

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1195 Health Care Facility Regulation
SPONSOR(S): Miller and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 1760

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee	12 Y, 0 N	Roth	Poche
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

HB 1195 amends various authorizing and licensing statutes for entities regulated by the Agency for Health Care Administration (AHCA). The bill clarifies existing licensure and enforcement requirements, amends certain provisions to eliminate conflict among licensure statutes in Part I of Chapter 395, F.S., Chapter 400, F.S., and Part II of Chapter 408, F.S., increases administrative efficiency at AHCA, and repeals redundant or obsolete statutes. Specifically, the bill:

- Repeals Part I of ch. 483, F.S. regulating clinical laboratories. Clinical laboratories that perform testing on specimens derived from within Florida will no longer be required to obtain state licensure. Clinical laboratories will continue to be certified by the federal Clinical Laboratory Improvement Amendments program.
- Repeals the health care risk manager licensure requirements and the Health Care Risk Manager Advisory Council.
- Addresses unlicensed assisted living facilities (ALF) by strengthening the enforcement capabilities of AHCA. The statutory changes help protect residents of ALFs, and individuals seeking care in an ALF.
- Repeals the Subscriber Assistance Program, which resolves disputes between health maintenance organizations and subscribers. Subscribers have several other options in state and federal law to resolve such disputes.
- Eliminates the mobile surgical facility license. To date, no license has been issued for a mobile surgical facility.
- Repeals obsolete special designations of rural hospitals.
- Eliminates conflict between part II of chapter 408, F.S., and home health agency licensure statutes.
- Protects vulnerable adults receiving health or custodial care by deeming unlicensed activity as abuse and neglect for purpose of triggering adult protective services under chapter 415, F.S.
- Repeals the Statewide Managed Care Ombudsman Committee. The last activity on record was in 2010, and there are currently no active committees.
- Eliminates the special procedures for investigating emergency access complaints against hospitals, allowing AHCA to use existing hospital complaint investigation procedures used for all other types of complaints.
- Repeals an exemption to licensure for any facility that was providing obstetrical and gynecological surgical services and was owned and operated by a board-certified obstetrician on June 15, 1984. There are currently no providers who meet the definition.
- Removes broad language that prevents nurse registries from marketing their services.
- Makes necessary conforming changes throughout the statutes to reflect the changes proposed in the bill.

The bill has a significant, negative fiscal impact on AHCA. Please see Section II.A. for more information.

Except where expressly provided otherwise, the bill has an effective date of July 1, 2017.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Agency for Health Care Administration – Division of Health Quality Assurance

The Division of Health Quality Assurance (HQA), housed within the Agency for Health Care Administration (AHCA), licenses, certifies, and regulates 40 different types of health care providers. In total, HQA regulates more than 42,000 individual providers.¹ Regulated providers include:

- Laboratories performing testing under the Drug-Free Workplace program, pursuant to s. 440.102(9), F.S.
- Birth centers, as provided under chapter 383, F.S.
- Abortion clinics, as provided under chapter 390, F.S.
- Crisis stabilization units, as provided under parts I and IV of chapter 394, F.S.
- Short-term residential treatment facilities, as provided under parts I and IV of chapter 394, F.S.
- Residential treatment facilities, as provided under part IV of chapter 394, F.S.
- Residential treatment centers for children and adolescents, as provided under part IV of chapter 394, F.S.
- Hospitals, as provided under part I of chapter 395, F.S.
- Ambulatory surgical centers, as provided under part I of chapter 395, F.S.
- Mobile surgical facilities, as provided under part I of chapter 395, F.S.
- Health care risk managers, as provided under part I of chapter 395, F.S.
- Nursing homes, as provided under part II of chapter 400, F.S.
- Assisted living facilities, as provided under part I of chapter 429, F.S.
- Home health agencies, as provided under part III of chapter 400, F.S.
- Nurse registries, as provided under part III of chapter 400, F.S.
- Companion services or homemaker services providers, as provided under part III of chapter 400, F.S.
- Adult day care centers, as provided under part III of chapter 429, F.S.
- Hospices, as provided under part IV of chapter 400, F.S.
- Adult family-care homes, as provided under part II of chapter 429, F.S.
- Homes for special services, as provided under part V of chapter 400, F.S.
- Transitional living facilities, as provided under part XI of chapter 400, F.S.
- Prescribed pediatric extended care centers, as provided under part VI of chapter 400, F.S.
- Home medical equipment providers, as provided under part VII of chapter 400, F.S.
- Intermediate care facilities for persons with developmental disabilities, as provided under part VIII of chapter 400, F.S.
- Health care services pools, as provided under part IX of chapter 400, F.S.
- Health care clinics, as provided under part X of chapter 400, F.S.
- Clinical laboratories, as provided under part I of chapter 483, F.S.
- Multiphasic health testing centers, as provided under part II of chapter 483, F.S.
- Organ, tissue, and eye procurement organizations, as provided under part V of chapter 765, F.S.

¹ Agency for Health Care Administration, *Health Quality Assurance*, 2017, available at <http://ahca.myflorida.com/MCHQ/> (last viewed March 8, 2017).

Clinical Laboratories

Background

A clinical laboratory is the physical location in which services are performed to provide information or materials for use in the diagnosis, prevention, or treatment of a disease or the identification or assessment of a medical or physical condition.² Services performed in clinical labs include:

- The examination of fluids or other materials taken from the human body.³
- The examination of tissue taken from the human body.⁴
- The examination of cells from individual tissues or fluid taken from the human body.⁵

Clinical labs are regulated under Part I of ch. 483, F.S. In keeping with federal law and regulations, clinical laboratories must meet appropriate standards.⁶ Such standards include overall standards of performance that comply with the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA), and the federal rules adopted thereunder, for a comprehensive quality assurance program⁷ and standards of performance in the examination of specimens for clinical laboratory proficiency testing programs using external quality control procedures.⁸ AHCA may impose an administrative fine of no more than \$1,000 per violation of any statute or rule.⁹ In determining the penalty to be imposed for a violation, the following factors must be considered:

- The severity of the violation.
- Actions taken by the licensee to correct the violation or to remedy the complaint.
- Any previous violation by the licensee.
- The financial benefit to the licensee of committing or continuing the violation.¹⁰

Clinical Laboratory Improvement Amendments of 1988

The Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing performed on humans in the United States through the CLIA.¹¹ The CLIA program was established to ensure quality laboratory testing. The Division of Laboratory Services, within the Survey and Certification Group, under the Center for Clinical Standards and Quality (CCSQ) in CMS has the responsibility for implementing the CLIA Program.¹² In total, CLIA covers approximately 254,000 laboratory entities.¹³

In October 1993, Florida passed legislation requiring all facilities, including doctor's offices, performing clinical laboratory testing to be licensed.¹⁴ AHCA first adopted rules regulating clinical laboratories in 1994, in what is now Chapter 59A-7, F.A.C. Previously, in September 1992, the federal government required all facilities, including doctor's offices, performing clinical laboratory testing to register with the CLIA program.¹⁵

² S. 483.041, F.S.

³ S. 483.041(2)(a), F.S.

⁴ S. 483.041(2)(b), F.S.

⁵ S. 483.041(2)(c), F.S.

⁶ S. 483.021, F.S.

⁷ S. 483.051(2)(a), F.S.

⁸ S. 483.051(2)(b), F.S.

⁹ S. 483.221(1), F.S.

¹⁰ S. 483.221(2)(a)-(d), F.S.

¹¹ Centers for Medicare & Medicaid Services, *Clinical Laboratory Improvement Amendments (CLIA)*, available at https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/CLIA/10_Categorization_of_Tests.asp (last viewed March 7, 2017).

