sup>1</sup> Florida Health Source, Florida Department of Health, *accessible at*: <a href="http://www.flhealthsource.gov/">http://www.flhealthsource.gov/</a> (Last accessed February 28, 2014).

<sup>&</sup>lt;sup>2</sup> Section 456.001, F.S.

<sup>&</sup>lt;sup>3</sup> Section 456.025(3), F.S., provides that a complaint is legally sufficient if it contains the ultimate facts that show a violation of the relevant practice act or any rule adopted by the Department or the relevant board.

<sup>&</sup>lt;sup>4</sup> Section 395.3025, F.S. This appears to be caused by a failure to update this section of law when MQA was moved from AHCA to the Department in 1999.

<sup>&</sup>lt;sup>5</sup> The fee assessed by the Department for a wall certificate may not exceed \$25. Section 456.025(4), F.S.

<sup>&</sup>lt;sup>6</sup> Section 456.013(2), F.S.

- An initial application fee;
- An initial unlicensed activity fee of \$5;and,<sup>7</sup>
- Fees associated with criminal background checks.

Each board, or the Department when there is no board, determines by rule the amount of license fees for each profession it regulates. Fees are allocated to the MQA Trust Fund.<sup>8</sup>

#### MQA Trust Fund

Funds allocated to the MQA Trust Fund consist of fees and fines related to the licensing of health care professionals. Funds must be used for the purpose of providing administrative support for the regulation of health care professionals and for other such purposes as may be appropriate pursuant to legislative appropriation. Every 2 years each board, or the Department when there is no board, collects applications and additional licensing fees from applicants and renewal fees from current practitioners. Since Fiscal Year 2008-2009, the cost of regulating health care practitioners has averaged \$63,198,327 annually, and the MQA has collected an average of \$72,035,217 in revenue annually. As of December 31, 2013, there was \$20,749,755 in the MQA Trust Fund. In

## Certified Nursing Assistants

To maintain certification, Certified Nursing Assistants (CNAs) must show proof of having completed inservice training hours, which are the equivalent of continuing education hours for other health care professions. Currently, a CNA must complete 12 hours of in-service training each calendar year. CNA certificates are issued for a biennium with a May 31st expiration date.

The Council on Certified Nursing Assistants (Council)<sup>13</sup> proposes rules to implement in-service training requirements. The Council meets every 2 months in conjunction with the Board of Nursing. During these meetings the Council makes recommendations to the Department and the Board of Nursing regarding CNA policies and procedures, licensure, and other regulatory issues.<sup>14</sup> The Council is composed of 5 members:

- 2 Registered Nurses appointed by the chair of the Board of Nursing;
- 1 Licensed Practical Nurse appointed by the chair of the Board of Nursing; and,
- 2 Certified Nursing Assistants appointed by the State Surgeon General.

## Massage Therapist Licensure

Section 480.033, F.S., defines "apprentice" as a person approved by the Board of Massage Therapy to study massage under the instruction of a licensed massage therapist. To qualify for an apprenticeship, the applicant must have secured the sponsorship of a sponsoring massage therapist, complete a Department application, pay a \$100 fee, and must not be enrolled simultaneously as a student in a board-approved massage school. <sup>15</sup> For a 10-year period ending on June 21, 2013, the Board of

<sup>10</sup> DOH Analysis of HB 819, dated March 17, 2014 (on file with Health and Human Services Committee staff).

<sup>&</sup>lt;sup>7</sup> Section 455.2281, F.S., refers to the unlicensed activity fee which funds regulation of licensed professions, including investigations of persons conducting unlicensed health care activities.

Section 456.025(8), F.S.
 Section 20.435(4), F.S.

<sup>&</sup>lt;sup>11</sup> This amount pertains to the licensed practitioner portion of the MQA Trust Fund. The MQA Trust Fund also contains funds used for investigating unlicensed activities. Summary Expenditures by Functions Report, Florida Department of Health (on file with Health Quality Subcommittee staff).

<sup>&</sup>lt;sup>12</sup> Section 464.203, F.S.

<sup>&</sup>lt;sup>13</sup> Section 464.2085(2)(b), F.S.

<sup>&</sup>lt;sup>14</sup> Council on Certified Nursing Assistants, Florida Board of Nursing, *accessible at*: <a href="http://www.floridasnursing.gov/board-comm/council-of-certified-nursing-assistants/">http://www.floridasnursing.gov/board-comm/council-of-certified-nursing-assistants/</a> (Last accessed: March 2, 2014).

<sup>&</sup>lt;sup>15</sup> Rule 64B7-29.002, F.A.C.

Massage Therapy has received 300 applications for apprenticeship. Of those 300 applicants, only 8 have obtained full licensure as a massage therapist. 16

Section 480.042, F.S., authorizes the Department, in accordance with rules established by the Board of Massage Therapy, to administer examinations for persons who apply for massage therapy licensure. The Department contracts with a national testing vendor, Pearson Vue, to administer the examinations.<sup>17</sup>

## Dental Laboratory Operators

According to s. 466.032, F.S., a dental laboratory operator is required to renew his or her dental laboratory operator registration every 2 years. Renewal notices are sent to the last known address of the dental laboratory operator 120 days prior to the expiration date of the registration. If a dental laboratory operator fails to timely renew his or her dental laboratory operator registration, the operator must be notified by registered mail by the Department. After the Department has provided notice of the failure to timely renew a dental laboratory operator registration, the dental laboratory operator is then given 3 additional months to renew the registration with no late fee.

During the most recent license renewal period, the Department mailed 281 registered mail returnreceipt notices to delinquent dental laboratory operators; 86 were returned as undeliverable. This notification requirement costs the Department over \$2,000 every two years. This process is not required for any other regulated health care professionals.<sup>18</sup>

## Nursing Home Administrators

The Board of Nursing Home Administrators, within the Department, licenses and regulates nursing home administrators. The board is comprised of 7 members appointed by the Governor and confirmed by the Senate. The board members serve 4-year terms, or for the remainder of an unexpired vacancy. The membership of the board consists of:

- 3 licensed nursing home administrators;
- 2 health care practitioners; and,
- 2 laypersons who have never been members of any health care profession.<sup>20</sup>

Any person who wishes to be a nursing home administrator must take a licensure examination. To be eligible for examination, a person must hold a bachelor's degree majoring in health care administration, health services administration, or an equivalent major.<sup>21</sup>

The Board of Nursing Home Administrators may establish by rule requirements for issuance of a provisional license. A provisional license is issued by the board to fill a nursing home administrator position that unexpectedly becomes vacant due to illness, sudden death of the administrator, or abandonment of the position and is issued for not more than 6 months.<sup>22</sup>

The last nursing home administrator provisional license issued by the Board of Nursing Home Administrators was in December 2007. The board repealed Rule 64B10-11.011, F.A.C., Provisional License, in May 2010, because provisional licenses were no longer necessary for the regulation of the profession.<sup>23</sup>

<sup>&</sup>lt;sup>16</sup> Supra fn. 10

<sup>&</sup>lt;sup>17</sup> Email correspondence with DOH, March 1, 2014 (on file with Health Quality Subcommittee staff).

<sup>&</sup>lt;sup>18</sup> DOH MQA Analysis, dated July 22, 2013 (on file with Health Quality Subcommittee staff).

<sup>&</sup>lt;sup>19</sup> Section 468.1665, F.S.

<sup>&</sup>lt;sup>20</sup> At least 1 member of the Board of Nursing Home Administrators must be 60 years of age or older.

<sup>&</sup>lt;sup>21</sup> Section 468.1695, F.S.

<sup>&</sup>lt;sup>22</sup> Section 468.1735, F.S.

<sup>&</sup>lt;sup>23</sup> Supra fn 10.

## Continuing Medical Education

Section 456.013, F.S., establishes continuing education requirements for many health care practitioners, <sup>24</sup> including allopathic physicians which are governed by ch. 458, F.S. Rule 64B8-13.005, F.A.C., Continuing Education for Biennial Renewal, requires physicians licensed under ch. 458, F.S., to complete 40 hours of continuing medical education courses approved by the Board in the 24 months preceding each biennial renewal period as established by the Department.

Section 456.013(7), F.S., requires health care professionals, including medical doctors, to complete 2 hours of continuing education relating to the prevention of medical errors. Similarly, s. 456.033, F.S., requires many health care professionals to complete a continuing education course on human immunodeficiency virus and acquired immune deficiency syndrome. In addition, up to 5 hours, per biennium, of continuing education credit may be fulfilled by performing pro bono medical services to the indigent, underserved populations or patients in critical need areas.

The Board of Medicine, the Board of Osteopathic Medicine, the Board of Chiropractic Medicine, and the Board of Podiatric Medicine require licensees to complete at least 40 hours of continuing education every 2 years. Each of those boards may require additional or specific continuing education requirements by rule.

## **Effect of Proposed Changes**

## Department of Health, Division of Medical Quality Assurance

## Department Investigations

This bill allows the Department to enter into an interagency agreement with the Florida Department of Highway and Safety Motor Vehicles (DHSMV) to access current digital photographic records of licensed health care practitioners who live in Florida. This is current practice for other agencies; for example, under s. 322.142, F.S., DHSMV reproduces images for reproduction of licenses issued by the Department of Business and Professional Regulation. These images will assist the Department with identifying persons in investigations.

This bill amends s. 395.3025, F.S., authorizing the Department, instead of AHCA, to obtain patient records by subpoena for use by a professional board or the Department in its investigation, prosecution, or appeal of disciplinary proceedings of a health care practitioner.

