

**The Florida Senate**  
**BILL ANALYSIS AND FISCAL IMPACT STATEMENT**

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

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Prepared By: The Professional Staff of the Appropriations Subcommittee on Health and Human Services

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BILL: PCS/SB 1760 (805502)

INTRODUCER: Appropriations Subcommittee on Health and Human Services; and Senators Grimsley and Campbell

SUBJECT: Health Care Facility Regulation

DATE: April 20, 2017

REVISED: \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Stovall	HP	<b>Favorable</b>
2.	Stovall/Forbes	Williams	AHS	<b>Recommend: Fav/CS</b>
3.			AP	
4.			RC	

**Please see Section IX. for Additional Information:**

COMMITTEE SUBSTITUTE - Substantial Changes

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**I. Summary:**

PCS/SB 1760 includes regulatory reductions, revisions to minimize or eliminate conflicts with federal or state requirements, and new provisions to recognize changing needs, and deletes obsolete provisions in the regulation of health care facilities by the Agency for Health Care Administration (AHCA or agency). The bill:

- Abolishes the licensure of clinical laboratories and health care risk managers. The requirement for clinical laboratories to be certified under federal requirements remains in effect. Health care risk managers remain an integral part of a comprehensive risk management program, but will no longer require licensure.
- Removes mobile surgical facilities from health care facility regulation.
- Authorizes hospitals to use alternate-site testing for certain laboratory services.
- Requires the agency to adopt rules for minimum licensure requirements relating to pediatric cardiac catheterization, pediatric open-heart surgery, organ transplantation, neonatal intensive care services, psychiatric services, and comprehensive medical rehabilitation.
- Requires each home health agency to identify the home health services it provides and indicate whether each service is considered skilled care. Additional regulatory requirements will apply to home health agencies providing skilled services.
- Establishes a voluntary process to apply for a certificate of exemption from licensure for a person providing home health services that are exempt from licensure.

- Enhances and clarifies the provisions affecting unlicensed activity for nurse registries and assisted living facilities.
- Removes prohibitions on a nurse registry providing remuneration to certain individuals who may provide referrals.
- Deletes certain provisions within specific facility licensing chapters to eliminate inconsistencies with the general facility licensing chapter, or to reduce regulatory burdens.
- Authorizes a licensee to request the alignment of the expiration date for multiple licenses held by the licensee.
- Repeals the subscriber assistance program, the statewide managed care ombudsman committee, and the district managed care ombudsman committees.
- Assigns the exclusive jurisdiction of a designated facility owned or operated by a public health trust to the county creating it, excluding it from a municipality's jurisdiction.
- Requires the agency to adopt rules addressing the care and treatment of patients residing in distinct part nursing units of hospitals.
- Imposes a 2-year expiration date on a voluntary certificate of exemption issued to a person or entity providing health care services which is not a clinic under part X of ch. 400, F.S.
- Strengthens background screening requirements for persons with a controlling interest and certain contracted workers with access to client funds, property, or living areas.
- Strengthens the disqualifying conditions for a Medicaid provider.
- Adds numerous revisions to the regulation of ALFs, including but not limited to: resident contract revisions, reading the medication label aloud when assisting a resident with the self-administration of medication, clarifying certain provisions within the resident bill of rights, conducting monitoring visits, and eliminating a conflict in the timeframe for providing resident records.
- Exempts from the regulation of clinical laboratory personnel under part II (renumbered in this bill) persons performing testing within a physician's office for patients in a group practice if the laboratory is under common ownership with an hospital or ASC.
- Requires the Department of Corrections to develop a procedure to certify certain law enforcement personnel to perform urine screen drug tests.

The AHCA estimates a total annual revenue reduction of \$1,448,266 due to the repeal of licensure for clinical laboratories and health care risk managers.

The act is effective July 1, 2017.

## II. Present Situation:

The AHCA is created in s. 20.42, F.S. It is the chief health policy and planning entity for the state and is responsible for, among other things, health facility licensure, inspection, and regulatory enforcement. It licenses or certifies and regulates 40 different types of health care providers, including hospitals, nursing homes, assisted living facilities, and home health agencies. In total, the agency licenses, certifies, regulates or provides exemptions for more than 42,000 providers.<sup>1</sup>

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<sup>1</sup> See the Agency for Health Care Administration, Division of Health Quality Assurance web page available at: <http://ahca.myflorida.com/MCHQ/index.shtml> (last visited March 22, 2017).

Generally applicable provisions of health care provider licensure are addressed in the Health Care Licensing Procedures Act in part II of ch. 408, F.S. Additional chapters or sections in the Florida Statutes provide specific licensure or regulatory requirements pertaining to health care providers in this state.<sup>2</sup>

Due to the many diverse issues within the bill, pertinent background is provided within the effect of proposed changes for the reader's convenience.

### **III. Effect of Proposed Changes:**

#### **Clinical Laboratories and Clinical Laboratory Personnel**

##### *Clinical Laboratories*

The federal Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA).<sup>3</sup> Facilities that provide clinical laboratory services are required to be certified by the CMS CLIA laboratory certification program which operates in conjunction with the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). Certain laboratories may qualify as a waived testing laboratory and receive a CLIA Certificate of Waiver.<sup>4</sup>

Clinical laboratories in the state performing non-waived tests must also obtain a state license from the AHCA and comply with part I of ch. 483, F.S., relating to clinical laboratories, and the general licensing provisions in part II of ch. 408, F.S. This requirement also applies to a clinical laboratory operated by one or more practitioners such as physicians, chiropractors, podiatrists, optometrists, or dentists, exclusively in connection with the diagnosis and treatment of their own patients.<sup>5</sup>

As of July 1, 2016, the agency licenses 3,862 clinical laboratories and collects an average of \$1,129,000 per year in recurring licensure fees and an average of \$254,400 per year in recurring biennial assessments required by s. 408.033, F.S. The federal CLIA program certifies another 17,877 Florida-based laboratories that only perform waived testing which is exempt from state licensure requirements.<sup>6</sup>

Section 92 of the bill repeals part I of ch. 483, F.S., relating to the licensure and regulation of clinical laboratories by the agency. Part I includes ss. 483.011 - 483.26, F.S. Laboratories will continue to be certified by, or receive a certificate of waiver from the CMS under the CLIA.

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<sup>2</sup> See s. 408.802, F.S., for the health care provider types and applicable licensure statutes.

<sup>3</sup> <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/CLIA> (last visited Mar. 17, 2017).