¹² *Id.*

¹³ *Id.*

¹⁴ Agency for Health Care Administration, *Clinical Laboratory Regulation in Florida*, pg. 2, available at http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Laboratory_Licensure/docs/clin_lab/OverviewBrochure_lab.pdf (last viewed March 7, 2017).

¹⁵ *Id.*

AHCA previously issued two types of clinical laboratory licenses: waived and non-waived.¹⁶ A waived test is a test that CMS has determined qualifies for a certificate of waiver under the CLIA program and associated federal rules.¹⁷ Examples of waived tests include dip stick urinalysis, urine pregnancy tests, and blood glucose.¹⁸ Any laboratory conducting waived tests must have a valid CLIA certificate of waiver.¹⁹

The CLIA program issues four types of certificates:

- Certificate of Waiver – Issued to a laboratory to perform only waived tests.
- Certificate of Provider-Performed Microscopy Procedures (PPMP)²⁰ - Issued to a laboratory in which a physician, midlevel practitioner or dentist performs no tests other than the microscopy procedures. This certificate permits the laboratory to also perform waived tests.
- Certificate of Compliance - Issued to a laboratory after an inspection that finds the laboratory to be in compliance with all applicable CLIA requirements.
- Certificate of Accreditation - Issued to a laboratory on the basis of the laboratory's accreditation by an accreditation organization approved by the Centers for Medicare and Medicaid.²¹

Facilities performing any non-waived clinical laboratory testing or testing using microscopes must obtain a clinical laboratory license before the laboratory is authorized to perform testing.²² In July 2009, the requirement for laboratories that performed waived testing to obtain a state license was repealed. After July 2009, the state issued only the non-waived clinical laboratory license.²³ Rule 59A-7.021, F.A.C., sets out the application process for non-waived state licensure.

Currently, all clinical laboratories performing non-waived testing in Florida must hold both a valid state license and federal CLIA certificate.²⁴

Alternate Site Laboratory Testing

Generally, clinical laboratory testing may be done at a hospital's main or central laboratory or satellite laboratories, which are licensed clinical laboratories established on the same or adjoining grounds of a hospital licensed under Chapter 395. Testing at satellite labs must be done by licensed clinical laboratory personnel. Section 483.051(9), F.S., allows for alternate-site testing, which is any laboratory testing done under the administrative control of a hospital, but performed out of the physical or administrative confines of the hospital's central laboratory. This allows tests to be performed bedside, at a nurse station, in an operating room or the emergency room, or anywhere else under the administrative control of a hospital. Alternate-site testing is regulated under rule 59A-7.034, F.A.C.

¹⁶ Id.

¹⁷ S. 483.041(10), F.S.

¹⁸ Supra, FN 19.

¹⁹ Agency for Health Care Administration, *Waived Laboratories*, available at

http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Laboratory_Licensure/waived_apps.shtml (last viewed March 7, 2017).

²⁰ Center for Surveillance, Epidemiology, and Laboratory Services, *Provider-Performed Microscopy Procedures: A Focus on Quality Practices*, February 2016, available at https://wwwn.cdc.gov/clia/Resources/PPMP/pdf/15_258020-A_Stang_PPMP_Booklet_FINAL.pdf (last reviewed March 7, 2017). PPMPs are a select group of moderately complex microscopy tests commonly performed by health care providers during patient office visits. Tests included in PPMP do not meet the criteria for waiver because they are not simple procedures, but rather require training and specific skills to conduct such tests.

²¹ Id.

²² Agency for Health Care Administration, *Clinical Laboratories*, 2017, available at

http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Laboratory_Licensure/non-waived_apps.shtml (last viewed March 7, 2017).

²³ Supra, FN 14.

²⁴ Id. In July 2006, Florida enacted comprehensive basic licensure requirements under Part II of Chapter 408, F.S. that impacted all facilities licensed by AHCA, including clinical laboratories, in an effort streamline the licensing process. Health care facility licensing procedures can also be found in Chapter 59A-35, F.A.C.

Effect of Proposed Changes

The bill repeals Part I of ch. 483, F.S., which regulates clinical laboratories. Clinical laboratories that perform testing on specimens from within the state will no longer be required to obtain state licensure, which duplicated the federal regulatory scheme. Clinical laboratories must continue to be certified by the CLIA program.²⁵ The bill moves the language which grants AHCA rulemaking authority, in consultation with the Board of Clinical Laboratory Personnel, to adopt criteria for alternate-site testing to be performed under the supervision of a clinical laboratory director, from s. 483.051, F.S., which is being repealed, and puts it in s. 395.0091, F.S., to continue AHCA's rulemaking authority.

The bill also makes conforming changes to the following statutes to reflect the repeal of state licensure requirements for clinical laboratories: ss. 20.43(3)(g), 381.0034, 381.0031(2), 381.004, 383.313(1), 384.31, 395.009, 395.7015(2)(b), 400.9905(4), 400.0625(1), 408.033(2)(a), 408.07(11), 408.802, 408.806, 408.820(26), 409.905(7), 456.001, 456.057, 483.294, 483.801(3), 483.803, 483.813, 491.003, F.S., 627.351(4)(h), 766.202(4), and 945.36(1), F.S.

Health Care Risk Managers

Background

A health care risk manager assesses and minimizes various risks to staff, patients and the public in a health care organization,²⁶ and can play a role in reducing safety, finance, and patient problems in the organization or facility.²⁷ Health care risk managers are trained to handle public relations, personnel, operations, or financial problems.²⁸ Health care risk managers also assist with managing minor, daily problems and major, unexpected events.²⁹

Every hospital and ambulatory surgical center (ASC) licensed under part I of chapter 395, F.S., is required to establish and maintain an internal risk management program.³⁰ The purpose of the risk management program is to control and prevent medical accidents and injuries.³¹ The internal risk management program must include:

- A process to investigate and analyze the frequency and causes of adverse incidents to patients.
- Appropriate measures to minimize the risk of adverse incidents to patients.
- The analysis of patient grievances that relate to patient care and the quality of medical services.
- A system for informing a patient or an individual that she or he was the subject of an adverse incident.
- An incident reporting system which allows for the reporting of adverse incidents to the risk manager within 3 business days after their occurrence.³²

Each licensed facility must hire a licensed health care risk manager who is responsible for implementation and oversight of the facility's internal risk management program.³³

²⁵ Agency for Health Care Administration, *2017 Agency Legislative Bill Analysis*, December 2016, pg. 7 (on file with the Health Innovation Subcommittee).

²⁶ Healthcare Administration Degree Programs, *What is a Health Care Risk Manager?*, available at <http://www.healthcare-administration-degree.net/faq/what-is-a-health-care-risk-manager/> (last viewed March 8, 2017).

²⁷ Id.

²⁸ Id.

²⁹ Id.

³⁰ S. 395.0197(1), F.S.

³¹ S. 395.10971, F.S.

³² S. 395.0197(1)(a)-(d), F.S.

³³ S. 395.0197(2), F.S.