#### Licenses and Fees

<sup>24</sup> Section 456.001(4), F.S., defines "health care practitioner" to mean any person licensed under: ch. 457, F.S., (acupuncture); ch. 458, F.S., (medicine); ch. 459, F.S., (osteopathic medicine); ch. 460, F.S., (chiropractic medicine); ch. 461, F.S., (podiatric medicine); ch. 462, F.S., (naturopathic medicine); ch. 463, F.S., (optometry); ch. 464, F.S., (nursing); ch. 465, F.S., (pharmacy); ch. 466, F.S., (dentistry and dental hygiene); ch. 467, F.S., (midwifery); parts I, II, III, V, X, XIII, and XIV of ch. 468, F.S., (speech-language pathology and audiology, nursing home administration, occupational therapy, respiratory therapy, dietetics and nutrition practice, athletic trainers, and orthotics, prosthetics, and pedorthics); ch. 478, F.S., (electrology or electrolysis); ch. 480, F.S., (massage therapy); parts III and IV of ch. 483, F.S., (clinical laboratory personnel or medical physics); ch. 484, F.S., (opticianry and hearing aid specialists); ch. 486, F.S., (physical therapy); ch. 490, F.S., (psychology); and ch. 491, F.S., (psychotherapy).

<sup>25</sup> Practitioners licensed or certified under: ch. 457, F.S., (acupuncture); ch. 458, F.S., (allopathic medicine); ch. 459, F.S., (osteopathic medicine); ch. 460, F.S., (chiropractic medicine); ch. 461, F.S., (podiatric medicine); ch. 463, F.S., (optometry); part I of ch. 464, F.S., (nursing): ch, 465, F.S., (pharmacy); ch. 466, F.S. (dentistry and dental hygiene); parts II, III, V, and X of ch.468, F.S., (nursing home administration; occupational therapy; respiratory therapy; and dietetics and nutrition); are required to complete a course on HIV/AIDS no later than first renewal of license. Section 456.033, F.S.

<sup>26</sup> Rule 64B8-13.005, F.A.C., Continuing Education for Biennial Renewal.

STORAGE NAME: h0819d.HHSC.DOCX

This bill removes the requirement that the Department issue a wallet-sized identification card and a wall certificate upon the licensure of a health practitioner. The bill also deletes the corresponding fee for the wall certificate, which currently may not exceed \$25.

The bill allows, the board, or the Department when there is no board, to waive the payment of initial application and licensure fees received from applicants and renewal fees received from licensed health care practitioners. This is permitted when a health care profession's trust fund balance is in excess of the amount required to cover the costs of regulating that profession. The waiver of renewal fees may not exceed 2 years.

#### Certified Nursing Assistants

This bill aligns current in-service training requirements for a Certified Nursing Assistant's license renewal with the established biennial renewal cycle for that practitioner. The bill also repeals s. 464.285, F.S., to abolish the Council on Certified Nursing Assistants.

## Massage Therapist Licensure

This bill removes the option of apprenticeship as a pathway to licensure for massage therapists. This bill also repeals obsolete statutory language in s. 480.042, F.S., referring to the Department administering and overseeing an in-state licensure examination for massage therapists.

## Dental Laboratory Operators

This bill amends s. 466.032 (2), F.S., to remove the requirement that the Department send a notification by registered mail to each Florida dental laboratory operator who has failed to renew his or her registration.

## Nursing Home Administrators

This bill revises s. 468.1695, F.S., to allow those with a master's degree in health care administration, health services administration, or an equivalent major to be eligible to take the nursing home administrator licensure examination, regardless of the type of bachelor's degree they earned. The bill also revises the membership of the Board of Nursing Home Administrators to allow nursing home administrators to represent a majority of members on the board.

This bill repeals s. 468.1735, F.S., to no longer authorize the Board of Nursing Home Administrators to establish by rule requirements for the issuance of a provisional license for a nursing home administrator, and thereby eliminates provisional licenses for nursing home administrators.

## Continuing Medical Education

This bill amends s. 456.013, F.S., to no longer require the Board of Medicine (Board) to require in rule that medical doctors complete a 2-hour course relating to the prevention of medical errors for initial licensure or renewal of licensure. This bill also amends s. 456.033, F.S., to no longer require the Board to require in rule that medical doctors complete a course relating to HIV and AIDS no later than first renewal of license. The bill also removes the authority of the Board to adopt rules requiring continuing medical education from s. 456.013, F.S., and instead, places the Board's authority to adopt such rules in s. 458.319, F.S., which is within the Medical Practice Act. In addition to moving the Board's authority in statute, the bill provides additional authority to the Board allowing it to require by rule specific continuing education requirements and authorize in rule the fulfillment of continuing education requirements for:

Continuing medical education courses approved by the American Medical Association;

- Attendance at board meetings in which a licensee is being disciplined;
- Service as a volunteer expert witness in a disciplinary proceeding or service as a member of a probable cause panel;
- Pro bono services to indigent and underserved populations or patients in critical need areas;
- · Performing research in critical need areas; or
- Training for advanced professional certification.

## This bill makes technical changes to:

- Correct the statutory reference to the authorized midwifery program accrediting body to update the name (the Council on Higher Education Accreditation), and to recognize any future organizations.
- Correct the statutory reference to the accrediting body for registered dieticians, to update the name (the Academy of Nutrition and Dietetics).<sup>27</sup>

#### **B. SECTION DIRECTORY:**

- **Section 1.** Amends s. 322.142, F.S., relating to color photographic or digital imaged licenses.
- **Section 2.** Amends s. 395.3025, F.S., relating to patient and personnel records, copies, and examination.
- **Section 3.** Amends s. 456.013, F.S., relating to the Department of Health and general licensing provisions.
- **Section 4.** Amends s. 456.025, F.S., relating to fees, receipts, and disposition.
- **Section 5.** Amends s. 456.033, F.S., relating to requirement for instruction for certain licensees on HIV and AIDS.
- **Section 6.** Amends s. 458.319, F.S., relating to renewal of license.
- **Section 7.** Amends s. 464.203, F.S., relating to certified nursing assistants and certification requirement.
- **Section 8.** Repeals s. 464.2085, F.S., relating to the Council on Certified Nursing Assistants.
- Section 9. Amends s. 466.032, F.S., relating to registration.
- **Section 10.** Amends s. 467.009, F.S., relating to midwifery programs, education and training requirements.
- Section 11. Amends s. 468.1665, F.S., relating to the Board of Nursing Home Administrators.
- Section 12. Amends s. 468.1695, F.S., relating to licensure by examination.
- Section 13. Repeals s. 468.1735, F.S., relating to provisional licenses.
- Section 14. Amends s. 468.503, F.S., relating to definitions.
- Section 15. Amends s. 468.505, F.S., relating to exemptions and exceptions.
- **Section 16.** Amends s. 480.033, F.S., relating to definitions.
- **Section 17.** Amends s. 480.041, F.S., relating to massage therapists, qualifications, licensure, and endorsement.
- Section 18. Amends s. 480.042, F.S., relating to examinations.
- **Section 19.** Amends s. 480.044, F.S., relating to fees and disposition.
- **Section 20.** Amends s. 823.05, F.S., relating to places and groups engaged in criminal gang-related activity declared a nuisance; massage establishments engaged in prohibited activity; may be abated and enjoined.
- Section 21. Provides an effective date of July 1, 2014.

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<sup>&</sup>lt;sup>27</sup>In January 2012 the American Dietetic Association changed its name to the Academy of Nutrition and Dietetics. "New Name, Same Commitment to Public's Nutritional Health: American Dietetic Association Becomes Academy of Nutrition and Dietetics," Academy of Nutrition and Dietetics, accessible at:

<sup>&</sup>lt;u>http://www.eatright.org/Media/content.aspx?id=6442465361#.Uzmt6mwpDcs</u>(last accessed March 31, 2014). To practice as a dietician in Florida a person must be licensed; being a registered dietician by the Academy of Nutrition and Dietetics is an acceptable pathway to licensure. Email correspondence with DOH, March 31, 2014 (on file with Health and Human Services Committee staff).

#### II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

## A. FISCAL IMPACT ON STATE GOVERNMENT:

#### 1. Revenues:

The Department and the boards will experience a decrease in revenues when a fee waiver is approved for a specific profession. The fee waiver for a board would not be approved unless the profession's long range projections indicate sufficient cash to absorb the reduction in revenue.

The State General Revenue Fund may experience a minimal decrease in revenues when any board, or the Department when there is no board, elects to implement the fee waiver due to the 8% surcharge on revenues collected being reduced.<sup>28</sup> This is not expected to be significant.

## 2. Expenditures:

The elimination of the specific size for a license will provide the Department flexibility to explore more cost-effective alternatives for printed licenses. The paper for a license is purchased in bulk and currently costs .142 cents per license. The fiscal impact is indeterminate at this time, yet anticipated to result in cost savings for the Department.<sup>29</sup>

The elimination of the Council on Certified Nursing Assistants will result in an annual cost-savings of approximately \$40,700. The current costs associated with the council include council members' per diem of \$50 per day and their travel costs, and the costs for MQA to staff 6 meetings annually.<sup>30</sup>

The elimination of the requirement to notify dental laboratory operators of registration delinquencies by certified mail will save the Department approximately \$2.000 biennially.31

## **B. FISCAL IMPACT ON LOCAL GOVERNMENTS:**

1. Revenues:

None.

2. Expenditures:

None.

#### C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Applicants and/or licensees of specific professions licensed and regulated by the appropriate board, or the Department when there is no board, will experience cost-savings if the fee waiver is implemented.

#### 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.

STORAGE NAME: h0819d.HHSC.DOCX

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2. Other:

None.

#### B. RULE-MAKING AUTHORITY:

This bill grants each board, or the Department when there is no board, specific authority to adopt rules to waive initial application fees, initial licensure fees, unlicensed activity fees, or renewal fees for health care professionals.

This bill grants the Board of Medicine specific authority to adopt rules related to continuing medical education requirements.

#### C. DRAFTING ISSUES OR OTHER COMMENTS:

Authorization provided in lines 285-301 for the Board of Medicine to allow the substitution of continuing medical education for pro bono services to the indigent or underserved populations is redundant as this authorization is currently provided for in s. 456.013(9), F.S.