<sup>4</sup> Waived testing laboratories: employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible, pose no reasonable risk of harm to the patient if the test is performed incorrectly, use tests that are cleared by the FDA for home use, and conduct testing that is considered non-technical requiring little or no difficulty. See Agency for Health Care Administration, Waived Laboratories:

[http://ahca.myflorida.com/MCHO/Health\\_Facility\\_Regulation/Laboratory\\_Licensure/waived\\_apps.shtml](http://ahca.myflorida.com/MCHO/Health_Facility_Regulation/Laboratory_Licensure/waived_apps.shtml) (last visited Mar. 17, 2017).

<sup>5</sup> Section 483.035(1), F.S.

<sup>6</sup> Agency for Health Care Administration, *Senate Bill 1760 Analysis* (March 10, 2017), p. 5, (on file with the Senate Committee on Health Policy).

Included within the repeal is a requirement that lab results must be reported directly to the licensed practitioner or other authorized person who requested it, and the authorization for a laboratory to disclose the results without a patient's consent to other health care practitioners and providers involved in the care or treatment of the patient as specified in s. 456.057(7)(a), F.S.

Conforming amendments:

- Section 1 amends s. 20.43, F.S., to renumber the Board of Clinical Laboratory Personnel under the Division of Medical Quality Assurance in the Department of Health from part III to part II to conform to the repeal of part I of ch. 483, F.S.
- Sections 6, 8, 18, and 24 amend ss. 381.0031, 381.004, 384.31, and 395.009, F.S., respectively, to remove references to a laboratory licensed under ch. 483, F.S., and to instead refer to a laboratory certified by the CMS under the CLIA and the federal rules adopted thereunder.
- Section 7 amends s. 381.0034, F.S., to conform a cross-reference to the repeal of part I of ch. 483, F.S.
- Section 15 amends s. 383.313, F.S., to conform the performance of laboratory services by a birth center with the repeal of clinical laboratory licensure and expressly require all laboratory services performed by a birth center to obtain and maintain a CLIA Laboratory Certification or CLIA Certification of Waiver.
- Section 41 amends s. 395.7015, F.S., to remove licensed clinical laboratories from the annual assessment imposed on health care entities.
- Section 42 amends s. 400.0625, F.S., to require all clinical laboratory tests performed for a nursing home to be performed by a laboratory certified by the CMS under the CLIA, with certain exceptions. The bill also deletes the requirement that clinical laboratory tests performed prior to admission in the nursing home by qualified labs shall be accepted in lieu of additional laboratory tests that might be required as a part of the routine examinations for admission.
- Section 55 amends s. 400.9905, F.S., relating to health care clinics, to remove cross-reference to licensure under part I of ch. 483.
- Section 57 amends s. 408.033, F.S., relating to local and state health planning, to remove the assessment imposed on clinical laboratories as a funding source of local health councils.
- Section 60 amends s. 408.07, F.S., relating to the Florida Center for Health Information and Transparency and related reporting by licensed health care facilities to remove the definition of clinical laboratories.
- Section 63 amends s. 408.802, F.S., to delete clinical laboratories from regulation under part II of ch. 408, F.S.
- Section 69 amends s. 408.820, F.S., to delete specified exemptions applicable to the regulation of clinical laboratories.
- Section 70 amends s. 409.905, F.S., to delete reference to licensure under ch. 483 and add the requirement for certification by the CMS under CLIA for laboratory services that are paid for by Medicaid.
- Sections 73, 90, 91 and 123 amend ss. 409.975, 458.345, s. 459.021, and 1011.52, F.S., respectively, to conform a cross-reference to the renumbered definitions in s. 408.07, F.S., in section 60.
- Sections 87 and 88 amend ss. 456.001, and 456.057 F.S., to conform cross-references that have changed due to the repeal of part I of ch. 483, F.S.

- Sections 96, 97, and 98 amend ss. 483.813, 483.823, and 491.003, F.S., to remove references to provisions in part I of ch. 483, F.S.
- Section 99 amends s. 627.351, F.S., relating to medical malpractice risk apportionment to remove clinical laboratories from the definition of health care provider.
- Section 121 amends s. 945.36, F.S., to affirmatively authorize certain law enforcement personnel to administer a urine screen drug test on inmates and releases, rather than exempting the law enforcement personnel from part I of ch. 483, F.S. The Department of Corrections is required to develop a procedure to certify these law enforcement personnel to perform urine screen drug tests.

### ***Clinical Laboratory Personnel***

Individuals who perform testing in licensed clinical laboratories are required to be licensed by the Department of Health, Board of Clinical Laboratory Personnel (board). Licenses issued by the board are specific to the role of the individuals and the specialties in which they perform that role. Certain exemptions from licensure by the board apply, such as for physicians, chiropractors, podiatrists, or dentists, and certain researchers.<sup>7</sup> The board is composed of seven members and has authority to adopt rules to implement the provisions of part III of ch. 483, F.S., relating to clinical laboratory personnel.

Section 94 amends s. 483.801, F.S., to exempt from licensure persons engaged in testing performed by laboratories that are wholly owned and operated by one or more practitioners licensed under Florida law as allopathic or osteopathic physicians, chiropractors, podiatrists, optometrists, or dentists and practice in the same group practice, and in which no clinical laboratory work is performed for patients referred by a health care provider who is not a member of the same group. Another exemption is provided for persons performing laboratory testing within a group practice for the patients referred by a provider who is a member of the same practice if the laboratory is under common ownership, directly or indirectly, with an ambulatory surgical center (ASC) or hospital.

Section 95 amends s. 483.803, F.S., to revise definitions to conform to the repeal of part I of ch. 483, F.S. The definitions of “clinical laboratory” and “clinical laboratory examination” currently found in part I of ch. 483, F.S., are moved to the definitions relating to clinical laboratory personnel.

### **Hospital and Health Care Facility Licensure**

The regulation of, and all references to, mobile surgical facilities are removed from health care facility regulation. Part I of ch. 395, F.S., was amended to include mobile surgical facility as a license type in 1998. A definition of a mobile surgical facility restricts its use to the Department of Corrections (DOC) or a private correctional facility to provide surgical procedures to inmates. No license has ever been issued for a mobile surgical facility and none are anticipated. The DOC operates one hospital which does not offer surgical services directly to its inmates; rather it contracts with a licensed ambulatory surgical center (ASC). A separate license type is not needed in order to meet the surgical needs of the inmate population.<sup>8</sup>

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<sup>7</sup> Sections 483.801 and 483.813, F.S.