Licensure

Health care risk managers must be licensed by AHCA. In order to qualify for licensure, an applicant must demonstrate competence, by education or experience, in:

- 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.
- Medical terminology.³⁴

A license must be issued if an applicant can affirmatively prove that he or she is:

- 18 years of age or over;
- A high school graduate or equivalent; and
 - Has fulfilled the requirements of a 1-year program or its equivalent in health care risk management training which may be developed or approved by AHCA;
 - Has completed 2 years of college-level studies which would prepare the applicant for health care risk management, to be further defined by rule; or
 - Has obtained 1 year of practical experience in health care risk management.³⁵

AHCA currently licenses 2,458 health care risk managers and 602, or 24.5 percent, report working in a licensed capacity for at least one hospital or ASC.³⁶ On average, for the past five years, approximately 174 initial applications for licensure are received and 181 licensees fail to renew each year.³⁷

Denial, Suspension, or Revocation of a License

AHCA may deny, suspend, revoke, or refuse to renew or continue the license of an applicant or health care risk manager if any one or more of the following grounds exist:

- Any cause for which issuance of the license could have been refused had it then existed and been known to AHCA.
- Giving false or forged evidence to AHCA for the purpose of obtaining a license.
- Having been found guilty of, or having pleaded guilty or nolo contendere to, a crime in this state or any other state relating to the practice of risk management or the ability to practice risk management, whether or not a judgment or conviction has been entered.
- Having been found guilty of, or having pleaded guilty or nolo contendere to, a felony, or a crime involving moral turpitude punishable by imprisonment of 1 year or more under the law of the United States, any state, or any other country, without regard to whether a judgment of conviction has been entered by the court having jurisdiction of such cases.
- Making or filing a report or record which the licensee knows to be false; or intentionally failing to file a report or record required by state or federal law; or willfully impeding or obstructing, or inducing another person to impede or obstruct, the filing of a report or record required by state or federal law.

³⁴ S. 395.10974(1), F.S.

³⁵ S. 395.10974(2), F.S.

³⁶ Supra, FN 25 at pg. 3.

³⁷ Id.

- Fraud or deceit, negligence, incompetence, or misconduct in the practice of health care risk management.
- Violation of any provision of this part or any other law applicable to the business of health care risk management.
- Violation of any lawful AHCA order or rule or failure to comply with a lawful subpoena issued by the Department of Health.
- Practicing with a revoked or suspended health care risk manager license.
- Repeatedly acting in a manner inconsistent with the health and safety of the patients of the licensed facility in which the licensee is the health care risk manager.
- Being unable to practice health care risk management with reasonable skill and safety to patients by reason of illness; drunkenness; or use of drugs, narcotics, chemicals, or any other material or substance or as a result of any mental or physical condition.
- Willfully permitting unauthorized disclosure of information relating to a patient or a patient's records.
- Discriminating against patients, employees, or staff on account of race, religion, color, sex, or national origin.³⁸

When a health care risk manager fails to complete his or her tasks, the licensed facility is cited for any applicable violations, not the health care risk manager. Health care risk managers are exempt from monetary liability for any act or proceeding performed within the scope of the internal risk management program if the risk manager acts without intent to defraud.³⁹

Health Care Risk Manager Advisory Council

The Secretary of AHCA may appoint a seven-member Health Care Risk Manager Advisory Council (Council) to advise AHCA on health care risk manager issues.⁴⁰ The Council must consist of:

- Two active health care risk managers, including one risk manager who is recommended by and a member of the Florida Society of Healthcare Risk Management.
- One active hospital administrator.
- One employee of an insurer or self-insurer of medical malpractice coverage.
- One public representative.
- Two licensed health care practitioners, one of whom must be a physician licensed under chapter 458 or chapter 459.⁴¹

Currently, there are no appointed Council members and there have been no Council meetings for at least ten years.⁴²

Effect of Proposed Changes

The bill repeals the health care risk manager program and the Council. Licensed facilities must maintain an internal risk management program, but may hire any risk manager to run the program who meets criteria established by each facility. Florida is the only state to require the licensure of health care risk managers.⁴³ Repeal of the Council is appropriate as it has no members and has not met in over ten years.

³⁸ S. 395.10975(1), F.S.

³⁹ S. 395.0197(16), F.S.

⁴⁰ S. 395.10972, F.S.

⁴¹ S. 395.10972(1)-(5), F.S.

⁴² Supra, FN 25 at pg. 3.

⁴³ American Society for Healthcare Risk Management, *A Brief History of ASHRM 1980-2010... 30 Years and Counting!*, 2010, pg. 7., available at http://www.ashrm.org/about/files/A_Brief_History_of_ASHRM.pdf (last viewed March 15, 2017).

The bill also makes conforming changes to the following statutes to reflect the repeal of the health care risk manager program and the Council: ss. 395.0197(2)(c), 395.10973, 408.802, 408.820(10) & (11), 458.307, and 641.55, F.S.

Assisted Living Facilities

Background

Licensure

An assisted living facility (ALF) is a residential establishment, or part of a residential establishment, that provides housing, meals, and one or more personal services for a period exceeding 24 hours to one or more adults who are not relatives of the owner or administrator.⁴⁴ A personal service is direct physical assistance with, or supervision of, the activities of daily living and the self-administration of medication.⁴⁵ Activities of daily living include ambulation, bathing, dressing, eating, grooming, toileting, and other similar tasks.⁴⁶

ALFs are licensed and regulated by AHCA under part I of ch. 429, F.S., and part II of ch. 408, F.S. ALFs are also regulated by Department of Elder Affairs (DOEA) under ch. 58A-5, F.A.C. DOEA is responsible for developing and enforcing training requirements for ALF administrators and staff.

An administrator is an individual who is at least 21 years of age and is responsible for the operation and maintenance of an ALF.⁴⁷ Administrators must meet minimum training and education requirements established by the Department of Elder Affairs (DOEA). The training and education requirements allow administrators to assist ALFs to appropriately respond to the needs of residents, to maintain resident care and facility standards, and to meet licensure requirements.⁴⁸ DOEA must establish a competency test and a minimum required score to indicate successful completion of the training and educational requirements. The required training and education must cover, at least, the following topics:

- State law and rules applicable to ALFs.
- Resident rights and identifying and reporting abuse, neglect, and exploitation.
- Special needs of elderly persons, persons with mental illness, and persons with developmental disabilities, and how to meet those needs.
- Nutrition and food service, including acceptable sanitation practices for preparing, storing, and serving food.
- Medication management, recordkeeping, and proper techniques for assisting residents with self-administered medication.
- Fire safety requirements, including fire evacuation drill procedures and other emergency procedures.
- Care of persons with Alzheimer's disease and related disorders.⁴⁹

Administrators are required to participate in continuing education for a minimum of 12 contact hours every 2 years.⁵⁰ Effective October 1, 2015, each new ALF employee, who has not previously completed core training, must attend a preservice orientation provided by the ALF before interacting with residents. The preservice orientation must be at least 2 hours in duration and cover topics that help the employee provide responsible care and respond to the needs of ALF residents.⁵¹ The ALF core training

⁴⁴ S. 429.02(5), F.S. An ALF does not include an adult family-care home or a non-transient public lodging establishment.

⁴⁵ S. 429.02(16), F.S.

⁴⁶ S. 429.02(1), F.S.

⁴⁷ S. 429.02(2), F.S.

⁴⁸ S. 429.52(2), F.S.

⁴⁹ S. 429.52(3), F.S.

⁵⁰ S. 429.52(5), F.S.