The accrediting body for midwifery programs is the Council "for" Education Accreditation not the Council "on" Education Accreditation.

#### IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

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

- Removed the section of the bill that transfers the medical complaint hotline from the Agency for Health Care Administration to the Department.
- Revised the membership of the Board of Nursing Home Administrators to consist as follows:
  - o 4 registered nursing home administrators.
  - o 1 health care practitioner.
  - o 2 laypersons who have never been members of any health care profession.
- Permitted those with a master's degree in health care administration or equivalent major, to be eligible to take the nursing home administrator licensure examination, regardless of the type of bachelor's degree they earned.
- Revised the requirement for an inter-facility transfer in an ambulance to include those patients who are:
  - o Bed confined.
  - o Require the administration of medical oxygen.

On March 18, 2014, the Health Care Appropriations Subcommittee adopted one amendment and reported the bill favorably as a committee substitute. The amendment made the following changes to the bill:

- Removed the section of the bill that revised the requirement for an inter-facility transfer in an ambulance to include those patients who are:
  - o Bed confined.
  - o Require the administration of medical oxygen.

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

STORAGE NAME: h0819d.HHSC.DOCX

1 A bill to be entitled 2 An act relating to the Department of Health; amending 3 s. 322.142, F.S.; authorizing the Department of Highway Safety and Motor Vehicles to provide 4 5 reproductions of specified records to the Department 6 of Health under certain circumstances; amending s. 7 395.3025, F.S.; clarifying duties of the Department of 8 Health to maintain the confidentiality of patient 9 records that it obtains under subpoena pursuant to an 10 investigation; authorizing licensees under 11 investigation to inspect or receive copies of patient 12 records connected with the investigation, subject to 13 certain conditions; amending s. 456.013, F.S.; deleting requirements for the physical size of 14 15 licenses issued for various health professions; 16 exempting Board of Medicine licensees from certain 17 continuing education requirements applicable to other 18 health professions; amending s. 456.025, F.S.; 19 deleting fee for issuance of wall certificates for 20 various health profession licenses; authorizing the 21 boards or the department to adopt rules waiving 22 certain fees for a specified period in certain 23 circumstances; amending s. 456.033, F.S.; exempting Board of Medicine licensees from certain continuing 24 25 education requirements relating to instruction on HIV 26 and AIDS; amending s. 458.319, F.S.; providing

Page 1 of 18

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continuing medical education requirements for Board of Medicine licensees; authorizing the board to adopt rules; amending s. 464.203, F.S.; revising certified nursing assistant inservice training requirements; repealing s. 464.2085, F.S., relating to the creation, membership, and duties of the Council on Certified Nursing Assistants; amending s. 466.032, F.S.; deleting a requirement that the department provide certain notice to a dental laboratory operator who fails to renew her or his registration; amending s. 467.009, F.S.; revising the organization that must accredit certain midwifery programs; amending s. 468.1665, F.S.; revising membership of the Board of Nursing Home Administrators; amending s. 468.1695, F.S.; revising an educational requirement for an applicant to be eligible to take the nursing home administrator licensure examination; repealing s. 468.1735, F.S., relating to provisional licenses for nursing home administrators; amending ss. 468.503 and 468.505, F.S.; revising the organization with whom an individual must be registered to be a registered dietitian; revising a definition; amending ss. 480.033 and 480.041, F.S.; deleting provisions relating to massage therapy apprentices and apprenticeship programs; deleting a definition and revising licensure requirements for massage therapists, to conform;

Page 2 of 18

amending s. 480.042, F.S.; revising requirements for conducting massage therapist licensing examinations and maintaining examination records; amending s. 480.044, F.S.; deleting fee for massage therapy apprentices; amending s. 823.05, F.S.; conforming a cross-reference; providing an effective date.

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

Section 1. Paragraphs (j) and (k) of subsection (4) of section 322.142, Florida Statutes, are amended, and paragraph (1) is added to that subsection, to read:

322.142 Color photographic or digital imaged licenses.

- (4) The department may maintain a film negative or print file. The department shall maintain a record of the digital image and signature of the licensees, together with other data required by the department for identification and retrieval. Reproductions from the file or digital record are exempt from the provisions of s. 119.07(1) and shall be made and issued only:
- (j) To district medical examiners pursuant to an interagency agreement for the purpose of identifying a deceased individual, determining cause of death, and notifying next of kin of any investigations, including autopsies and other laboratory examinations, authorized in s. 406.11; or
  - (k) To the following persons for the purpose of

Page 3 of 18

identifying a person as part of the official work of a court:

1. A justice or judge of this state;

- 2. An employee of the state courts system who works in a position that is designated in writing for access by the Chief Justice of the Supreme Court or a chief judge of a district or circuit court, or by his or her designee; or
- 3. A government employee who performs functions on behalf of the state courts system in a position that is designated in writing for access by the Chief Justice or a chief judge, or by his or her designee; or
- (1) To the Department of Health, pursuant to an interagency agreement to access digital images to verify the identity of an individual during an investigation under chapter 456, and for the reproduction of licenses issued by the Department of Health.
- Section 2. Paragraph (e) of subsection (4) of section 395.3025, Florida Statutes, is amended to read:
- 395.3025 Patient and personnel records; copies; examination.—
- (4) Patient records are confidential and <u>may must</u> not be disclosed without the consent of the patient or his or her legal representative, but appropriate disclosure may be made without such consent to:
- (e) The <u>department</u> agency upon subpoena issued pursuant to s. 456.071.7 but The records obtained thereby must be used solely for the purpose of the department agency and the

Page 4 of 18

appropriate professional board in its investigation,
prosecution, and appeal of disciplinary proceedings. If the
department agency requests copies of the records, the facility
shall charge <u>a fee pursuant to this section</u> <del>no more than its</del>
actual copying costs, including reasonable staff time. The
department and the appropriate professional board must maintain
the confidentiality of patient records obtained under this
paragraph pursuant to s. 456.057. A licensee who is the subject
of a department investigation may inspect or receive a copy of a
patient record connected with the investigation if the licensee
agrees in writing to maintain the confidentiality of the patient
record pursuant to s. 456.057 must be sealed and must not be
available to the public pursuant to s. 119.07(1) or any other
statute providing access to records, nor may they be available
to the public as part of the record of investigation for and
prosecution in disciplinary proceedings made available to the
public by the agency or the appropriate regulatory board.
However, the agency must make available, upon written request by
a practitioner against whom probable cause has been found, any
such records that form the basis of the determination of
<del>probable cause.</del>
Section 3. Subsections (2), (6), and (7) of section
456.013, Florida Statutes, are amended to read:
456.013 Department; general licensing provisions
(2) Before the issuance of <u>a</u> any license, the department
shall charge an initial license fee as determined by the

Page 5 of 18

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applicable board or, if there is no board, by rule of the department. Upon receipt of the appropriate license fee, the department shall issue a license to <u>a</u> any person certified by the appropriate board, or its designee, as having met the licensure requirements imposed by law or rule. The license shall consist of a wallet-size identification card and a wall card measuring 6 1/2 inches by 5 inches. The licensee shall surrender the license to the department the wallet-size identification card and the wall card if the licensee's license was is issued in error or is revoked.

(6) As a condition of renewal of a license, the Board of Medicine, the Board of Osteopathic Medicine, the Board of Chiropractic Medicine, and the Board of Podiatric Medicine shall each require their respective licensees which they respectively regulate to periodically demonstrate their professional competency by completing at least 40 hours of continuing education every 2 years. The boards may require by rule that up to 1 hour of the required 40 or more hours be in the area of risk management or cost containment. This provision does shall not be construed to limit the number of hours that a licensee may obtain in risk management or cost containment to be credited toward satisfying the 40 or more required hours. This provision does shall not be construed to require the boards to impose any requirement on licensees except for the completion of at least 40 hours of continuing education every 2 years. Each of the such boards shall determine whether any specific continuing education

Page 6 of 18

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requirements not otherwise mandated by law will shall be mandated and shall approve criteria for, and the content of, any continuing education mandated by such board. Notwithstanding any other provision of law, the board, or the department when there is no board, may approve by rule alternative methods of obtaining continuing education credits in risk management. The alternative methods may include attending a board meeting at which another licensee is disciplined, serving as a volunteer expert witness for the department in a disciplinary case, or serving as a member of a probable cause panel following the expiration of a board member's term. Other boards within the Division of Medical Quality Assurance, or the department if there is no board, may adopt rules granting continuing education hours in risk management for attending a board meeting at which another licensee is disciplined, for serving as a volunteer expert witness for the department in a disciplinary case, or for serving as a member of a probable cause panel following the expiration of a board member's term.

(7) The boards, except the Board of Medicine, or the department when there is no board, shall require the completion of a 2-hour course relating to prevention of medical errors as part of the licensure and renewal process. The 2-hour course shall count towards the total number of continuing education hours required for the profession. The course shall be approved by the board or department, as appropriate, and shall include a study of root-cause analysis, error reduction and prevention,

Page 7 of 18

and patient safety. In addition, the course approved by the Board of Medicine and the Board of Osteopathic Medicine shall include information relating to the five most misdiagnosed conditions during the previous biennium, as determined by the board. If the course is being offered by a facility licensed pursuant to chapter 395 for its employees, the board may approve up to 1 hour of the 2-hour course to be specifically related to error reduction and prevention methods used in that facility.

Section 4. Subsections (5) through (11) of section 456.025, Florida Statutes, are renumbered as subsections (4) through (10), respectively, and present subsections (4) and (6) are amended to read:

456.025 Fees; receipts; disposition.—

(4) Each board, or the department if there is no board, may charge a fee not to exceed \$25, as determined by rule, for the issuance of a wall certificate pursuant to s. 456.013(2) requested by a licensee who was licensed prior to July 1, 1998, or for the issuance of a duplicate wall certificate requested by any licensee.