<sup>8</sup> *Supra* note 6, p. 3.

## Conforming amendments:

- Sections 19, 20, 72, 73, and 102 amend ss. 385.211, 394.4787, 409.9116, 409.975, and 627.64194, F.S., respectively, to conform a cross-reference to the renumbered definitions in s. 395.002, F.S.
- Sections 21, 22, 23, 26, 27, 119, and 120 amend ss. 395.001, 395.002, 395.003, 395.0161, 395.0163, 766.118, and 766.202, F.S., respectively, to remove reference to a mobile surgical facility in the section.
- Section 41 amends s. 395.7015, F.S., to remove mobile surgical facilities from the annual assessment imposed on health care entities.
- Section 58 amends s. 408.036, F.S., to remove mobile surgical facilities as a project subject to an exemption for certificates of need (CON).
- Section 63 amends s. 408.802, F.S., to delete mobile surgical facilities from regulation under part II of ch. 408, F.S.
- Section 69 amends s. 408.820, F.S., to delete specified exemptions applicable to the regulation of mobile surgical facilities.

Section 25 creates s. 395.0091, F.S., relating to alternate-site testing to enable hospitals to use a laboratory testing site in which the testing is done under the administrative control of a hospital but performed out of the physical or administrative confines of the central laboratory. The bill directs the agency, in consultation with the Board of Clinical Laboratory Personnel, to adopt by rule the criteria for alternate-site testing to be performed under the supervision of a clinical laboratory director. The rule must address, at a minimum, a hospital internal needs assessment, a protocol of implementation, criteria to be used in selecting the method of testing, minimum training and education requirements of professionals in the laboratory, an internal and external quality control protocol, tracking mechanisms between the alternate-site and the central laboratory, and recordkeeping. An alternate-site testing location must be registered when the hospital renews its license.

Sections 28 and 34. Section 34 repeals s. 395.10974, F.S., which establishes the licensure requirements for health care risk managers. Section 28 amends s. 395.0197, F.S., to require an internal risk manager of a health care facility to demonstrate to the hiring facility or its governing board, competence, by education or experience in the same areas<sup>9</sup> as required to be demonstrated to the agency for licensure as a health care risk manager. This section also removes references to licensure under s. 395.10974, F.S., as a risk manager.

## Conforming amendments:

- Section 31 repeals s. 395.10971, F.S., which provides Legislative findings and intent with respect to the health care risk manager program.
- Section 32 repeals s. 395.10972, F.S., which establishes a health care risk manager advisory council within the agency. There are no current council members and have been no council

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<sup>9</sup> These areas include: applicable standards of health care risk management; applicable federal, state, and local health and safety laws and rules; general risk management administration; patient care; medical care; personal and social care; accident prevention; departmental organization and management; community interrelationships; and medical terminology. *See* s. 395.10974(1), F.S.

meetings for at least 10 years. In addition, the statute contains no defined role or responsibilities for the council.<sup>10</sup>

- Section 33 amends s. 395.10973, F.S., to remove the agency's rulemaking authority for licensure standards, determination of qualification, and licensure of a health care risk manager.
- Section 35 repeals s. 395.10975, F.S., relating to grounds for denial, suspension, or revocation of a health care risk manager's license.
- Section 63 amends s. 408.802, F.S., to delete health care risk managers from regulation under part II of ch. 408, F.S.
- Section 69 amends s. 408.820, F.S., to delete specified exemptions applicable to the regulation of health care risk managers.
- Sections 89 and 112 amend ss. 458.307 and 641.55, F.S., to remove reference to the licensure requirement for a health care risk manager.

Section 29 repeals s. 395.1046, F.S., relating to the complaint investigation procedures for alleged violation of the emergency access to care provisions found in s. 395.1041, F.S. The state's emergency access to care provisions are similar to the federal Emergency Medical Treatment and Labor Act, commonly known as EMTALA.<sup>11</sup> The agency enforces the emergency access to care requirements through the uniform complaint investigation procedure used for all license types and these complaints are given top priority. Section 395.1046, F.S., duplicates the complaint investigation procedures found in the general licensing provisions in part II of ch. 408, F.S. Also, s. 395.1046, F.S., provides confidentiality protections and a public records exemption for the results in the investigation report, that the agency proposes is an unnecessary level of confidentiality.<sup>12</sup>

Section 30 amends s. 395.1055, F.S., to require the agency to adopt rules to ensure that all hospitals providing pediatric cardiac catheterization, pediatric open-heart surgery, organ transplantation, neonatal intensive care services, psychiatric services, or comprehensive medical rehabilitation meet the minimum licensure requirements adopted by the agency. The licensure requirement shall include quality of care, nurse staffing, physician staffing, physical plant, equipment, emergency transportation, and data reporting standards. The agency indicates that adopted rules for all these procedures may take some time due to the interaction of various stakeholders.<sup>13</sup> The CON process includes standards; however, these conditions are not required to be met for continued licensure.<sup>14</sup>

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<sup>10</sup> *Supra* n. 6, p. 4.

<sup>11</sup> EMTALA, also known as the patient antidumping statute, was passed in 1986 as part of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA), Public Law 99-272. Section 1867 of the Act sets forth requirements for medical screening examinations for individuals who come to the emergency department of a hospital and request examination or treatment for an emergency medical condition, regardless of ability to pay. The statute further provides that, if a hospital finds that such an individual has an emergency medical condition, it is obligated to provide that individual with either necessary stabilizing treatment or an appropriate transfer to another medical facility. *See* the CMS.gov website at: <https://www.cms.gov/Regulations-and-Guidance/Legislation/EMTALA/index.html> (last visited March 18, 2017).

<sup>12</sup> *Supra* n. 6, p. 3.

<sup>13</sup> *Supra* note 6, p. 4.

<sup>14</sup> *Id.*

The bill also requires the agency to adopt rules relating to the care and treatment of patients residing in distinct part nursing units of hospitals. The agency is directed to consider the types of patients treated, typical patient acuity levels, and the average length of stay in such units in rulemaking, and to require level 2 background screening for personnel of distinct part nursing units. Hospital based skilled nursing units are state licensed under the hospital but federally certified as skilled nursing unit beds. These units are inspected under the same federal criteria as a nursing home. Currently, there are nine hospitals with skilled nursing units. These units range in size from 23-113 beds.<sup>15</sup> Hospital licensure regulations do not specifically address these units.