⁵¹ S. 429.52(1), F.S.

requirements must consist of a minimum of 26 hours of training plus a competency test.⁵² Administrators must successfully complete the ALF core training requirements within 3 months from the date of becoming an ALF administrator. Successful completion of the core training requirements includes passing the competency test. The minimum passing score for the competency test is 75 percent.⁵³

An ALF is required to provide care and services that are appropriate for the needs of the residents admitted to the facility.⁵⁴ The owner or facility administrator determines whether an individual is appropriate for admission to the facility based on certain criteria.⁵⁵ If a resident no longer meets the criteria for continued residency, or the facility is unable to meet the resident's needs, as determined by the facility administrator or a health care provider, the resident must be discharged in accordance with the Resident Bill of Rights.⁵⁶

As of March 12, 2017, there are 3,101 licensed ALFs in Florida with 96,933 beds.⁵⁷

Specialty Licensed Facilities

In addition to a standard license, an ALF may have one or more specialty licenses that allow the ALF to provide additional care. These specialty licenses include limited nursing services,⁵⁸ limited mental health services,⁵⁹ and extended congregate care services.⁶⁰

Limited Mental Health License

A mental health resident is an individual who receives social security disability income due to a mental disorder as determined by the Social Security Administration or receives supplemental security income due to a mental disorder as determined by the Social Security Administration and receives optional state supplementation.⁶¹ A limited mental health (LMH) license is required for any ALF serving three or more mental health residents.⁶² To obtain this license, the ALF may not have any current uncorrected deficiencies or violations, and the facility administrator and staff providing direct care to residents must complete six hours of training related to LMH duties, which is either provided by or approved by the Department of Children and Families (DCF).⁶³ A LMH license can be obtained during initial licensure, during relicensure, or upon request of the licensee.⁶⁴ Of the 3,101 licensed ALFs in the state, there are 837 facilities with LMH licenses, providing 13,598 beds.⁶⁵

Extended Congregate Care License

The Extended Congregate Care License (ECC) allows an ALF to provide, directly or through contract, services performed by licensed nurses and supportive services to individuals who would otherwise be disqualified from continued residency in an ALF.⁶⁶ AHCA must first determine that all requirements in

⁵² Rule 58A-5.0191(a), F.A.C.

⁵³ Rule 58A-5.0191(b), F.A.C.

⁵⁴ For specific minimum standards, see Rule 58A-5.0182, F.A.C.

⁵⁵ S. 429.26, F.S., and Rule 58A-5.0181, F.A.C.

⁵⁶ S. 429.28, F.S.

⁵⁷ Agency for Health Care Administration, *Facility/Provider Search Results-Assisted Living Facilities*, available at <http://www.floridahealthfinder.gov/facilitylocator/ListFacilities.aspx> (report generated on March 12, 2017).

⁵⁸ S. 429.07(3)(c), F.S.

⁵⁹ S. 429.075, F.S.

⁶⁰ S. 429.07(3)(b), F.S.

⁶¹ S. 429.02, F.S.

⁶² S. 429.075, F.S.

⁶³ Id.

⁶⁴ Id.

⁶⁵ Agency for Health Care Administration, *Assisted Living Facilities with Limited Mental Health*, as of March 12, 2017, available at http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Assisted_Living/docs/alf/LMH_Directory_02-9-2017.pdf (last viewed on March 12, 2017).

⁶⁶ S. 429.07(3)(b), F.S.

law and rule are met before an ALF can be licensed to provide ECC services. Such licensure is regulated pursuant to s. 429.07, F.S., and Chapter 58A-5, F.A.C.

The primary purpose of ECC services is to allow residents, as their acuity level rises, to remain in a familiar setting. An ALF licensed to provide ECC services may also admit an individual who exceeds the admission criteria for a facility with a standard license, if the individual is determined appropriate for admission to the ECC facility. A licensed facility must adopt its own requirements within guidelines for continued residency set forth by rule. However, the facility may not serve residents who require 24-hour supervision.

Licensed ECC facilities may provide the following additional services:

- Total help with bathing, dressing, grooming, and toileting;
- Nursing assessments conducted more frequently than monthly;
- Measuring and recording basic vital functions and weight;
- Dietary management, including providing special diets, monitoring nutrition, and observing the resident's food and fluid intake and output;
- Assisting with self-administered medications;
- Supervising residents with dementia and cognitive impairments;
- Health education, counseling, and implementing health-promoting programs;
- Rehabilitative services; and
- Escort services to health-related appointments.⁶⁷

Before being admitted to an ECC licensed facility to receive services, the prospective resident must undergo a medical examination.⁶⁸ The ALF must develop a service plan that sets forth how the facility will meet the resident's needs and must maintain a written progress report on each resident who receives ECC services.

ALFs with an ECC license must meet the following staffing requirements:

- Specify a staff member to serve as the ECC supervisor if the administrator does not perform this function;
- The administrator of an ECC licensed facility must have a minimum of two years of managerial, nursing, social work, therapeutic recreation, or counseling experience in a residential, long-term care, or acute care setting; and
- A baccalaureate degree may be substituted for one year of the required experience and a nursing home administrator licensed under chapter 468, F.S., shall be considered qualified.⁶⁹

An ECC administrator or a supervisor, if different from the administrator, must complete the core training required of a standard licensed ALF administrator⁷⁰, and four hours of initial training in ECC care within 3 months of beginning employment. The administrator must complete a minimum of four hours of continued education every two years.⁷¹

All staff providing direct ECC care to residents must complete at least two hours of initial service training, provided by the administrator, within six months of beginning employment.⁷²

ALFs with a standard license must pay a biennial license fee of \$300 per license, with an additional fee of \$50 per resident. The total fee may not exceed \$10,000. In addition to the total fee assessed for

⁶⁷ Rule 58A-5.030(8)(b), F.A.C.

⁶⁸ Rule 58A-5.030(6), F.A.C.

⁶⁹ Rule 58A-5.030(4), F.A.C.

⁷⁰ 26 hours of training plus satisfactory performance on a competency test.

⁷¹ Rule 58A-5.0191(7), F.A.C.

⁷² Id.

standard licensed ALFs, facilities providing ECC services must pay an additional fee of \$400 per license, with an additional fee of \$10 per resident.⁷³ Of the 3,101 licensed ALFs in Florida, there are 253 facilities with ECC licenses, providing 18,163 beds.⁷⁴

Limited Nursing Services License

Limited nursing services (LNS) are services beyond those provided by standard licensed ALFs. A licensed registered nurse in a facility with a LNS specialty license may only perform certain acts, as specified by rule.⁷⁵ Pursuant to Rule 58A-5.031, F.A.C., a licensed registered nurse may provide the following services in an ALF with an LNS license:

- Passive range of motion exercises;
- Ice caps or heat relief;
- Cutting toenails of diabetic residents;
- Ear and eye irrigations;
- Urine dipstick tests;
- Replacement of urinary catheters;
- Digital stool removal therapies;
- Applying and changing routine dressings that do not require packing or irrigation;
- Care for stage 2 pressure sores;
- Caring for casts, braces and splints;
- Conducting nursing assessments;
- Caring for and monitoring the application of anti-embolism stockings or hosiery;
- Administration and regulation of portable oxygen;
- Applying, caring for and monitoring a transcutaneous electric nerve stimulator; and
- Catheter, colostomy, and ileostomy care and maintenance.

A facility holding only a standard or LNS license must meet the following admission and continued residency criteria contained in Rule 59A-5.0181, F.A.C.:⁷⁶ Potential residents must:

- Be at least 18 years of age;
- Be free from signs and symptoms of any communicable disease;
- Be able to perform the activities of daily living;
- Be able to transfer, with assistance if necessary;
- Be capable of taking their own medications with assistance from staff, if necessary;
- Not be a danger to themselves or others;
- Not require licensed professional mental health treatment on a 24-hour per day basis;
- Not be bedridden;
- Not have any stage 3 or 4 pressure sores;
- Not require nursing services for oral or other suctioning, assistance with tube feeding, monitoring of blood gases, intermittent positive pressure breathing therapy, or treatment of surgical incisions or wounds;
- Not require 24-hour nursing supervision;
- Not require skilled rehabilitative services; and
- Have been determined by the administrator to be appropriate for admission to the facility.⁷⁷

⁷³ S. 429.07(4), F.S.