(5)(6) If the cash balance of the trust fund at the end of any fiscal year exceeds the total appropriation provided for the regulation of the health care professions in the prior fiscal year, the boards, in consultation with the department, may lower the license renewal fees. When the department determines, based on long-range estimates of revenue, that a profession's trust fund balance exceeds the amount required to cover necessary

Page 8 of 18

2014 CS/CS/HB 819

functions, each board, or the department when there is no board, may adopt rules to implement the waiver of initial application fees, initial licensure fees, unlicensed activity fees, or renewal fees for that profession. The waiver of renewal fees may not exceed 2 years.

Section 5. Section 456.033, Florida Statutes, is amended to read:

456.033 Requirement for instruction for certain licensees on HIV and AIDS.-The following requirements apply to each person licensed or certified under chapter 457; chapter 458; chapter 459; chapter 460; chapter 461; chapter 463; part I of chapter 464; chapter 465; chapter 466; part II, part III, part V, or

part X of chapter 468; or chapter 486:

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Each person shall be required by the appropriate board to complete no later than upon first renewal a continuing educational course, approved by the board, on human immunodeficiency virus and acquired immune deficiency syndrome as part of biennial relicensure or recertification. The course shall consist of education on the modes of transmission, infection control procedures, clinical management, and prevention of human immunodeficiency virus and acquired immune deficiency syndrome. Such course shall include information on current Florida law on acquired immune deficiency syndrome and its impact on testing, confidentiality of test results, treatment of patients, and any protocols and procedures applicable to human immunodeficiency virus counseling and

Page 9 of 18

testing, reporting, the offering of HIV testing to pregnant women, and partner notification issues pursuant to ss. 381.004 and 384.25.

- (2) Each person shall submit confirmation of having completed the course required under subsection (1), on a form as provided by the board, when submitting fees for first renewal.
- (3) The board shall have the authority to approve additional equivalent courses that may be used to satisfy the requirements in subsection (1). Each licensing board that requires a licensee to complete an educational course pursuant to this section may count the hours required for completion of the course included in the total continuing educational requirements as required by law.
- (4) Any person holding two or more licenses subject to the provisions of this section shall be permitted to show proof of having taken one board-approved course on human immunodeficiency virus and acquired immune deficiency syndrome, for purposes of relicensure or recertification for additional licenses.
- (5) Failure to comply with the above requirements shall constitute grounds for disciplinary action under each respective licensing chapter and s. 456.072(1)(e). In addition to discipline by the board, the licensee shall be required to complete the course.
- Section 6. Subsections (2), (3), and (4) of section 458.319, Florida Statutes, are renumbered as subsections (3), (4), and (5), respectively, and a new subsection (2) is added to

Page 10 of 18

261	that section to read:
262	458.319 Renewal of license.—
263	(2) Each licensee shall demonstrate his or her
264	professional competency by completing at least 40 hours of
265	continuing medical education every 2 years. The board, by rule,
266	may:
267	(a) Provide that continuing medical education approved by
268	the American Medical Association satisfies some or all of the
269	continuing medical education requirements.
270	(b) Mandate specific continuing medical education
271	requirements.
272	(c) Approve alternative methods for obtaining continuing
273	medical education credits, including, but not limited to:
274	1. Attendance at a board meeting at which another licensee
275	is disciplined;
276	2. Service as a volunteer expert witness for the
277	department in a disciplinary proceeding; or
278	3. Service as a member of a probable cause panel following
279	expiration of a board member's term.
280	(d) Provide that up to 25 percent of the required
281	continuing medical education hours may be fulfilled through pro
282	bono services to the indigent, underserved populations, or
283	patients in critical need areas in the state where the licensee
284	practices.
285	1. The board shall require that any pro bono service be

Page 11 of 18

approved in advance to receive credit for continuing medical

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87	education under this paragraph.
288	2. The standard for determining indigency shall be that
289	recognized by the federal poverty guidelines and shall be less
290	than 150 percent of the federal poverty level.
91	(e) Provide that a portion of the continuing medical
92	education hours may be fulfilled by performing research in
293	critical need areas or by training for advanced professional
294	certification.
295	(f) Adopt rules to define underserved and critical need
296	areas.
297	Section 7. Subsection (7) of section 464.203, Florida
298	Statutes, is amended to read:
299	464.203 Certified nursing assistants; certification
300	requirement
301	(7) A certified nursing assistant shall complete $\underline{24}$ $\underline{12}$
302	hours of inservice training during each biennium calendar year.
303	The certified nursing assistant $\underline{\text{is}}$ $\underline{\text{shall be}}$ responsible for
304	maintaining documentation demonstrating compliance with these
305	provisions. The Council on Certified Nursing Assistants, in
306	accordance with s. 464.2085(2)(b), shall propose rules to
307	implement this subsection.
308	Section 8. <u>Section 464.2085</u> , Florida Statutes, is
309	repealed.
310	Section 9. Subsection (2) of section 466.032, Florida
311	Statutes, is amended to read:
312	466.032 Registration

Page 12 of 18

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(2) Upon the failure of any dental laboratory operator to comply with subsection (1), the department shall notify her or him by registered mail, within 1 month after the registration renewal date, return receipt requested, at her or his last known address, of such failure and inform her or him of the provisions of subsections (3) and (4). Section 10. Subsection (8) of section 467.009, Florida Statutes, is amended to read: 467.009 Midwifery programs; education and training requirements.-(8)Nonpublic educational institutions that conduct approved midwifery programs shall be accredited by a member of the Council on Higher Education Accreditation Commission on Recognition of Postsecondary Accreditation and shall be licensed by the Commission for Independent Education. Section 11. Subsection (2) of section 468.1665, Florida Statutes, is amended to read: 468.1665 Board of Nursing Home Administrators; membership; appointment; terms.-Four Three members of the board must be licensed nursing home administrators. One member Two members of the board must be a health care practitioner practitioners. The remaining two members of the board must be laypersons who are not, and

Page 13 of 18

have never been, nursing home administrators or members of any

health care profession or occupation. At least one member of the

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board must be 60 years of age or older.

Section 12. Subsection (2) of section 468.1695, Florida Statutes, is amended to read:

468.1695 Licensure by examination.-

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- (2) The department shall examine each applicant who the board certifies has completed the application form and remitted an examination fee set by the board not to exceed \$250 and who:
- (a)1. Holds a baccalaureate or master's degree from an accredited college or university and majored in health care administration, health services administration, or an equivalent major, or has credit for at least 60 semester hours in subjects, as prescribed by rule of the board, which prepare the applicant for total management of a nursing home; and
- 2. Has fulfilled the requirements of a college-affiliated or university-affiliated internship in nursing home administration or of a 1,000-hour nursing home administrator-intraining program prescribed by the board; or
- (b)1. Holds a baccalaureate degree from an accredited college or university; and
- 2.a. Has fulfilled the requirements of a 2,000-hour nursing home administrator-in-training program prescribed by the board; or
- b. Has 1 year of management experience allowing for the application of executive duties and skills, including the staffing, budgeting, and directing of resident care, dietary, and bookkeeping departments within a skilled nursing facility, hospital, hospice, assisted living facility with a minimum of 60

Page 14 of 18

,051	ricensed beds, or gerrative residencial creatment program and,
366	if such experience is not in a skilled nursing facility, has
367	fulfilled the requirements of a 1,000-hour nursing home
368	administrator-in-training program prescribed by the board.
369	Section 13. Section 468.1735, Florida Statutes, is
370	repealed.
371	Section 14. Subsection (11) of section 468.503, Florida
372	Statutes, is amended to read:
373	468.503 Definitions.—As used in this part:
374	(11) "Registered dietitian" means an individual registered
375	with the accrediting body of the Academy of Nutrition and
376	Dietetics Commission on Dietetic Registration, the accrediting
377	body of the American Dietetic Association.
378	Section 15. Subsection (4) of section 468.505, Florida
379	Statutes, is amended to read:
380	468.505 Exemptions; exceptions
381	(4) Notwithstanding any other provision of this part, an
382	individual registered by the accrediting body of the Academy of
383	Nutrition and Dietetics Commission on Dietetic Registration of
384	the American Dietetic Association has the right to use the title
385	"Registered Dietitian" and the designation "R.D."
386	Section 16. Subsection (5) of section 480.033, Florida
387	Statutes, is amended to read:
388	480.033 Definitions.—As used in this act:
389	(5) "Apprentice" means a person approved by the board to
390	study massage under the instruction of a licensed massage

Page 15 of 18

391	<del>therapist.</del>
392	Section 17. Subsections (1) and (4) of section 480.041,
393	Florida Statutes, are amended to read:
394	480.041 Massage therapists; qualifications; licensure;
395	endorsement
396	(1) $\underline{A}$ $\underline{Any}$ person is qualified for licensure as a massage
397	therapist under this act who:
398	(a) Is at least 18 years of age or has received a high
399	school diploma or graduate equivalency diploma;
400	(b) Has completed a course of study at a board-approved
401	massage school <del>or has completed an apprenticeship program that</del>
402	meets standards adopted by the board; and
403	(c) Has received a passing grade on an examination
404	administered by the department.
405	(4) The board shall adopt rules:
406	(a) <del>Establishing a minimum training program for</del>
407	apprentices.
408	(b) Providing for educational standards, examination, and
409	certification for the practice of colonic irrigation, as defined
410	in s. $480.033$ $480.033(6)$ , by massage therapists.
411	(b)(c) Specifying licensing procedures for practitioners
412	desiring to be licensed in this state who hold an active license
413	and have practiced in any other state, territory, or
414	jurisdiction of the United States or any foreign national
415	jurisdiction which has licensing standards substantially similar
416	to, equivalent to, or more stringent than the standards of this

Page 16 of 18

117	state.
418	Section 18. Subsection (5) of section 480.042, Florida
419	Statutes, is amended to read:
420	480.042 Examinations.—
421	(5) All licensing examinations shall be conducted in such
422	manner that the applicant shall be known to the department by
123	number until her or his examination is completed and the proper
124	grade determined. An accurate record of each examination shall
425	be maintained, shall be made; and that record, together with all
426	examination papers, shall be filed with the State Surgeon
427	General and shall be kept by the testing entities for reference
428	and inspection for a period of not less than 2 years immediately
429	following the examination.
430	Section 19. Paragraph (h) of subsection (1) of section
431	480.044, Florida Statutes, is amended to read:
432	480.044 Fees; disposition
433	(1) The board shall set fees according to the following
434	schedule:
435	(h) Fee for apprentice: not to exceed \$100.
436	Section 20. Subsection (3) of section 823.05, Florida
437	Statutes, is amended to read:
438	823.05 Places and groups engaged in criminal gang-related
439	activity declared a nuisance; massage establishments engaged in
440	prohibited activity; may be abated and enjoined
441	(3) A massage establishment as defined in s. 480.033

Page 17 of 18

480.033(7) that operates in violation of s. 480.0475 or s.