Section 36 amends s. 395.602, F.S., relating to rural hospitals, to remove the definitions of “emergency care hospital,” “essential access community hospital,” “inactive rural hospital bed,” and “rural primary care hospital.” These definitions relate to obsolete rural hospital programs that are no longer available or applicable to rural hospitals. Hospitals are authorized to make changes to their bed inventory at will so there is no longer a need to maintain an inventory of inactive rural hospital beds for CON purposes.<sup>16</sup>

Conforming amendments:

- Section 9 amends s. 381.0405, F.S., to remove reference to the Essential Access Community Hospital Program from the responsibilities of the Office of Rural Health within the DOH.
- Section 37 amends s. 395.603, F.S., to remove provisions relating to the deactivation of general hospital beds in order to seek licensure for programs that are now obsolete.
- Section 38 repeals s. 395.604, F.S., relating to licensing hospitals for these obsolete programs.
- Section 39 repeals s. 395.605, F.S., relating to licensing emergency care hospitals which is now an obsolete program.
- Section 122 amends s. 1009.65, F.S., to conform a cross-reference to the renumbered definitions in s. 395.602, F.S.

Section 40 amends s. 395.701, F.S., relating to hospital assessments on inpatient and outpatient services. Current law excludes hospitals operated by the agency or the DOC. The bill expands the exclusion to any hospital operated by a state agency, to specifically exclude hospitals operated by the Department of Children and Families.<sup>17</sup> Section 61 amends s. 408.20, F.S., relating to assessments in the Health Care Trust Fund, to conform the exemption for hospitals operated by a state agency.

### **Home Health Agencies**

Section 43 amends s. 400.464, F.S., to require any license issued after July 1, 2017, to specify the home health services that the organization is authorized to perform and indicate whether each service is considered skilled care. In addition, providing or advertising services that require licensure and which are not specified on the face of the license issued after July 1, 2017, constitutes prohibited unlicensed activity.

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<sup>15</sup> Email from AHCA staff dated March 27, 2017, on file with the Senate Health Policy Committee.

<sup>16</sup> *Supra* note 6, p. 4.

<sup>17</sup> *Id.*

The bill authorizes a voluntary process for applying for a certificate of exemption from licensure for a person providing home health services who is exempt from licensure as a home health agency. The agency may charge a fee of \$100 or the actual cost of processing this certificate.

Conforming amendment:

Section 48 amends s. 400.497, F.S., relating to agency rulemaking to include applications for certificates of exemption from licensure.

Section 44 amends s. 400.471, F.S., to require application for a change of ownership or for the addition of skilled services. Applicants for license renewal no longer need to provide volume data. Under the bill, evidence of contingency funding refers to the general licensing provisions in part II of ch. 408, F.S., to eliminate an inconsistency between the two chapters. Under current law, a home health agency that is not Medicare or Medicaid certified and does not provide skilled care is exempt from providing proof of accreditation. This bill provides the exemption only if the home health agency does not provide skilled care. The bill further clarifies that the accrediting organization must be recognized by the agency, the survey must demonstrate compliance with Florida laws pertaining to home health agencies, and accreditation must be continuously maintained.

Section 44 and 45 amend ss. 400.471 and 400.474, F.S., respectively, to clarify that a licensed home health agency must provide the services specified in the written agreement with the patient except in emergency situations that are beyond the provider's control that make it impossible to provide the services.

Section 46 amends s. 400.476, F.S., to require a home health agency that provides skilled nursing care to have a director of nursing. Current law exempts a home health agency from this requirement if it is Medicare or Medicaid certified or provides only physical, occupational, or speech therapy. This exemption is repealed.

Section 47 amends s. 400.484, F.S., renaming deficiencies as violations with respect to providing care by home health agencies and tying these violations to the general licensing provisions for health care facilities in part II of ch. 408, F.S.

### **Nurse Registries**

Section 49 amends s. 400.506, F.S., to remove a grace period of 10-working days after notification from the agency that licensure is required, for an unlicensed nurse registry to cease operating to avoid committing a misdemeanor of the second degree. Under the bill, the unlicensed nurse registry must cease operations immediately. The agency is authorized to impose a fine of \$1,000 per day in accordance with s. 408.812, F.S., in the general licensing provisions pertaining to unlicensed activity, rather than the \$500 fine specified in this statute specifically relating to nurse registries.

In addition, this section of the bill removes the prohibitions on a nurse registry providing remuneration to a case manager, discharge planner, facility based staff member, third party vendor, physician, member of the physician's office staff, or an immediate family member of a physician for referrals. Current law already exempts nurse registries from this prohibition if they

do not bill Medicare or Medicaid or share a controlling interest with any entity that bills Medicare or Medicaid.

### **Assisted Living Facilities (ALF)**

Section 74 amends s. 429.02, F.S., to make technical revisions to the definition of personal services.

Section 75 amends s. 429.04, F.S., relating to exemptions from licensure to clarify and expand the exemptions to include a licensed hospital, nursing home, inpatient hospice, home for special services,<sup>18</sup> intermediate care facility, or transitional living facility. Additionally, the bill assigns the burden of providing documentation substantiating an exemption to the person or entity asserting an exemption in response to an agency investigation of unlicensed activity.

A current exemption from licensure includes any person who provides housing, meals, or one or more personal services on a 24-hour basis in the person's own home to not more than two adults who do not receive optional state supplementation. The bill specifies that in addition to owning or renting the home, the person who provides these services must have established the home as the person's permanent residence. If the person holds a homestead exemption at a different address, a presumption exists that the person has not established permanent residence as required by this section. Furthermore, the bill provides that the exemption does not apply to a person or entity who previously held a license issued by the agency and such license was revoked or licensure renewal was denied by final order, or when the license was voluntarily relinquished during agency enforcement proceedings.

Section 76 amends s. 429.08, F.S., relating to unlicensed facilities to clarify and create a felony of the third degree penalty for renting or otherwise maintaining a building or property that operates or maintains an unlicensed ALF. Similarly, this section now provides that any person who owns, operates, or maintains an unlicensed ALF after receiving notice from the agency that licensure is required and to cease such operation commits a felony of the third degree. Current law provides a six-month window after a statutory or rule change takes place if the change placed the person in the position of violating this provision before the violation occurs. The bill repeals this six-month grace period.

Section 78 amends s. 429.176, F.S., to prohibit an ALF from operating for more than 120 consecutive days without an administrator who has completed the core educational requirements.

Section 79 amends s. 429.24, F.S., relating to contracts with residents, to exempt the addition of a new service or accommodation to a resident's contract for which the resident was not previously charged, from the 30-day written notice of a rate increase.