⁷⁴ Agency for Health Care Administration, *Assisted Living Facilities with Extended Congregate Care*, as of March 12, 2017, available at http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Assisted_Living/docs/alf/ECC_Directory_02-9-2017.pdf (last viewed on March 12, 2017).

⁷⁵ S. 429.02(13), F.S.

⁷⁶ Rule 58A-5.031(2), F.A.C.

⁷⁷ Rule 58A-5.0181(1), F.A.C.

Facilities licensed to provide LNS must employ or contract with a nurse to provide necessary services to facility residents.⁷⁸ Licensed LNS facilities must maintain written progress reports on each resident receiving LNS. A registered nurse representing AHCA must visit these facilities at least twice a year to monitor residents and determine compliance.⁷⁹ A nursing assessment must be conducted at least monthly on each resident receiving LNS.⁸⁰

Facilities licensed to provide LNS must pay the standard licensure fee of \$300 per license, with an additional fee of \$50 per resident and the total fee may not exceed \$10,000. In addition to the standard fee, in order to obtain the LNS specialty license, facilities must pay an additional biennial fee of \$250 per license, with an additional fee of \$10 per bed.⁸¹ Of the 3,101 licensed ALFs in Florida, there are 566 facilities with LNS licenses, providing 31,904 beds.⁸²

Inspections and Surveys

AHCA must inspect each licensed ALF at least once every 24 months to determine compliance with statutes and rules. If an ALF is cited for a class I violation or three or more class II violations arising from separate surveys within a 60-day period or due to unrelated circumstances during the same survey, AHCA must conduct an additional licensure inspection within six months.⁸³

Abbreviated Surveys

An applicant for licensure renewal is eligible for an abbreviated biennial survey by AHCA if the applicant does not have any:

- Class I or class II violations or uncorrected class III violations.
- Confirmed long-term care ombudsman council complaints reported to AHCA by the council.
- Confirmed licensing complaints within the two licensing periods immediately preceding the current renewal date.⁸⁴

AHCA is required to expand an abbreviated survey or conduct a full survey if violations which threaten or potentially threaten the health, safety, or welfare of residents are identified during an abbreviated survey.⁸⁵

Monitoring Visits

Facilities with LNS or ECC licenses are subject to monitoring visits by AHCA in which AHCA inspects the facility for compliance with the requirements of the specialty license type. An LNS licensee is subject to monitoring inspections at least twice a year. At least one registered nurse must be included in the inspection team to monitor residents receiving LNS and to determine if the facility is complying with applicable regulatory requirements. An ECC licensee is subject to quarterly monitoring inspections. At least one registered nurse must be included in the inspection team. AHCA may waive one of the required yearly monitoring visits for an ECC facility that has been licensed for at least 24 months, if the registered nurse who participated in the monitoring inspections determines that the ECC services are being provided appropriately, and there are no serious violations or substantiated complaints about the quality of service or care.

⁷⁸ Rule 58A-5.031(2), F.A.C.

⁷⁹ S. 429.07(2)(c), F.S.

⁸⁰ Id.

⁸¹ S. 429.07(4)(c), F.S.

⁸² Agency for Health Care Administration, *Assisted Living Facilities with Limited Nursing Services*, as of March 12, 2017, available at http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Assisted_Living/docs/alf/LNS_Directory_02-9-2017.pdf (last viewed on March 12, 2017).

⁸³ S. 429.34(2), F.S.

⁸⁴ Rule 58A-5.033(1)(a), F.A.C.

⁸⁵ Rule 58A-5.033(1)(c), F.A.C.

Violations and Penalties

Under s. 408.813, F.S., ALFs may be subject to administrative fines imposed by AHCA for certain types of violations. Violations are categorized into four classes according to the nature of the violation and the gravity of its probable effect on residents.

- **Class I violations** are those conditions that AHCA determines present an imminent danger to residents or a substantial probability of death or serious physical or emotional harm. Examples include resident death due to medical neglect, risk of resident death due to inability to exit in an emergency, and the suicide of a mental health resident in an ALF licensed for Limited Mental Health. AHCA must issue a fine between \$5,000 and \$10,000 for each violation.
- **Class II violations** are those conditions that AHCA determines directly threaten the physical or emotional health, safety, or security of the clients. Examples include having no qualified staff in the facility, the failure to call 911 in a timely manner for resident in a semi-comatose state, and rodents in the food storage area. AHCA must issue a fine between \$1,000 and \$5,000 for each violation.
- **Class III violations** are those conditions that AHCA determines indirectly or potentially threaten the physical or emotional health, safety, or security of clients. Examples include missing or incomplete resident assessments, erroneous documentation of medication administration, and failure to correct unsatisfactory DOH food service inspection findings in a timely manner. AHCA must issue a fine between \$500 and \$1,000 for each violation, but no fine may be imposed if the facility corrects the violation.
- **Class IV violations** are those conditions that do not have the potential of negatively affecting clients. Examples include failure to file an adverse incident report, incorrect phone numbers posted for advocacy resources, and failure to post current menus. AHCA can only fine a facility (between \$100 and \$200 for each violation) if the problem is not corrected.^{86,87}

In addition to financial penalties, AHCA can take other actions against a facility. AHCA may deny, revoke, or suspend any license for any of the actions listed in s. 429.14(1)(a)-(k), F.S., such as an intentional or negligent act seriously affecting the health, safety, or welfare of a resident of the facility or a determination by AHCA that the owner lacks the financial responsibility to provide continuing adequate care to residents. AHCA is required to deny or revoke the license of an ALF that has two or more class I violations that are similar to violations identified during a survey, inspection, monitoring visit, or complaint investigation occurring within the previous 2 years.⁸⁸ AHCA may also impose an immediate moratorium or emergency suspension on any provider if it determines that any condition presents a threat to the health, safety, or welfare of a client.⁸⁹ AHCA is required to publicly post notification of a license suspension or revocation, or denial of a license renewal, at the facility.⁹⁰ Finally, Florida's Criminal Code, under ch. 825, F.S., provides criminal penalties for the abuse, neglect, and exploitation of elderly persons⁹¹ and disabled adults.⁹²

⁸⁶ When determining the amount of the fine, AHCA must consider the following factors: the gravity of the violation and the extent to which any laws or rules were violated, actions taken to correct the violations, any previous violations, the financial benefit of committing or continuing the violation, and the licensed capacity of the facility. S. 429.19(3), F.S.

⁸⁷ S. 429.19(2), F.S.

⁸⁸ S. 429.14(4), F.S.

⁸⁹ S. 408.814(1), F.S.

⁹⁰ S. 429.14(7), F.S.

⁹¹ "Elderly person" means a person 60 years of age or older who is suffering from the infirmities of aging as manifested by advanced age or organic brain damage, or other physical, mental, or emotional dysfunction, to the extent that the ability of the person to provide adequately for the person's own care or protection is impaired. S. 825.101(5), F.S. It does not constitute a defense to a prosecution for any violation of Chapter 825, F.S., that the accused did not know the age of the victim. S. 825.104, F.S.

⁹² "Disabled adult" means a person 18 years of age or older who suffers from a condition of physical or mental incapacitation due to a developmental disability, organic brain damage, or mental illness, or who has one or more physical or mental limitations that restrict the person's ability to perform the normal activities of daily living. S. 825.101(4), F.S.