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443 480.0535(2) is declared a nuisance and may be abated or enjoined 444 as provided in ss. 60.05 and 60.06.

Section 21. This act shall take effect July 1, 2014.

Page 18 of 18



# COMMITTEE/SUBCOMMITTEE AMENDMENT Bill No. CS/CS/HB 819 (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
1	Committee/Subcommittee hearing bill: Health & Human Services
2	Committee
3	Representative Pigman offered the following:
4	
5	Amendment (with title amendment)
6	Remove everything after the enacting clause and insert:
7	Section 1. Paragraphs (j) and (k) of subsection (4) of
8	section 322.142, Florida Statutes, are amended, and paragraph
9	(1) is added to that subsection, to read:
10	322.142 Color photographic or digital imaged licenses.—
11	(4) The department may maintain a film negative or print
12	file. The department shall maintain a record of the digital
13	image and signature of the licensees, together with other data
14	required by the department for identification and retrieval.
15	Reproductions from the file or digital record are exempt from
16	the provisions of s. 119.07(1) and shall be made and issued
17	only:

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Bill No. CS/CS/HB 819 (2014)

Amendment No.

- (j) To district medical examiners pursuant to an interagency agreement for the purpose of identifying a deceased individual, determining cause of death, and notifying next of kin of any investigations, including autopsies and other laboratory examinations, authorized in s. 406.11; or
- (k) To the following persons for the purpose of identifying a person as part of the official work of a court:
  - A justice or judge of this state;
- 2. An employee of the state courts system who works in a position that is designated in writing for access by the Chief Justice of the Supreme Court or a chief judge of a district or circuit court, or by his or her designee; or
- 3. A government employee who performs functions on behalf of the state courts system in a position that is designated in writing for access by the Chief Justice or a chief judge, or by his or her designee; or
- (1) To the Department of Health, pursuant to an interagency agreement to access digital images to verify the identity of an individual during an investigation under chapter 456, and for the reproduction of licenses issued by the Department of Health.

Section 2. Subsection (1), paragraphs (a), (b), (g), and (h) of subsection (2), and paragraph (d) of subsection (4) of section 381.004, Florida Statutes, are amended, and subsection (1) of that section is reordered, to read:

381.004 HIV testing.-

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Amendment No.

- (1) DEFINITIONS.—As used in this section:
- (a) "Health care setting" means a setting devoted to both the diagnosis and care of persons, such as county health department clinics, hospital emergency departments, urgent care clinics, substance abuse treatment clinics, primary care settings, community clinics, mobile medical clinics, and correctional health care facilities.
- (b) (a) "HIV test" means a test ordered after July 6, 1988, to determine the presence of the antibody or antigen to human immunodeficiency virus or the presence of human immunodeficiency virus infection.
- (c) (b) "HIV test result" means a laboratory report of a human immunodeficiency virus test result entered into a medical record on or after July 6, 1988, or any report or notation in a medical record of a laboratory report of a human immunodeficiency virus test. As used in this section, The term "HIV test result" does not include test results reported to a health care provider by a patient.
- (d) "Nonhealth care setting" means a site that conducts
  HIV testing for the sole purpose of identifying HIV infection.
  Such setting does not provide medical treatment but may include community-based organizations, outreach settings, county health department HIV testing programs, and mobile vans.
  - <u>(f)</u> (c) "Significant exposure" means:
- 1. Exposure to blood or body fluids through needlestick, instruments, or sharps;

169507 - h0819-strike.docx



Bill No. CS/CS/HB 819 (2014)

#### Amendment No.

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2.	Exposure	of r	nucous	membranes	s to	visible	blood	or	body
fluids,	to which	unive	ersal p	precaution	ns ap	oply acc	ording	to	the
National	Centers	for I	Disease	e Control	and	Prevent	ion, ir	ıclı	ding
without	limitatio	ns, t	the fo	llowing bo	ody i	fluids:			

- a. Blood.
- b. Semen.
- c. Vaginal secretions.
- d. Cerebrospinal Cerebrospinal fluid (CSF).
- e. Synovial fluid.
- f. Pleural fluid.
- q. Peritoneal fluid.
- h. Pericardial fluid.
- i. Amniotic fluid.
- j. Laboratory specimens that contain HIV (e.g., suspensions of concentrated virus); or
- 3. Exposure of skin to visible blood or body fluids, especially when the exposed skin is chapped, abraded, or afflicted with dermatitis or the contact is prolonged or involving an extensive area.
- (e) (d) "Preliminary HIV test" means an antibody or antibody-antigen screening test, such as the enzyme-linked immunosorbent assays (IA), or a rapid test approved by the United States Food and Drug Administration (ELISAs) or the Single-Use Diagnostic System (SUDS).
- (g) (e) "Test subject" or "subject of the test" means the person upon whom an HIV test is performed, or the person who has

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Amendment No.

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legal authority to make health care decisions for the test subject.

- (2) HUMAN IMMUNODEFICIENCY VIRUS TESTING; INFORMED CONSENT; RESULTS; COUNSELING; CONFIDENTIALITY.—
  - (a) Before performing an HIV test:
- In a health care setting, the person to be tested shall be provided information about the test, and shall be notified that the test is planned, that he or she has the right to decline the test, and that he or she has the right to confidential treatment of information identifying the subject of the test and of the results of the test as provided by the law. If the person to be tested declines the test, such decision shall be documented in the medical record. No person in this state shall order a test designed to identify the human immunodeficiency virus, or its antigen or antibody, without first obtaining the informed consent of the person upon whom the test is being performed, except as specified in paragraph (h). Informed consent shall be preceded by an explanation of the right to confidential treatment of information identifying the subject of the test and the results of the test to the extent provided by law. Information shall also be provided on the fact that a positive HIV test result will be reported to the county health department with sufficient information to identify the test subject and on the availability and location of sites at which anonymous testing is performed. As required in paragraph (3) (c), each county health department shall maintain a list of

169507 - h0819-strike.docx



Amendment No.

sites at which anonymous testing is performed, including the locations, phone numbers, and hours of operation of the sites. Consent need not be in writing provided there is documentation in the medical record that the test has been explained and the consent has been obtained.

2. In a nonhealth care setting, a provider shall obtain the informed consent of the person upon whom the test is being performed. Informed consent shall be preceded by an explanation of the right to confidential treatment of information identifying the subject of the test and the results of the test as provided by law.

The test subject shall also be informed that a positive HIV test result will be reported to the county health department with sufficient information to identify the test subject and on the availability and location of sites at which anonymous testing is performed. As required in paragraph (3)(c), each county health department shall maintain a list of sites at which anonymous testing is performed, including the locations, telephone numbers, and hours of operation of the sites.

- (b) Except as provided in paragraph (h), informed consent must be obtained from a legal guardian or other person authorized by law if when the person:
- 1. Is not competent, is incapacitated, or is otherwise unable to make an informed judgment; or

169507 - h0819-strike.docx



Amendment No.

- 2. Has not reached the age of majority, except as provided in s. 384.30.
- (g) Human immunodeficiency virus test results contained in the medical records of a hospital licensed under chapter 395 may be released in accordance with s. 395.3025 without being subject to the requirements of subparagraph (e)2., subparagraph (e)9., or paragraph (f) if; provided the hospital has notified the patient of the limited confidentiality protections afforded HIV test results contained in hospital medical records obtained written informed consent for the HIV test in accordance with provisions of this section.
- (h) Notwithstanding the provisions of paragraph (a), informed consent is not required:
- 1. When testing for sexually transmissible diseases is required by state or federal law, or by rule including the following situations:
- a. HIV testing pursuant to s. 796.08 of persons convicted of prostitution or of procuring another to commit prostitution.
- b. HIV testing of inmates pursuant to s. 945.355 <u>before</u> prior to their release from prison by reason of parole, accumulation of gain-time credits, or expiration of sentence.
- c. Testing for HIV by a medical examiner in accordance with s. 406.11.
  - d. HIV testing of pregnant women pursuant to s. 384.31.
- 2. Those exceptions provided for blood, plasma, organs, skin, semen, or other human tissue pursuant to s. 381.0041.

169507 - h0819-strike.docx



Amendment No.

- 3. For the performance of an HIV-related test by licensed medical personnel in bona fide medical emergencies <u>if</u> when the test results are necessary for medical diagnostic purposes to provide appropriate emergency care or treatment to the person being tested and the patient is unable to consent, as supported by documentation in the medical record. Notification of test results in accordance with paragraph (c) is required.
- 4. For the performance of an HIV-related test by licensed medical personnel for medical diagnosis of acute illness where, in the opinion of the attending physician, providing notification obtaining informed consent would be detrimental to the patient, as supported by documentation in the medical record, and the test results are necessary for medical diagnostic purposes to provide appropriate care or treatment to the person being tested. Notification of test results in accordance with paragraph (c) is required if it would not be detrimental to the patient. This subparagraph does not authorize the routine testing of patients for HIV infection without notification informed consent.
- 5. <u>If When HIV testing is performed as part of an autopsy</u> for which consent was obtained pursuant to s. 872.04.
- 6. For the performance of an HIV test upon a defendant pursuant to the victim's request in a prosecution for any type of sexual battery where a blood sample is taken from the defendant voluntarily, pursuant to court order for any purpose, or pursuant to the provisions of s. 775.0877, s. 951.27, or s.