Section 80 amends s. 429.256, F.S., to require as a part of the facility's assistance with the self-administration of medication that the name, medication, and dosage indicated on the label of the medication be read aloud in the presence of the resident.

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<sup>18</sup> Homes for special services is defined in s. 400.801, F.S., as a site licensed by the agency prior to January 1, 2006, where specialized health care services are provided, including personal and custodial care, but not continuous nursing services.

Section 81 amends s. 429.28, F.S., relating to the resident bill of rights, to clarify that the resident has the right to “assistance with obtaining” access to adequate and appropriate health care, which is defined in the bill to include the management of medications, assistance in making appointments, providing or arranging for transportation, and the performance of health care services in accordance with provisions set forth in s. 429.255, F.S.

Provisions in s. 429.28, F.S., requiring the agency to conduct monitoring visits and complaint investigations are deleted from this section. Authority to conduct these monitoring visits and inspections are moved to s. 429.34, F.S. Section 77 amends s. 429.19, F.S., relating to imposition of administrative fines, to delete a reference to monitoring visits conducted under s. 429.28, F.S., to conform to the changes made to this section of law.

Section 82 amends s. 429.294, F.S., to remove the requirement that resident records be provided within 10 days in accordance with s. 400.145, F.S. This eliminates a conflict because s. 400.145, F.S., requires records to be provided to a current resident within 14 working days of the request and to a former resident within 30 days of a request.

Section 83 amends s. 429.34, F.S., to remove the requirement that the agency conduct an inspection of each licensed ALF at least every 24 months. Section 408.811(1)(b), F.S., requires relicensure inspections biennially. The provision authorizing the agency to conduct at least one monitoring visit of each facility cited in the previous year for a class I or class II violation, or more than three uncorrected class III violations in any calendar year in which a survey is not conducted, is moved into this section from s. 429.28, F.S.

Section 84 amends s. 429.52, F.S., to require a new facility administrator to complete all required training, education, and competency tests within 90 days of the date of employment. Current law requires completion of those requirements within a reasonable time after being employed, as determined by the department.

### **Multiphasic Health Testing Centers**

Section 93 amends s. 483.294, F.S., to remove the requirement that a multiphasic health testing center be inspected at least annually. Inspections are to be done in accordance with s. 408.811, F.S., which provides that inspections for relicensure shall occur biennially; however, an inspection may be performed at any time as needed. The general licensing provisions in part II of ch. 408, F.S., allow for accreditation inspections to be accepted in lieu of a full licensure inspection.

### **Health Care Clinic Certificate of Exemption**

Section 56 amends s. 400.9935, F.S., to establish a 2-year expiration for a certificate of exemption from licensure issued to a person or entity providing health care services which does not meet the definition of a clinic for which licensure is required. Obtaining a certificate of exemption is voluntary.

A clinic is defined in s. 400.9905, F.S., for purposes of licensure and regulation under part X of ch. 400, F.S., as an entity where health care services are provided to individuals and which tenders charges for reimbursement for such services, including a mobile clinic and a portable equipment provider. However, 14 exemptions to this definition exist. Examples include: entities and various ownership configurations of entities otherwise licensed or registered by the state and providing only health care services within the scope of services authorized under their licenses; entities that are wholly owned by one or more licensed health care practitioners and their immediate family members; clinical facilities affiliated with an accredited medical school; certain publicly traded corporations; and other entities meeting certain sales, revenue, or staffing criteria.<sup>19</sup>

### **Amendments referencing General Licensing Provisions and Technical Amendments**

#### ***Hospices***

Section 50 amends s. 400.606, F.S., to remove the required submission of certain financial information at licensure renewal. This requirement conflicts with submission requirements in the general licensure requirements in part II of ch. 408, F.S.

#### ***Home Medical Equipment Providers***

Section 51 is a technical amendment to s. 400.925, F.S., to move wheelchairs and related seating and positioning devices to a separate paragraph within the definition of home medical equipment.

Section 52 amends s. 400.931, F.S., to require a licensed home medical equipment provider to notify the agency of a change in the general manager within the timeframes established in part II of ch. 408, F.S., which is 21 days, rather than the 45-day timeframe provided in this section of law.

Section 53 is a technical amendment to s. 400.933, F.S., correcting the name of the state agency that issues medical oxygen retail establishment permits. It is now the Department of Business and Professional Regulation.

#### ***Health Care Service Pools***

Section 54 amends s. 400.980, F.S., to require changes of information contained on the original registration application to be submitted to the agency within the timeframes established in part II of ch. 408, F.S., rather than 14 days prior to the change as required in this section of law.

#### ***General Licensing Provisions***

Section 64 amends s. 408.803, F.S., to define the term “relative.”

Section 65 amends s. 408.806, F.S., relating to the license application process, to authorize a licensee that holds a license for multiple providers licensed by the agency to request alignment of

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<sup>19</sup> See s. 400.9905(4)(a)-(n), F.S. However, notwithstanding these exemptions, most entities that receive reimbursement under the Florida Motor Vehicle No-Fault Law are deemed clinics and must be licensed and subject to regulation under this part.

all license expiration dates. In order to accomplish this, the agency is authorized to issue a license for an abbreviated licensure period with a prorated licensure fee.

Section 66 amends s. 408.809, F.S., relating to background screening requirements, to impose background screening requirements on any person who is a controlling interest, regardless of whether the agency has reason to believe the person has been convicted of certain offenses, and on persons contracting with a licensee for 20 or more hours per week who will have access to client funds, personal property, or living areas.

Section 67 amends s. 408.810, F.S., to exempt an applicant for a change of ownership from submitting proof of financial ability to operate if the provider has been licensed for at least five years and the change is the result of a corporate reorganization under which the controlling interest is unchanged or solely due to the death of a controlling interest, and the surviving controlling interests continue to hold at least 51 percent of the ownership.

The agency is authorized to adopt rules to address the circumstances under which a controlling interest, an administrator, an employee, a contractor, or a representative thereof who is not a relative of the patient or client may act as a legal representative, agent, health care surrogate, power of attorney, or guardian of a patient or client. According to the agency, licensure regulations are currently inconsistent in this area. Due to the vulnerability of persons receiving health or custodial care, allowing the paid caregiver to control finances or health care decisions of the patient can result in exploitation or abuse. In some cases, the facility has a surety bond, but this is not required for all provider types.<sup>20</sup>

The bill also amends s. 408.810(12), F.S., to prohibit ownership by a persons who has a disqualifying offense pursuant to s. 408.809, F.S. Section 408.809, F.S., requires level 2 background screening on certain persons and if the results trigger the disqualifying offenses listed in s. 435.04, F.S., and the person does not meet an exemption from disqualification, then the person may not own a facility. This subsection also prohibits ownership by someone that has had a license revoked for false representations; intentional or negligent acts affecting a client; demonstrating a pattern of deficient performance; or being excluded, suspended, or terminated from participation in any state's Medicaid program or Medicare.