Unlicensed Assisted Living Facilities

A person who owns, operates, or maintains an unlicensed ALF commits a felony of the third degree.⁹³ Any person found guilty of operating an unlicensed ALF a second or subsequent time commits a felony of the second degree.⁹⁴ Health care practitioners are mandatory reporters and must report an unlicensed ALF to AHCA.⁹⁵ Any provider who knowingly discharges a patient to an unlicensed ALF is subject to sanction by AHCA.⁹⁶

AHCA has been concerned with the operation of unlicensed ALFs for years. AHCA works with the DCF, the Attorney General's Medicaid Fraud Control Unit, Medicaid Program Integrity, and DOEA when unlicensed activity is discovered.⁹⁷

Effect of Proposed Changes

The bill makes several statutory changes to address unlicensed ALF activity:

- AHCA may immediately refer unlicensed activity to the state attorney's office in each judicial district.
- AHCA may impose immediate sanctions if the operator of an unlicensed ALF has previously applied for or held a license from AHCA to operate any health care provider.
- The state may criminally pursue any person who owns, operates, or maintains an unlicensed ALF as soon as the person receives notice from AHCA, instead of granting a 10-day grace period to cease the unlawful activity.
- The state may criminally pursue penalties against the property owners where the ALF is located, in addition to the operators, if the location is found to host unlicensed activity on more than one occasion.
- An unlicensed ALF asserting an exemption from licensure has the burden of providing documentation proving that it is entitled to the licensure exemption.
- An ALF is prohibited from providing personnel services to individuals who are not residents of the facility, with the exception of facilities that are licensed to provide adult day care services.
- An ALF is prohibited from operating for more than 120 consecutive days without an administrator who has completed the core educational requirements.

Each proposed change should deter individuals from operating unlicensed ALFs, protect the residents of facilities, and strengthen AHCA enforcement capabilities against unlicensed operators.

Subscriber Assistance Program

Background

Managed Health Care

Managed care refers to a variety of methods of financing and organizing the delivery of comprehensive health care in an effort to control costs and improve quality by controlling the provision of services. Managed care, in varying degrees, integrates the financing and delivery of medical care through contracts with selected physicians, hospitals, and other health care providers that provide comprehensive health care services to enrolled members for a predetermined monthly premium. The term "managed care organization" or "entity" includes health maintenance organizations, exclusive

⁹³ S. 429.08(1)(b), F.S.

⁹⁴ S. 429.08(1)(c), F.S.

⁹⁵ S. 429.08(2)(a), F.S.

⁹⁶ S. 429.08(2)(b), F.S.

⁹⁷ *Supra*, at FN 25 at pg. 4.

provider organizations, prepaid health clinics and Medicaid prepaid health plans. In addition, a health insurer that sells a preferred provider contract may be considered to be a “managed care” plan.⁹⁸

Since 1973, under federal law,⁹⁹ HMOs have been required to establish and provide meaningful procedures for hearing and resolving grievances between the HMO and members of the organization. Medical groups and other health care delivery entities providing health care services for the organization must also be afforded grievance procedures under the federal law. Grievance procedures provide a mechanism to ensure that subscribers have a means of receiving further consideration of a HMO’s decisions that deny care, treatment, or services. Under state law, such mechanisms are extended to adverse decisions of other types of managed care entities.¹⁰⁰

Health insurance regulators have also had a substantial role in helping to resolve disputes arising between consumers and their health insurance carriers and health plans.¹⁰¹ The types of disputes that regulators consider relate to decisions to deny or limit coverage and judgments about medical necessity or appropriateness of care.¹⁰²

External Review Process

Section 641.47(1), F.S., defines the term “adverse determination” to mean a coverage determination by a HMO or prepaid health clinic that an admission, availability of care, continued stay, or other health care service has been reviewed and, based upon the information provided, does not meet the organization’s requirements for medical necessity, appropriateness, health care setting, level of care or effectiveness, and coverage for the requested service is therefore denied, reduced, or terminated. An adverse determination may be the basis for a grievance. A subscriber who chooses to challenge an adverse determination or file another type of grievance is required to first go through the managed care entity’s internal grievance procedure. Once a final decision is rendered through this process, if the decision is unsatisfactory to the subscriber, then the subscriber may appeal through a binding arbitration process provided by the managed care entity or to the SAP.¹⁰³

Subscriber Assistance Program

In 1985, Florida became the second state, following Michigan, to provide a mechanism for consumers to resolve managed care disputes through a state-administered external review process. The Florida program was moved from the Department of Health and Rehabilitative Services (HRS) to AHCA in 1993, and renamed the Statewide Provider and Subscriber Assistance Program (SAP).¹⁰⁴

Section 408.7056, F.S., requires AHCA to implement the SAP to assist consumers of managed care entities with grievances that have not been satisfactorily resolved through the managed care entity’s internal grievance process. The program can hear grievances of subscribers of HMOs, prepaid health clinics and exclusive provider organizations.¹⁰⁵

Section 408.7056(11), F.S., provides that the panel must consist of:

- Members employed by AHCA and members employed by the Department of Insurance (DOI), chosen by their respective agencies;

⁹⁸ The Florida Senate, *Review of the Implementation of the Statewide Provider and Subscriber Assistance Program*, September 2001, pg. 1-2, available at http://archive.flsenate.gov/data/Publications/2002/Senate/reports/interim_reports/pdf/2002-138hc.pdf (last viewed March 7, 2017).

⁹⁹ Health Maintenance Organization Act of 1973, Title 42, Sec. 300e, et seq.

¹⁰⁰ *Supra*, FN 98 at pg. 2.

¹⁰¹ Pollitz, K., Dallek, G., et al., *External Review of Health Plan Decisions: An Overview of Key Program Features in the States and Medicare*, (prepared for Kaiser Family Foundation) Institute for Health Care Research and Policy, November 1998.

¹⁰² *Supra*, FN 98 at pg. 2.

¹⁰³ *Id.*

¹⁰⁴ *Id.*

¹⁰⁵ *Id.*

- A consumer appointed by the Governor;
- A physician appointed by the Governor, as a standing member; and
- Physicians who have expertise relevant to the case to be heard, on a rotating basis.

The agency may contract with a medical director and a primary care physician who may provide additional expertise. The medical director must be selected from a Florida licensed HMO.¹⁰⁶

SAP hearings are public, unless a closed hearing is requested by the subscriber. A portion of a hearing may be closed by the panel when deliberating information of a sensitive personal nature, such as medical records.¹⁰⁷ In addition to hearings, the panel must meet as often as necessary to timely review, consider, and hear grievances about disputes between a subscriber, or a provider on behalf of a subscriber, and a managed care entity. Following its review, the panel must make a recommendation to AHCA or DOI. The recommendation may include specific actions the managed care entity must take to comply with state laws or rules. AHCA or DOI may adopt all or some of the panel's recommendations and may impose administrative sanctions on the managed care entity.¹⁰⁸ The following chart shows the number of cases received by the SAP, the number of cases heard by the panel, and the outcome of each case heard since FY 2009-2010.

Number of Cases Received by SAP FY 2009-2010 through FY 2016-2017 (YTD)¹⁰⁹

SAP Cases	FY 2009-2010	FY 2010-2011	FY 2011-2012	FY 2012-2013	FY 2013-2014	FY 2014-2015	FY 2015-2016	FY 2016-2017 (YTD)
Cases Received	498	506	415	213	160	238	350	134
Cases Heard	124	96	74	17	19	29	53	15
Outcomes of Cases	FY 2009-2010	FY 2010-2011	FY 2011-2012	FY 2012-2013	FY 2013-	FY 2009-2010	FY 2010-2011	FY 2011-2012
Determined Non-jurisdictional	246	260	224	145	115	166	221	84
Incomplete Application	39	37	40	24	11	27	31	8
Request Withdrawn	27	21	20	9	6	11	26	5
Resolved Prior to Hearing	68	82	55	18	9	7	19	16
Found in Favor of Subscriber	23	23	19	5	7	7	27	1
Found in Favor of Plan	95	83	57	12	12	17	25	14

Effect of Proposed Changes

The bill repeals s. 408.7056, F.S. which established the SAP. Consumers will no longer be able to use the SAP as an alternative appeal option after exhausting the managed care entity's grievance process. However, the number of cases received by the SAP and the number of cases heard by the panel have steadily decreased over the past eight years. Subscribers have access to other grievance resolution programs; for example, Medicaid beneficiaries enrolled in a managed care plan may challenge an adverse decision by the plan through the Medicaid Fair Hearing process. Also, AHCA has contracted

¹⁰⁶ S. 408.7056(11)(a), F.S.