169507 - h0819-strike.docx



Amendment No.

960.003; however, the results of <u>an</u> any HIV test performed shall be disclosed solely to the victim and the defendant, except as provided in ss. 775.0877, 951.27, and 960.003.

- 7. If When an HIV test is mandated by court order.
- 8. For epidemiological research pursuant to s. 381.0031, for research consistent with institutional review boards created by 45 C.F.R. part 46, or for the performance of an HIV-related test for the purpose of research, if the testing is performed in a manner by which the identity of the test subject is not known and may not be retrieved by the researcher.
- 9. <u>If When</u> human tissue is collected lawfully without the consent of the donor for corneal removal as authorized by s. 765.5185 or enucleation of the eyes as authorized by s. 765.519.
- who comes into contact with medical personnel in such a way that a significant exposure has occurred during the course of employment or within the scope of practice and where a blood sample is available which that was taken from that individual voluntarily by medical personnel for other purposes. The term "medical personnel" includes a licensed or certified health care professional; an employee of a health care professional or health care facility; employees of a laboratory licensed under chapter 483; personnel of a blood bank or plasma center; a medical student or other student who is receiving training as a health care professional at a health care facility; and a

169507 - h0819-strike.docx



Bill No. CS/CS/HB 819 (2014)

Amendment No.

paramedic or emergency medical technician certified by the department to perform life-support procedures under s. 401.23.

- a. Before performing Prior to performance of an HIV test on a voluntarily obtained blood sample, the individual from whom the blood was obtained shall be requested to consent to the performance of the test and to the release of the results. If consent cannot be obtained within the time necessary to perform the HIV test and begin prophylactic treatment of the exposed medical personnel, all information concerning the performance of an HIV test and any HIV test result shall be documented only in the medical personnel's record unless the individual gives written consent to entering this information on the individual's medical record.
- b. Reasonable attempts to locate the individual and to obtain consent shall be made, and all attempts must be documented. If the individual cannot be found or is incapable of providing consent, an HIV test may be conducted on the available blood sample. If the individual does not voluntarily consent to the performance of an HIV test, the individual shall be informed that an HIV test will be performed, and counseling shall be furnished as provided in this section. However, HIV testing shall be conducted only after appropriate medical personnel under the supervision of a licensed physician documents, in the medical record of the medical personnel, that there has been a significant exposure and that, in accordance with the written protocols based on the National Centers for Disease Control and

169507 - h0819-strike.docx



Amendment No.

Prevention guidelines on HIV postexposure prophylaxis and in the physician's medical judgment, the information is medically necessary to determine the course of treatment for the medical personnel.

- c. Costs of <u>an</u> any HIV test of a blood sample performed with or without the consent of the individual, as provided in this subparagraph, shall be borne by the medical personnel or the employer of the medical personnel. However, costs of testing or treatment not directly related to the initial HIV tests or costs of subsequent testing or treatment may not be borne by the medical personnel or the employer of the medical personnel.
- d. In order to <u>use utilize</u> the provisions of this subparagraph, the medical personnel must either be tested for HIV pursuant to this section or provide the results of an HIV test taken within 6 months <u>before</u> prior to the significant exposure if such test results are negative.
- e. A person who receives the results of an HIV test pursuant to this subparagraph shall maintain the confidentiality of the information received and of the persons tested. Such confidential information is exempt from s. 119.07(1).
- f. If the source of the exposure will not voluntarily submit to HIV testing and a blood sample is not available, the medical personnel or the employer of such person acting on behalf of the employee may seek a court order directing the source of the exposure to submit to HIV testing. A sworn statement by a physician licensed under chapter 458 or chapter

169507 - h0819-strike.docx



Amendment No.

459 that a significant exposure has occurred and that, in the physician's medical judgment, testing is medically necessary to determine the course of treatment constitutes probable cause for the issuance of an order by the court. The results of the test shall be released to the source of the exposure and to the person who experienced the exposure.

- 11. For the performance of an HIV test upon an individual who comes into contact with medical personnel in such a way that a significant exposure has occurred during the course of employment or within the scope of practice of the medical personnel while the medical personnel provides emergency medical treatment to the individual; or notwithstanding s. 384.287, an individual who comes into contact with nonmedical personnel in such a way that a significant exposure has occurred while the nonmedical personnel provides emergency medical assistance during a medical emergency. For the purposes of this subparagraph, a medical emergency means an emergency medical condition outside of a hospital or health care facility that provides physician care. The test may be performed only during the course of treatment for the medical emergency.
- a. An individual who is capable of providing consent shall be requested to consent to an HIV test <u>before</u> prior to the testing. If consent cannot be obtained within the time necessary to perform the HIV test and begin prophylactic treatment of the exposed medical personnel and nonmedical personnel, all information concerning the performance of an HIV test and its

169507 - h0819-strike.docx



Bill No. CS/CS/HB 819 (2014)

Amendment No.

result, shall be documented only in the medical personnel's or nonmedical personnel's record unless the individual gives written consent to entering this information <u>in</u> on the individual's medical record.

- b. HIV testing shall be conducted only after appropriate medical personnel under the supervision of a licensed physician documents, in the medical record of the medical personnel or nonmedical personnel, that there has been a significant exposure and that, in accordance with the written protocols based on the National Centers for Disease Control and Prevention guidelines on HIV postexposure prophylaxis and in the physician's medical judgment, the information is medically necessary to determine the course of treatment for the medical personnel or nonmedical personnel.
- c. Costs of any HIV test performed with or without the consent of the individual, as provided in this subparagraph, shall be borne by the medical personnel or the employer of the medical personnel or nonmedical personnel. However, costs of testing or treatment not directly related to the initial HIV tests or costs of subsequent testing or treatment may not be borne by the medical personnel or the employer of the medical personnel or nonmedical personnel.
- d. In order to <u>use utilize</u> the provisions of this subparagraph, the medical personnel or nonmedical personnel shall be tested for HIV pursuant to this section or shall provide the results of an HIV test taken within 6 months before

169507 - h0819-strike.docx



Amendment No.

 <del>prior to</del> the significant exposure if such test results are negative.

- e. A person who receives the results of an HIV test pursuant to this subparagraph shall maintain the confidentiality of the information received and of the persons tested. Such confidential information is exempt from s. 119.07(1).
- f. If the source of the exposure will not voluntarily submit to HIV testing and a blood sample was not obtained during treatment for the medical emergency, the medical personnel, the employer of the medical personnel acting on behalf of the employee, or the nonmedical personnel may seek a court order directing the source of the exposure to submit to HIV testing. A sworn statement by a physician licensed under chapter 458 or chapter 459 that a significant exposure has occurred and that, in the physician's medical judgment, testing is medically necessary to determine the course of treatment constitutes probable cause for the issuance of an order by the court. The results of the test shall be released to the source of the exposure and to the person who experienced the exposure.
- 12. For the performance of an HIV test by the medical examiner or attending physician upon an individual who expired or could not be resuscitated while receiving emergency medical assistance or care and who was the source of a significant exposure to medical or nonmedical personnel providing such assistance or care.

169507 - h0819-strike.docx



Amendment No.

- a. HIV testing may be conducted only after appropriate medical personnel under the supervision of a licensed physician documents in the medical record of the medical personnel or nonmedical personnel that there has been a significant exposure and that, in accordance with the written protocols based on the National Centers for Disease Control and Prevention guidelines on HIV postexposure prophylaxis and in the physician's medical judgment, the information is medically necessary to determine the course of treatment for the medical personnel or nonmedical personnel.
- b. Costs of  $\underline{an}$   $\underline{any}$  HIV test performed under this subparagraph may not be charged to the deceased or to the family of the deceased person.
- c. For the provisions of this subparagraph to be applicable, the medical personnel or nonmedical personnel must be tested for HIV under this section or must provide the results of an HIV test taken within 6 months before the significant exposure if such test results are negative.
- d. A person who receives the results of an HIV test pursuant to this subparagraph shall comply with paragraph (e).
- 13. For the performance of an HIV-related test medically indicated by licensed medical personnel for medical diagnosis of a hospitalized infant as necessary to provide appropriate care and treatment of the infant <u>if when</u>, after a reasonable attempt, a parent cannot be contacted to provide consent. The medical records of the infant must shall reflect the reason consent of

169507 - h0819-strike.docx



Amendment No.

the parent was not initially obtained. Test results shall be provided to the parent when the parent is located.

- 14. For the performance of HIV testing conducted to monitor the clinical progress of a patient previously diagnosed to be HIV positive.
- 15. For the performance of repeated HIV testing conducted to monitor possible conversion from a significant exposure.
- (4) HUMAN IMMUNODEFICIENCY VIRUS TESTING REQUIREMENTS;
  REGISTRATION WITH THE DEPARTMENT OF HEALTH; EXEMPTIONS FROM
  REGISTRATION.—No county health department and no other person in
  this state shall conduct or hold themselves out to the public as
  conducting a testing program for acquired immune deficiency
  syndrome or human immunodeficiency virus status without first
  registering with the Department of Health, reregistering each
  year, complying with all other applicable provisions of state
  law, and meeting the following requirements:
- (d) A program in a health care setting shall meet the notification criteria contained in subparagraph (2)(a)1. A program in a nonhealth care setting shall meet all informed consent criteria contained in subparagraph (2)(a)2. The program must meet all the informed consent criteria contained in subsection (2).

Section 3. Paragraph (e) of subsection (4) of section 395.3025, Florida Statutes, is amended to read:

395.3025 Patient and personnel records; copies; examination.—

169507 - h0819-strike.docx



Amendment No.