Section 408.810(13), F.S., is added to recognize that publicly traded corporations on national exchanges may be full or partial owners of health care facilities. It allows the corporation to own a facility by exempting shareholders from the requirement for background screening if the shareholder's only relationship to the corporation is as a shareholder.

Section 68 amends s. 408.812, F.S., relating to unlicensed activity to pronounce that unlicensed activity constitutes abuse and neglect, as defined in s. 415.102, F.S.<sup>21</sup> The bill removes the requirement that a person or entity must apply for a license after receiving notification from the

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<sup>20</sup> *Supra* note 6, pp. 6-7.

<sup>21</sup> In summary, s. 415.102, F.S., defines "abuse" as any willful act or threatened act by a relative, caregiver, or household member which causes or is likely to cause significant impairment to a vulnerable adult's physical, mental, or emotional health; and that abuse includes acts and omissions. "Neglect" is defined as the failure or omission on the part of the caregiver or vulnerable adult to provide the care, supervision, and services necessary to maintain the physical and mental health of the vulnerable adult. Refer to s. 415.102(16), F.S., for additional acts that constitute neglect.

agency that the person or entity is engaging in unlicensed activity. If a controlling interest or licensee has more than one provider and fails to license all providers that require licensure, the agency may impose a fine, regardless of correction, as one of the authorized sanctions.

### **Subscriber Assistance Program**

Section 62 of the bill repeals s. 408.7056, F.S., relating to the subscriber assistance program.

The subscriber assistance panel (SAP) was created in 1985 to assist members of managed care entities whose grievances or appeals were not satisfactorily resolved by the managed care entity upon exhaustion of the managed care entity's internal grievance and appeal process. Under the federal Patient Protection and Affordable Care Act (PPACA),<sup>22</sup> managed care entities were given an option to either comply with the state's external review requirement or opt-out and participate in the federal external review program. The majority of health plans in Florida elected to use the federal program and the SAP program experienced a significant decrease in the number of cases being reviewed by the panel.<sup>23</sup>

The SAP is currently available to members of managed care entities with coverage by: Statewide Medicaid Managed Care, Healthy Kids, Prepaid Health Clinics, or grandfathered policies<sup>24</sup> that have not elected to have all of their health insurance policies subject to an external review process by independent review organization(s). Medicaid recipients in managed care can file for an external review through a Medicaid Fair Hearing and members with grandfathered commercial policies may appeal through independent review organizations.<sup>25</sup>

Repeal of the SAP eliminates this program as an external appeal option for members in Healthy Kids and Prepaid Health Clinics, although according to the agency, no Prepaid Health Clinic members have used the SAP. At this time, these members do not have another avenue in which to file an external appeal.<sup>26</sup>

Conforming amendments:

- Sections 3, 4, 5, 109, and 111 amend ss. 220.1845, 376.30781, 376.86, 641.51, and 641.515, F.S., respectively, to strike a cross-reference to s. 408.7056, F.S., to conform those provisions to repeal of the subscriber assistance program.

<sup>22</sup> Pub. Law No. 111-148 (Mar. 23, 2010) amended by Pub. Law. No. 111-152 (Mar. 30, 2010).

<sup>23</sup> According to the agency, between FY 2011-2012 and FY 2012-2013, when the majority of plans opted to use the federal external review program, the number of cases received by the SAP dropped from 415 to 213. The number of cases heard by the SAP dropped from 74 to 17. There has been an uptick in both number of cases received by the subscriber assistance program and the number of cases heard by the panel for FY 2014-2015 and FY 2015-2016, with the latest full year of data showing 350 cases received and 53 cases heard. The predominant outcome of the cases in FY 2015-2016 was a determination of non-jurisdiction (#221), followed by submission of an incomplete application (#31) and found in favor of the subscriber (#27). See the chart prepared by the agency for activity since FY 2009-2010 at *supra* note 4, p. 7.

<sup>24</sup> A grandfathered health plan is a plan that existed on March 23, 2010, the date that the PPACA was enacted, and that at least one person had been continuously covered for 1 year. Plans or policies may lose their "grandfathered" status if they make certain significant changes that reduce benefits or increase costs to consumers. See Healthcare.gov, *Grandfathered Health Plans*, <https://www.healthcare.gov/glossary/grandfathered-health-plan/> (last visited Mar. 23, 2017).

<sup>25</sup> *Supra* note 6, p. 7.

<sup>26</sup> *Id.*

- Sections 100, 103, and 83 amend ss. 627.602, 627.6513, and 641.312, F.S., respectively, to delete an exemption for a health insurance policy, group health insurance policy, and health maintenance organization (HMO) contract that is subject to the subscriber assistance program.
- Section 105 amends s. 641.185, F.S., to remove a principle concerning regulatory oversight by various state entities relating to an HMO's expedited review of unresolved grievances pursuant to the subscriber assistance program.
- Section 108 amends s. 641.3154, F.S., to remove reference to an action after a recommendation is made by the SAP.
- Section 110 amends s. 641.511, F.S., relating to HMOs, to remove notice requirements to subscribers regarding the subscriber assistance program and authorizations for a subscriber to submit a grievance to the subscriber assistance program. The bill maintains the requirement that an HMO have a grievance procedure available to its subscribers for the purpose of addressing complaints and grievance and broad requirements concerning notice to subscribers, but deletes detailed procedures an HMO must follow concerning the HMO's internal grievance procedure.

### **Managed Care Ombudsman Committees**

The Statewide Managed Care Ombudsman Committee (statewide committee) and the district managed care ombudsman committees (district committees) were established in 1996.<sup>27</sup> The statewide committee is created within the agency as a consumer protection and advocacy organization on behalf of managed care subscribers. The statewide committee has administrative authority over the district committees and consists of the chairpersons of the district committees.