¹⁰⁷ S. 408.7056(14)(b), F.S.

¹⁰⁸ Supra, FN 98 at pg. 3.

¹⁰⁹ Email from Tony Guzzo, Deputy Legislative Affairs Director, Agency for Health Care Administration, RE: SAP stats, (February 28, 2017)(on file with the Health Innovation Subcommittee staff).

with MAXIMUS, an independent dispute resolution organization, to provide assistance to health care providers and health plans for resolving claim disputes.¹¹⁰

The Patient Protection and Affordable Care Act (PPACA) governs how insurance companies handle initial appeals and how consumers can request reconsideration of a payment denial.¹¹¹ If an insurance company upholds its decision to deny payment, the law provides consumers with the right to appeal the decision to an outside, independent decision-maker. Managed care plans that elected to participate in the federal program established by PPACA are no longer required to participate in the SAP.¹¹² Following enactment of PPACA, the majority of the health plans elected to use the federal program, and as a result, the SAP is no longer an external appeal option for the majority of their members.¹¹³ There will be an insignificant adverse effect to consumers as a result of repeal of the SAP because of the small percentage of people currently taking advantage of the program.

The bill also makes conforming changes to the following statutes to reflect repeal of the SAP: ss. 220.1845(2)(k), 376.30781(3)(f), 376.86(1), 627.602(1)(h), 627.6513, 641.185, 641.312, 641.3154, 641.51(5), 641.511, and 641.515(1), F.S.

Mobile Surgical Facilities

Background

Section 395.002(21), F.S., defines a “mobile surgical facility” as:

[A] mobile facility in which licensed health care professionals provide elective surgical care under contract with the Department of Corrections or a private correctional facility operating pursuant to chapter 957 and in which inmate patients are admitted to and discharged from said facility within the same working day and are not permitted to stay overnight. However, mobile surgical facilities may only provide health care services to the inmate patients of the Department of Corrections, or inmate patients of a private correctional facility operating pursuant to chapter 957, and not to the general public.

In addition, section 395.002(3), F.S., defines “mobile surgical facility”, along with “ambulatory surgical center”, as:

[A] facility the primary purpose of which is to provide elective surgical care, in which the patient is admitted to and discharged from such facility within the same working day and is not permitted to stay overnight, and which is not part of a hospital. However, a facility existing for the primary purpose of performing terminations of pregnancy, an office maintained by a physician for the practice of medicine, or an office maintained for the practice of dentistry shall not be construed to be an ambulatory surgical center, provided that any facility or office which is certified or seeks certification as a Medicare ambulatory surgical center shall be licensed as an ambulatory surgical center pursuant to s. 395.003. Any structure or vehicle in which a physician maintains an office and practices

¹¹⁰ Agency for Health Care Administration, *Statewide Provider and Health Plan Claim Dispute Resolution Program*, October 15, 2013, pg. 1, available at https://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Commercial_Managed_Care/docs/SPHPClaimDRP/claimsdisputeprogramsummary.pdf (last viewed March 7, 2017).

¹¹¹ 42 U.S.C. 300gg-19.

¹¹² Centers for Medicaid and Medicare Services, *The Center for Consumer Information & Insurance Oversight*, available at <https://www.cms.gov/ccio/Programs-and-Initiatives/Consumer-Support-and-Information/External-Appeals.html> (last viewed March 15, 2017).

¹¹³ Agency for Health Care Administration, *2017 Agency Legislative Bill Analysis*, March 2017, pg. 7 (on file with the Health Innovation Subcommittee).

surgery, and which can appear to the public to be a mobile office because the structure or vehicle operates at more than one address, shall be construed to be a mobile surgical facility.

AHCA licenses and regulates mobile surgical facilities.¹¹⁴ The initial application for licensure must include:

- Proof of fictitious name registration, if applicable;
- Articles of Incorporation or a similarly titled document registered by the applicant with the Florida Department of State; and
- The center's Zoning Certificate or proof of compliance with zoning requirements.¹¹⁵

After the initial application is filed, AHCA will perform an initial licensure inspection. Some of the documents that must be available for during the initial licensure inspection are:

- The governing board bylaws, rules and regulations, or other written organizational plan;
- Roster of medical staff members;
- Roster of registered nurses and licensed practical nurses with current license numbers; and
- The Comprehensive Emergency Management Plan, pursuant to Rule 59A-5.018, F.A.C.¹¹⁶

A license fee of \$1,679.82 must accompany an application for an initial, renewal, or change of ownership license for a mobile surgical facility.¹¹⁷ Upon receipt of the required information, AHCA will conduct a licensure inspection to determine compliance with both the applicable statutes and rules.¹¹⁸ Once the mobile surgical facility is in compliance and has received all approvals, AHCA will issue a license, which identifies the licensee and the name and location of the center.¹¹⁹ A license issued to a mobile surgical facility will be revoked or denied by AHCA in any case where AHCA finds there has been substantial failure to comply with the applicable statutes and rules.¹²⁰

Rule 59A-3.081, F.A.C., sets out the physical plant requirements for a mobile surgical facility, which include staying in compliance with the requirements of the National Fire Protection Association, site requirements, architectural design requirements, mechanical requirements, and electrical system requirements.

Effect of Proposed Changes

The bill eliminates the "mobile surgical facility" license category from statute by deleting the definition of mobile surgical facility and all other references to such a facility. Since the enactment of the mobile surgical facility license in statute, no such license has been issued and no applications for the license are anticipated.¹²¹

¹¹⁴ S. 395.003, F.S. and Rule 59A-5.003, F.A.C., contain the licensure provisions for mobile surgical facilities.

¹¹⁵ Rule 59A-5.003(4)(a)-(c), F.A.C.

¹¹⁶ Rule 59A-5.003(5), F.A.C.

¹¹⁷ Rule 59A-5.003(7), F.A.C.

¹¹⁸ Rule 59A-5.003(12), F.A.C.

¹¹⁹ Rule 59A-5.003(13), F.A.C.

¹²⁰ Rule 59A-5.003(15), F.A.C. A "substantial failure to comply" means that there has been a major, or significant, breach of a requirement in law or rule. If a licensee fails to pay its renewal fee after receiving notice, AHCA may find that there is a substantial failure to comply and may suspend or revoke the license.

¹²¹ Supra, FN 25 at pg. 2.

The bill also makes conforming changes to the following statutes to reflect the repeal of “mobile surgical facility” definitions from statute: ss. 385.211(2), 395.001, 394.4787(7), 395.0161(1)(f), 395.0163(3), 395.1055(2), 395.7015(2)(b), 408.036(3)(e), 408.802, and 408.820(10) & (11), 409.975(1), 627.64194(1), 766.118(6)(b), and 766.202(4), F.S.