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- (4) Patient records are confidential and <u>may</u> <u>must</u> not be disclosed without the consent of the patient or his or her legal representative, but appropriate disclosure may be made without such consent to:
- The department agency upon subpoena issued pursuant to (e) s. 456.071., but The records obtained thereby must be used solely for the purpose of the department agency and the appropriate professional board in its investigation, prosecution, and appeal of disciplinary proceedings. If the department agency requests copies of the records, the facility shall charge a fee pursuant to this section no more than its actual copying costs, including reasonable staff time. The department and the appropriate professional board must maintain the confidentiality of patient records obtained under this paragraph pursuant to s. 456.057. A licensee who is the subject of a department investigation may inspect or receive a copy of a patient record connected with the investigation if the licensee agrees in writing to maintain the confidentiality of the patient record pursuant to s. 456.057 must be sealed and must not be available to the public pursuant to s. 119.07(1) or any other statute providing access to records, nor may they be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the agency or the appropriate regulatory board. However, the agency must make available, upon written request by a practitioner against whom probable cause has been found, any

169507 - h0819-strike.docx



Bill No. CS/CS/HB 819 (2014)

Amendment No.

such records that form the basis of the determination of probable cause.

Section 4. Subsection (2) of section 456.013, Florida Statutes, is amended to read:

456.013 Department; general licensing provisions.-

shall charge an initial license fee as determined by the applicable board or, if there is no board, by rule of the department. Upon receipt of the appropriate license fee, the department shall issue a license to a any person certified by the appropriate board, or its designee, as having met the licensure requirements imposed by law or rule. The license shall consist of a wallet size identification card and a wall card measuring 6 1/2 inches by 5 inches. The licensee shall surrender the license to the department the wallet size identification card and the wall card if the licensee's license was is issued in error or is revoked.

Section 5. Subsections (5) through (11) of section 456.025, Florida Statutes, are renumbered as subsections (4) through (10), respectively, and present subsections (4) and (6) are amended to read:

456.025 Fees; receipts; disposition.-

(4) Each board, or the department if there is no board, may charge a fee not to exceed \$25, as determined by rule, for the issuance of a wall certificate pursuant to s. 456.013(2) requested by a licensee who was licensed prior to July 1, 1998,

169507 - h0819-strike.docx



Amendment No.

 or for the issuance of a duplicate wall certificate requested by any licensee.

(5)(6) If the cash balance of the trust fund at the end of any fiscal year exceeds the total appropriation provided for the regulation of the health care professions in the prior fiscal year, the boards, in consultation with the department, may lower the license renewal fees. When the department determines, based on long-range estimates of revenue, that a profession's trust fund balance exceeds the amount required to cover necessary functions, each board, or the department when there is no board, may adopt rules to implement the waiver of initial application fees, initial licensure fees, unlicensed activity fees, or renewal fees for that profession. The waiver of renewal fees may not exceed 2 years.

Section 6. Subsection (2) of section 456.032, Florida Statutes, is amended to read:

456.032 Hepatitis B or HIV carriers.-

(2) Any person licensed by the department and any other person employed by a health care facility who contracts a blood-borne infection shall have a rebuttable presumption that the illness was contracted in the course and scope of his or her employment, provided that the person, as soon as practicable, reports to the person's supervisor or the facility's risk manager any significant exposure, as that term is defined in s.  $\frac{381.004(1)(f)}{381.004(1)(c)}$ , to blood or body fluids. The employer may test the blood or body fluid to determine if it is

169507 - h0819-strike.docx



Amendment No.

infected with the same disease contracted by the employee. '	The
employer may rebut the presumption by the preponderance of	the
evidence. Except as expressly provided in this subsection,	there
shall be no presumption that a blood-borne infection is a joint to the state of the	ob-
related injury or illness.	

Section 7. Subsection (17) of section 456.057, Florida Statutes, is amended to read:

456.057 Ownership and control of patient records; report or copies of records to be furnished; disclosure of information.—

(17) A health care practitioner or records owner furnishing copies of reports or records or making the reports or records available for digital scanning pursuant to this section shall charge no more than the actual cost of copying, including reasonable staff time, or the amount specified in administrative rule by the appropriate board, or the department when there is no board. The rates charged for reproduction of written or typed medical records must be the same regardless of format or medium.

Section 8. Subsections (2), (3), and (4) of section 458.319, Florida Statutes, are renumbered as subsections (3), (4), and (5), respectively, and a new subsection (2) is added to that section to read:

458.319 Renewal of license.

(2) Each licensee shall demonstrate his or her professional competency by completing at least 40 hours of

169507 - h0819-strike.docx



Amendment No.

508	continuing medical education every 2 years. The board, by rule,
509	<pre>may:</pre>
510	(a) Provide that continuing medical education approved by
511	the American Medical Association satisfies some or all of the
512	continuing medical education requirements.
513	(b) Mandate specific continuing medical education
514	requirements.
515	(c) Approve alternative methods for obtaining continuing
516	medical education credits, including, but not limited to:
517	1. Attendance at a board meeting at which another licensee
518	is disciplined;
519	2. Service as a volunteer expert witness for the
520	department in a disciplinary proceeding; or
521	3. Service as a member of a probable cause panel following
522	expiration of a board member's term.
523	Section 9. Subsection (3) of section 458.3485, Florida
524	Statutes, is amended to read:
525	458.3485 Medical assistant.—
526	(3) CERTIFICATION. Medical assistants may be certified by
527	the American Association of Medical Assistants or as a
528	Registered Medical Assistant by the American Medical
529	<del>Technologists.</del>
530	Section 10. Subsection (7) of section 464.203, Florida
531	Statutes, is amended to read:
532	464.203 Certified nursing assistants; certification

169507 - h0819-strike.docx

requirement.-

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### COMMITTEE/SUBCOMMITTEE AMENDMENT Bill No. CS/CS/HB 819

(2014)

Amendment No.

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(7) A certified nursing assistant shall complete $24$ $12$
hours of inservice training every 2 years during each calendar
year. The certified nursing assistant <u>is</u> shall be responsible
for maintaining documentation demonstrating compliance with
these provisions. The Council on Certified Nursing Assistants,
in accordance with s. 464.2085(2)(b), shall propose rules to
implement this subsection.

Section 11. Section 464.2085, Florida Statutes, is repealed.

Section 12. Subsection (2) of section 466.032, Florida Statutes, is amended to read:

466.032 Registration.—

(2) Upon the failure of any dental laboratory operator to comply with subsection (1), the department shall notify her or him by registered mail, within 1 month after the registration renewal date, return receipt requested, at her or his last known address, of such failure and inform her or him of the provisions of subsections (3) and (4).

Section 13. Subsection (8) of section 467.009, Florida Statutes, is amended to read:

467.009 Midwifery programs; education and training requirements.-

Nonpublic educational institutions that conduct approved midwifery programs shall be accredited by a member of the Council of on Higher Education Accreditation Commission on

169507 - h0819-strike.docx



Amendment No.

Recognition of Postsecondary Accreditation and shall be licensed by the Commission for Independent Education.

Section 14. Subsection (2) of section 468.1665, Florida Statutes, is amended to read:

468.1665 Board of Nursing Home Administrators; membership; appointment; terms.—

(2) Four Three members of the board must be licensed nursing home administrators. One member Two members of the board must be a health care practitioner practitioners. The remaining two members of the board must be laypersons who are not, and have never been, nursing home administrators or members of any health care profession or occupation. At least one member of the board must be 60 years of age or older.

Section 15. Subsection (2) of section 468.1695, Florida Statutes, is amended to read:

468.1695 Licensure by examination.-

- (2) The department shall examine each applicant who the board certifies has completed the application form and remitted an examination fee set by the board not to exceed \$250 and who:
- (a)1. Holds a baccalaureate <u>or master's</u> degree from an accredited college or university and majored in health care administration, health services administration, or an equivalent major, or has credit for at least 60 semester hours in subjects, as prescribed by rule of the board, which prepare the applicant for total management of a nursing home; and

169507 - h0819-strike.docx



Amendment No.

	2.	Has	fulf	illed	the	requir	ements of	fac	ollege-affiliated
or	unive	rsity	-aff:	iliate	ed ir	nternsh	ip in nu	rsing	home
adm	inist	ratio	n or	of a	1,00	0-hour	nursing	home	administrator-in
tra	ining	prog	gram g	presci	cibed	by the	e board;	or	

- (b)1. Holds a baccalaureate degree from an accredited college or university; and
- 2.a. Has fulfilled the requirements of a 2,000-hour nursing home administrator-in-training program prescribed by the board; or
- b. Has 1 year of management experience allowing for the application of executive duties and skills, including the staffing, budgeting, and directing of resident care, dietary, and bookkeeping departments within a skilled nursing facility, hospital, hospice, assisted living facility with a minimum of 60 licensed beds, or geriatric residential treatment program and, if such experience is not in a skilled nursing facility, has fulfilled the requirements of a 1,000-hour nursing home administrator-in-training program prescribed by the board.

Section 16. <u>Section 468.1735</u>, Florida Statutes, is repealed.

Section 17. Subsection (11) of section 468.503, Florida Statutes, is amended to read:

468.503 Definitions.—As used in this part:

(11) "Registered dietitian" means an individual registered with the accrediting body of the Academy of Nutrition and

169507 - h0819-strike.docx



Bill No. CS/CS/HB 819 (2014)

Amendment No.

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609	<u>Dietetics</u> Commission on Dietetic Registration,	the	accrediting
610	body of the American Dietetic Association.		