A district committee is created in s. 641.65, F.S., in each district of the agency that has staff assigned for the regulation of managed care programs. Each district committee must have no fewer than nine members or more than 16 members, including at least four physicians, one licensed under chs. 458, 459, 460, and 461; one psychologist; one registered nurse; one clinical social worker; one attorney; and one consumer.<sup>28</sup>

According to the agency, due to the very stringent committee composition requirements, the majority of districts could not form district committees. The first committee was established in 1999 and only three other districts were able to meet committee requirements. The last activity on record was in 2010 and there are currently no active committees.<sup>29</sup>

Sections 113 and 114 repeal ss. 641.60, and 641.65 F.S., respectively, which authorize the Statewide Managed Care Ombudsman Council and the district managed care ombudsman committees.

Conforming changes:

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<sup>27</sup> Chapter 96-391, L.O.F.

<sup>28</sup> Section 641.65(2), F.S.

<sup>29</sup> *Supra* note 6, p. 8.

- Sections 115, 116, 117, and 118 repeal ss. 641.67, 641.68, 641.70, and 641.75, F.S., respectively, to remove all references to the statewide Managed Care Ombudsman Council and the district managed care ombudsman committees.

### **Designated Facilities/Public Health Trust**

Chapter 73-102, Laws of Florida, authorized the governing body of each county to create a public health trust in and for the county. The purpose of a public health trust is to exercise supervisory control over the operation, maintenance, and governance of 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>30</sup>

A public health trust's board of trustees, appointed by the governing body of the county, is responsible for the operation, governance, and management of a publicly funded health care facility designated by the county's governing body.<sup>31</sup>

Specifically, the board of trustees is empowered to:<sup>32</sup>

- 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. 1973];
- Sue and be sued;
- Have a seal;
- Adopt bylaws, rules, and regulations for the board's responsibilities;
- Execute contracts;
- Acquire and hold title to real or personal property;
- Appoint and remove a chief executive officer of the trust;
- Establish and collect fees for using or receiving services from the facility;
- Accept gifts of money, services, or real or personal property;
- Appoint, remove, or suspend employees or agents of the board, fix their compensation, and adopt personnel and management policies;
- Provide for employee benefits;
- Cooperate with and contract with any governmental agency or instrumentality, federal, state, municipal, or county;
- Adopt rules and regulations for the management and use of any properties under its control;
- Appoint originally the staff of physicians to practice in a designated facility and approve bylaws and rules to be adopted by the medical staff addressing the method of appointing or removing additional staff members; and
- Employ certified public accountants and legal counsel.

<sup>30</sup> Section 154.08, F.S. Designated facilities include: 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.

<sup>31</sup> See Part II of Chapter 154, Florida Statutes.

<sup>32</sup> Section 154.11(1), F.S. However, note that a public health trust may not impose any tax, issue bonds, or require the imposition of a tax or the issuance of any bond by the governing body of the county. Section 154.11(2), F.S.

A Public Health Trust was created in 1973 by the Miami-Dade<sup>33</sup> Board of County Commissioners as an independent governing body for Jackson Memorial Hospital. In 2003, the Board of County Commissioners amended the Miami-Dade County Code to expand the responsibilities of the Public Health Trust countywide to health care facilities within the Jackson Health System. The Trust is composed of volunteer citizens who set policies that assure that the Jackson Health System is responsive to community needs. This “citizen body” provides leadership for joint planning between Jackson Health System, the University of Miami’s Miller School of Medicine, Miami-Dade County, and other private and community organizations.<sup>34</sup> Miami-Dade County is the only county to have created a Public Health Trust.<sup>35</sup>

Section 2 creates s. 154.13, F.S., to assign the exclusive jurisdiction of a designated facility owned or operated by a public health trust to the county creating it, excluding it from a municipality’s jurisdiction. Among other things, this will eliminate duplication and overlap of regulatory oversight such as permitting requirements and reduce regulatory fee impacts.

### **Obsolete and Miscellaneous Provisions**

Section 17 repeals s. 383.335, F.S., to remove a birth center exemption to licensure for certain providers that existed over 30 years ago. Currently no providers meet this exemption.<sup>36</sup>

Conforming Amendment:

- Sections 10, 11, 12, 13, 14, 16, 55, 101, 104, and 106 amend ss. 383.30, 383.301, 383.302, 383.305, 383.309, 383.33, 400.9905, 627.6406, 627.6574, and 641.31, F.S., respectively, to conform the cross-reference to statutes affecting birth centers.

Section 59 amends s. 408.061, F.S., relating to data collection by the agency from health care facilities, to conform cross-references and to exclude hospitals operated by state agencies from the requirement to submit certain financial reports.

Section 71 amends s. 409.907, F.S., relating to Medicaid provider agreements, to remove certain disqualifying conditions for eligibility as a Medicaid provider. These provisions are moved into s. 435.04, F.S., relating to level 2 screening standards, specifically applicable to screening to participate in the Medicaid program. A person being screened for participation in the Medicaid program may not have been arrested for and is awaiting final disposition of; has not been found guilty of, regardless of adjudication, or entered a plea of nolo contendere or guilty to; and has not been adjudicated delinquent and the record sealed or expunged for those offenses moved from s. 409.907, F.S., or additional violations relating to:

- Criminal use of a public record or information in a public record;
- Unlawful compensation or reward for official behavior;
- Corruption by threat against a public servant;
- Official misconduct;
- Bid tampering;

<sup>33</sup> In 1973, the county was named Dade County.

<sup>34</sup> See Jackson Health System, *Public Health Trust*, <http://www.jacksonhealth.org/trust.asp>, (Last visited April 14, 2017).

<sup>35</sup> Email from AHCA staff, dated April 14, 2017, on file with the Senate Health Policy Committee.

<sup>36</sup> *Supra* note 6, p. 10.

- Falsifying records; or
- Misuse of confidential information.

Section 85 also amends s. 435.04, F.S., to add that level 2 screening under this section must ensure that no person subject to this section has been arrested for and is awaiting final disposition of any offense that constitutes domestic violence.

Section 86 amends s. 435.12, F.S. relating to the Care Provider Background Screening Clearinghouse, to authorize the extension of the screening renewal period for a person who passed a level 2 screening under s. 435.04, F.S., after December 31, 2012 until January 1, 2020, or until the Department of Law Enforcement (FDLE) begins participation in the national retained print arrest notification program before that date. The FDLE is authorized to retain fingerprints for this same period.

The effective date of the bill is July 1, 2017.

#### **IV. Constitutional Issues:**

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

#### **V. Fiscal Impact Statement:**

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Repealing the licensure requirement for health care risk managers will save each risk manager the cost of the licensure fee, which is \$104.54 for initial applicants and \$52.78 for renewal applicants.<sup>37</sup>

Repealing clinical laboratory licensure, will save each clinical laboratory that was required to be licensed and is accredited \$100 biennially. If not accredited the fee is

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<sup>37</sup> See the Application checklist available at:

[http://ahca.myflorida.com/MCHO/Health\\_Facility\\_Regulation/Hospital\\_Outpatient/risk\\_manager.shtml](http://ahca.myflorida.com/MCHO/Health_Facility_Regulation/Hospital_Outpatient/risk_manager.shtml) (last visited Mar. 24, 2017).

between \$400 - \$3,919 biennially, depending upon the annual volume of non-waived tests performed.<sup>38</sup>

Representatives of assisted living facilities have indicated that requiring staff to read aloud information on the label of medication each time medication is provided to residents as a part of assisting in the self-administration of medication, will be time-consuming and could negatively impact the cost of care and operations if additional staff is needed to comply with this new requirement. No specific fiscal impact has been reported, but would likely vary significantly depending upon the number of residents in a facility and the number and frequency of medications each resident receives.

**C. Government Sector Impact:**

This bill is expected to reduce revenues by \$1,383,400 per year related to risk manager application fees, approximately \$64,866 per year for laboratory licensure application and associated biennial assessment fees. The total reduction of revenue is approximately \$1,448,266 annually.

**VI. Technical Deficiencies:**

None.

**VII. Related Issues:**

None.

**VIII. Statutes Affected:**

This bill substantially amends the following sections of the Florida Statutes: 20.43, 220.1845, 376.30781, 376.86, 381.0031, 381.0034, 381.004, 381.0405, 381.30, 383.301, 383.302, 383.305, 383.309, 383.313, 384.31, 383.33, 385.211, 394.4787, 395.001, 395.002, 395.003, 395.009, 395.0161, 395.0163, 395.0197, 395.1055, 395.10973, 395.602, 395.603, 395.701, 395.7015, 400.0625, 400.464, 400.471, 400.474, 400.476, 400.484, 400.497, 400.506, 400.606, 400.925, 400.931, 400.933, 400.9935, 400.980, 400.9905, 408.033, 408.036, 408.061, 408.07, 408.20, 408.802, 408.803, 408.806, 408.809, 408.810, 408.812, 408.820, 409.905, 409.907, 409.9116, 409.975, 429.02, 429.04, 429.08, 429.176, 429.19, 429.24, 429.256, 429.28, 429.294, 429.34, 429.52, 435.04, 435.12, 456.001, 456.057, 458.307, 458.345, 459.021, 483.294, 483.801, 483.803, 483.813, 483.823, 491.003, 627.351, 627.602, 627.6406, 627.64194, 627.6513, 627.6574, 641.185, 641.31, 641.312, 641.3154, 641.51, 641.511, 641.515, 641.55, 766.118, 766.202, 945.36, 1009.65, and 1011.52.

This bill creates the following sections of the Florida Statutes: 154.13 and 395.0091.

<sup>38</sup> See AHCA Clinical laboratory fees, available at: [http://ahca.myflorida.com/MCHQ/Health\\_Facility\\_Regulation/Laboratory\\_Licensure/fees.shtml](http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Laboratory_Licensure/fees.shtml) (last visited Mar. 24, 2017).

This bill repeals the following sections of the Florida Statutes: 383.335, 395.1046, 395.10971, 395.10972, 395.10974, 395.10975, 395.604, 395.605, 408.7056, 483.011, 483.021, 483.031, 483.035, 483.041, 483.051, 483.061, 483.091, 483.101, 483.111, 483.172, 483.181, 483.191, 483.201, 483.221, 483.23, 483.245, 483.26, 641.60, 641.65, 641.67, 641.68, 641.70, and 641.75.

## IX. Additional Information:

### A. Committee Substitute – Statement of Substantial Changes:

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

#### **Recommended PCS by Appropriations Subcommittee on Health and Human Services on April 18, 2017:**

The substantive differences in the CS:

- Reinstates the Board of Clinical Laboratory Personnel under the organizational structure of the DOH Division of Medical Quality Assurance in s. 20.43.
- Provide that a designated facility owned or operated by a public health trust is under the exclusive jurisdiction of the county creating it and is not within, or subject to, the jurisdiction of the municipality.
- Expressly require all laboratory services performed by a birthing center to comply with and maintain CLIA certification requirements.
- Require the agency to adopt rules for the care and treatment of patients residing in distinct part nursing units of hospitals.
- Conform the requirement that laboratory services for nursing homes must be performed by a laboratory certified under the CLIA certification requirements.
- Revise the date by which licenses issued to a home health agency must specify whether services provided are skilled care to July 1, 2017, rather than June 30, 2017.
- Remove the new provisions relating to the status of personnel referred by a nurse registry.
- Move a new provision requiring a licensee to ensure that any person with an ownership interest in a licensee does not meet certain conditions to address a technical deficiency with the placement of the provision in the bill as filed.
- Impose background screening requirements on any person who is a controlling interest, regardless of whether the agency has reason to believe the person has been convicted of certain offenses, and on persons contracting with a licensee for 20 or more hours per week who will have access to client funds, personal property, or living areas.
- Allow a corporation that is traded on a national stock exchange to own a facility by exempting persons who are merely shareholders from the background screening requirements.
- Move disqualifying conditions of a Medicaid provider to another provision of law.
- Add numerous revisions to the regulation of ALFs, including but not limited to: resident contract revisions, reading the medication label aloud when assisting a resident with the self-administration of medication, clarifying certain provisions within the resident bill of rights, conducting monitoring visits, and eliminating a conflict in the timeframe for providing resident records.
- Revise and enhance level 2 background screening for participation in the Medicaid program.

- Extend the background screening renewal period for certain persons screened after December 31, 2012, until January 1, 2020, or until the FDLE participates in the national retained print arrest notification program.
- Exempt from the regulation of clinical laboratory personnel under part II (renumbered in this bill) for persons performing testing within a physician's office for patients in a group practice if the laboratory is under common ownership with an hospital or ASC.
- Reinstate the requirement for the HMO to maintain records of all grievances and report annually to the agency the total number of grievances handled, a categorization of the cases underlying the grievance, and the final disposition of the grievances.
- Repeal the district managed care ombudsman committees.
- Require the Department of Corrections to develop a procedure to certify certain law enforcement personnel to perform urine screen drug tests.
- Remove the January 1, 2018, effective date for certain provisions; all provisions in the bill are effective July 1, 2017.

B. Amendments:

None.