Section 18. Subsection (4) of section 468.505, Florida Statutes, is amended to read:

468.505 Exemptions; exceptions.

- (4) Notwithstanding any other provision of this part, an individual registered by the <u>accrediting body of the Academy of Nutrition and Dietetics Commission on Dietetic Registration of the American Dietetic Association</u> has the right to use the title "Registered Dietitian" and the designation "R.D."
- Section 19. Subsection (5) of section 480.033, Florida Statutes, is amended to read:
  - 480.033 Definitions.—As used in this act:
- (5) "Apprentice" means a person approved by the board to study massage under the instruction of a licensed massage therapist.
- Section 20. Subsections (1) and (4) of section 480.041, Florida Statutes, are amended to read:
- 480.041 Massage therapists; qualifications; licensure; endorsement.—
- (1)  $\underline{A}$  Any person is qualified for licensure as a massage therapist under this act who:
- (a) Is at least 18 years of age or has received a high school diploma or graduate equivalency diploma;

169507 - h0819-strike.docx



Amendment No.

(b)	Has	complete	d a	course	of	study	at	a bo	ard-app	roved
massage	school	or has	<del>com</del>	<del>pleted</del>	an a	a <del>pprent</del>	ice	ship	<del>progra</del>	m that
meets st	andard	<del>ls adopte</del>	<del>d b</del>	<del>y the b</del>	oar	and;				

- (c) Has received a passing grade on an examination administered by the department.
  - (4) The board shall adopt rules:
- (a) Establishing a minimum training program for apprentices.
- (b) Providing for educational standards, examination, and certification for the practice of colonic irrigation, as defined in s. 480.033 480.033(6), by massage therapists.
- (b) (e) Specifying licensing procedures for practitioners desiring to be licensed in this state who hold an active license and have practiced in any other state, territory, or jurisdiction of the United States or any foreign national jurisdiction which has licensing standards substantially similar to, equivalent to, or more stringent than the standards of this state.
- Section 21. Subsection (5) of section 480.042, Florida Statutes, is amended to read:
  - 480.042 Examinations.-
- (5) All licensing examinations shall be conducted in such manner that the applicant shall be known to the department by number until her or his examination is completed and the proper grade determined. An accurate record of each examination shall be maintained, shall be made; and that record, together with all

169507 - h0819-strike.docx



Bill No. CS/CS/HB 819 (2014)

Amendment No.

examination papers, shall be filed with the State Surgeon

General and shall be kept by the testing entities for reference

and inspection for a period of not less than 2 years immediately

following the examination.

Section 22. Paragraph (h) of subsection (1) of section 480.044, Florida Statutes, is amended to read:

480.044 Fees; disposition.-

- (1) The board shall set fees according to the following schedule:
  - (h) Fee for apprentice: not to exceed \$100.

Section 23. Subsection (4) of section 766.1115, Florida Statutes, is amended to read:

766.1115 Health care providers; creation of agency relationship with governmental contractors.—

(4) CONTRACT REQUIREMENTS.—A health care provider that executes a contract with a governmental contractor to deliver health care services on or after April 17, 1992, as an agent of the governmental contractor is an agent for purposes of s. 768.28(9), while acting within the scope of duties under the contract, if the contract complies with the requirements of this section and regardless of whether the individual treated is later found to be ineligible. A health care provider shall continue to be an agent for purposes of s. 768.28(9) for 30 days after a determination of ineligibility to allow for treatment until the individual transitions to treatment by another health care provider. A health care provider under contract with the

169507 - h0819-strike.docx



Amendment No.

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state may not be named as a defendant in any action arising out of medical care or treatment provided on or after April 17, 1992, under contracts entered into under this section. The contract must provide that:

- (a) The right of dismissal or termination of any health care provider delivering services under the contract is retained by the governmental contractor.
- (b) The governmental contractor has access to the patient records of any health care provider delivering services under the contract.
- (c) Adverse incidents and information on treatment outcomes must be reported by any health care provider to the governmental contractor if the incidents and information pertain to a patient treated under the contract. The health care provider shall submit the reports required by s. 395.0197. If an incident involves a professional licensed by the Department of Health or a facility licensed by the Agency for Health Care Administration, the governmental contractor shall submit such incident reports to the appropriate department or agency, which shall review each incident and determine whether it involves conduct by the licensee that is subject to disciplinary action. All patient medical records and any identifying information contained in adverse incident reports and treatment outcomes which are obtained by governmental entities under this paragraph are confidential and exempt from the provisions of s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

169507 - h0819-strike.docx



(2014)

Bill No. CS/CS/HB 819

Amendment No.

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(d)	) Pat	ient s	election	and	initial	refer	rral ı	must	be	made	рУ
the gove	ernmen	tal co	ntractor	or t	the prov	ider.	Pati	ents	may	not	be
transfe	rred to	o the	provider	base	ed on a	violat	cion (	of th	ıe		
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chapter	395.										

- (e) If emergency care is required, the patient need not be referred before receiving treatment, but must be referred within 48 hours after treatment is commenced or within 48 hours after the patient has the mental capacity to consent to treatment, whichever occurs later.
- (f) The provider is subject to supervision and regular inspection by the governmental contractor.

A governmental contractor that is also a health care provider is not required to enter into a contract under this section with respect to the health care services delivered by its employees.

Section 24. Subsection (3) of section 823.05, Florida Statutes, is amended to read:

- 823.05 Places and groups engaged in criminal gang-related activity declared a nuisance; massage establishments engaged in prohibited activity; may be abated and enjoined.—
- (3) A massage establishment as defined in s. <u>480.033</u> <del>480.033(7)</del> that operates in violation of s. 480.0475 or s. 480.0535(2) is declared a nuisance and may be abated or enjoined as provided in ss. 60.05 and 60.06.

169507 - h0819-strike.docx



Amendment No.

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737 Section 25. This act shall take effect July 1, 2014.
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#### TITLE AMENDMENT

Remove everything before the enacting clause and insert:

A bill to be entitled

An act relating to the Department of Health; amending s. 322.142, F.S.; authorizing the Department of Highway Safety and Motor Vehicles to provide reproductions of specified records to the Department of Health under certain circumstances; amending s. 381.004, F.S.; revising and providing definitions; specifying the notification and consent procedures for performing an HIV test in a health care setting and a nonhealth care setting; amending s. 395.3025, F.S.; clarifying duties of the Department of Health to maintain the confidentiality of patient records that it obtains under subpoena pursuant to an investigation; authorizing licensees under investigation to inspect or receive copies of patient records connected with the investigation, subject to certain conditions; amending s. 456.013, F.S.; deleting requirements for the physical size of licenses issued for various health professions; amending s. 456.025, F.S.; deleting fee for issuance of wall certificates for various health profession

169507 - h0819-strike.docx



(2014)

Bill No. CS/CS/HB 819

Amendment No.

763 licenses; authorizing the boards or the department to 764 adopt rules waiving certain fees for a specified 765 period in certain circumstances; amending s. 456.032, 766 F.S.; conforming a cross-reference; amending s. 767 456.057, F.S.; providing a requirement for rates charged for reproduction of certain records; amending 768 769 s. 458.319, F.S.; providing continuing medical 770 education requirements for Board of Medicine 771 licensees; authorizing the board to adopt rules; 772 amending s. 458.3485, F.S.; deleting a provision 773 authorizing medical assistants to be certified by 774 certain entities; amending s. 464.203, F.S.; revising 775 certified nursing assistant inservice training 776 requirements; repealing s. 464.2085, F.S., relating to 777 the creation, membership, and duties of the Council on 778 Certified Nursing Assistants; amending s. 466.032, 779 F.S.; deleting a requirement that the department 780 provide certain notice to a dental laboratory operator 781 who fails to renew her or his registration; amending s. 467.009, F.S.; revising the organization that must 782 accredit certain midwifery programs; amending s. 783 784 468.1665, F.S.; revising membership of the Board of 785 Nursing Home Administrators; amending s. 468.1695, 786 F.S.; revising an educational requirement for an 787 applicant to be eligible to take the nursing home 788 administrator licensure examination; repealing s.

169507 - h0819-strike.docx



Amendment No.

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468.1735, F.S., relating to provisional licenses for nursing home administrators; amending ss. 468.503 and 468.505, F.S.; revising the organization with whom an individual must be registered to be a registered dietitian; revising a definition; amending ss. 480.033 and 480.041, F.S.; deleting provisions relating to massage therapy apprentices and apprenticeship programs; deleting a definition and revising licensure requirements for massage therapists, to conform; amending s. 480.042, F.S.; revising requirements for conducting massage therapist licensing examinations and maintaining examination records; amending s. 480.044, F.S.; deleting fee for massage therapy apprentices; amending s. 766.1115, F.S.; requiring a health care provider to continue to be an agent for a specified period after determination of ineliqibility; amending s. 823.05, F.S.; conforming a crossreference; providing an effective date.

169507 - h0819-strike.docx



Amendment No.

COMMITTEE/SUBCOMM	ITTEE 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 Roberson, K. offered the following:

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# Amendment to Amendment (169507) by Representative Pigman (with title amendment)

Remove line 401 of the amendment and insert:

Section 2. Subsection (1) of section 382.011, Florida Statutes, is amended to read:

382.011 Medical examiner determination of cause of death.

(1) In the case of any death or fetal death <u>involving the</u> <u>circumstances</u> due to causes or conditions listed in s. <u>406.11(1)</u> 406.11, any death that occurred more than 12 months after the decedent was last treated by a primary or attending physician as defined in s. 382.008(3), or any death for which there is reason to believe that the death may have been due to an unlawful act or neglect, the funeral director or other person to whose

888641 - h0819-line 401.docx

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Amendment No.

attention the death may come shall refer the case to the
district medical examiner of the county in which the death
occurred or the body was found for investigation and
determination of the cause of death. A member of the public may
not be charged a fee by a county or district medical examiner
for any examination, investigation, or autopsy performed to
determine the cause of death pursuant to s. 406.11(1). However,
a county, by resolution or ordinance of the board of county
commissioners, may charge a medical examiner approval fee not to
exceed \$50 when a body is to be cremated, buried at sea, or
dissected.

Section 3. Paragraph (e) of subsection (4) of section

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### TITLE AMENDMENT

 Remove line 7 of the amendment and insert: 382.011, F.S.; Enter Amending Text Here

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