Rural Hospital Programs

Background

A rural hospital is an acute care hospital that has 100 or fewer licensed beds and an emergency room which is:¹²²

- The sole provider within a county with a population density of up to 100 persons per square mile;¹²³
- An acute care hospital in a county with a population density of up to 100 persons per square mile, which is at least 30 minutes of travel time, on normally traveled roads under normal traffic conditions, from any other acute care hospital within the same county;¹²⁴
- A hospital supported by a tax district or subdistrict whose boundaries encompass a population of up to 100 persons per square mile;¹²⁵
- A hospital classified as a sole community hospital under 42 C.F.R. § 412.92 which has up to 175 licensed beds;¹²⁶
- A hospital with a service area that has a population of up to 100 persons per square mile;¹²⁷ or
- A hospital designated as a critical access hospital, as defined in s. 408.07.¹²⁸

Rural hospitals are usually the only source of emergency medical care in rural areas.¹²⁹ Rural hospitals provide emergency department services, inpatient care, outpatient care, long-term care, and care coordination services for a population of people who do not live in an urban setting.¹³⁰ Rural hospitals face specific challenges that other hospitals may not experience:

- Rural residents are older, poorer, and more likely to have chronic diseases than urban residents.
- Rural hospitals are typically smaller than urban hospitals.
- Rural hospitals provide a higher percentage of care in outpatient settings and are more likely to offer home health, skilled nursing, and assisted living; all of which have lower Medicare margins than inpatient care.
- Rural hospitals rely more heavily on reimbursement from public programs whose payments fall short of costs.¹³¹

Health care spending in a community has a significant impact on the local economy. Rural hospitals impact communities in both their capacity to attract new businesses and the wages generated through the facility. Quality rural health services are needed in rural communities to attract business and industry, as well as retirees. On average, nationwide, the health sector constitutes 14 percent of total employment in rural communities, with rural hospitals typically being one of the largest employers in the

¹²² S. 395.602(2)(e), F.S.

¹²³ S. 395.602(2)(e)1., F.S.

¹²⁴ S. 395.602(2)(e)2., F.S.

¹²⁵ S. 395.602(2)(e)3., F.S.

¹²⁶ S. 395.602(2)(e)4., F.S.

¹²⁷ S. 395.602(2)(e)5., F.S. As used in this subparagraph, the term “service area” means the fewest number of zip codes that account for 75 percent of the hospital’s discharges for the most recent 5-year period, based on information available from the hospital inpatient discharge database at the Florida Center for Health Information and Transparency.

¹²⁸ S. 395.602(2)(e)6., F.S.

¹²⁹ S. 395.602(1)(a), F.S.

¹³⁰ Rural Health Information Hub, *Rural Hospitals*, April 29, 2015, available at <https://www.ruralhealthinfo.org/topics/hospitals> (last viewed March 5, 2017).

¹³¹ Id.

area. A Critical Access Hospital, the federal designation for a rural hospital, on average maintains a payroll of \$6.8 million and employs 141 people.¹³²

Some of the ways in which the legislature has supported rural hospitals is by providing financial incentives under the Medical Education Tuition Reimbursement Program for primary care physicians and nurses in rural areas; extending Medicaid reimbursements to rural hospital swing-beds; and promoting the location and relocation of health care practitioners in rural areas.¹³³

Special Designations for Rural Hospitals

AHCA licenses four classes of hospital.¹³⁴ Class I licenses are considered general hospitals and include rural hospitals.¹³⁵ All licensed hospitals must have:

- Inpatient beds;
- A governing authority legally responsible for the conduct of the hospital;
- A chief executive officer or others similarly titled official to whom the governing authority delegates the full-time authority for the operation of the hospital in accordance with the established policy of the governing authority;
- An organized medical staff to which the governing authority delegates responsibility for maintaining proper standards for medical and other health care;
- A current and complete medical record for each patient admitted to the hospital;
- A policy requiring that all patients be admitted on the authority of and under the care of a member of the organized medical staff;
- Facilities and professional staff available to provide food to patients to meet their nutritional needs;
- A procedure for providing care in emergency cases;
- A method and policy for infection control; and
- An on-going organized program to enhance the quality of patient care and review the appropriateness of utilization of services.¹³⁶

In addition, Class I hospitals must have:

- One licensed registered nurse on duty at all times on each floor or similarly titled part of the hospital for rendering patient care services;
- A pharmacy supervised by a licensed pharmacist either in the facility or by contract sufficient to meet patient needs;
- Diagnostic imaging services either in the facility or by contract sufficient to meet patient needs;
- Clinical laboratory services either in the facility or by contract sufficient to meet patient needs;
- Operating room services; and
- Anesthesia service.¹³⁷

Though not used in rule or statute for licensure of hospitals or otherwise, there are several designations of “rural hospitals” based on their services, bed capacity, and location. These designations are “emergency care hospital,” “essential access community hospital,” and “rural primary care hospital.”

An emergency care hospital is a medical facility which provides:

- Emergency medical treatment; and
- Inpatient care to ill or injured person prior to their transportation to another hospital; or

¹³² Id.

¹³³ S. 395.602(1)(b), F.S.

¹³⁴ Rule 59A-3.252(1), F.A.C.

¹³⁵ Rule 59A-3.252(1)(a)3., F.A.C.

¹³⁶ Rule 59A-3.252(2), F.A.C.

¹³⁷ Rule 59A-3.252(3), F.A.C.

- Inpatient medical care to persons needing such care up to 96 hours.¹³⁸

An essential access community hospital is a facility which:

- Has at least 100 beds;
- Is located more than 35 miles from any other essential access community hospital, rural referral center, or urban hospital meeting the criteria for classification as a regional referral center;¹³⁹
- Is part of a network that includes rural primary care hospitals;
- Provides emergency and medical backup services to rural primary care hospitals in its rural health network;
- Extends staff privileges to rural primary care hospital physicians in its network; and
- Accepts patients transferred from rural primary care hospitals in its network.¹⁴⁰

A rural primary care hospital is any facility meeting the criteria for a rural hospital or emergency care hospital which:

- Provides twenty-four-hour emergency medical care;
- Provides temporary inpatient care for 72 hours or less to patients requiring stabilization before discharge or transfer to another hospital; and
- Has no more than six licensed acute care inpatient beds.¹⁴¹

Florida does not have any emergency care hospitals, essential access community hospitals, or rural primary care hospitals.¹⁴² The essential access community hospital and rural primary care hospital designations were established under federal programs that were implemented in 1993 and subsequently replaced in 1997 by the Critical Access Hospital program.¹⁴³

Effect of Proposed Changes

The bill repeals the definitions of emergency care hospital, essential access community hospital, and rural primary care hospital. There are no rural hospitals with those designations, and the federal Critical Access Hospital program has replaced the essential access community hospital and rural primary care hospital designations. Rural hospitals will continue to operate as normal without the special designations, and the repeal will have no adverse effect on the application process for certificate of need or licensure of rural hospitals. The bill also repeals other rural hospital programs as those programs are obsolete once the special designations for rural hospitals are removed from statute.

An inactive rural hospital bed is a licensed acute care hospital bed, as defined in s. 395.002(13), that cannot be occupied by an acute care inpatient.¹⁴⁴ There is no longer a need for hospitals to track inactive beds because AHCA no longer maintains a list of facilities with inactive beds for the purpose of publishing the need for additional acute care beds under the CON program.¹⁴⁵

The bill also makes conforming changes to the following statutes to reflect the repeal of “emergency care hospital,” “essential access community hospital,” “inactive rural hospital bed,” and “rural primary care hospital” definitions from statute, as well as the repeal of other rural hospital programs and emergency care hospitals: ss. 395.603, 409.9116(6), 409.975(1), 458.345(1), 1009.65(2)(b), F.S.

¹³⁸ S. 395.602(2)(a), F.S.

¹³⁹ Rural Referral Centers are high-volume acute care rural hospitals that treat a large number of complicated cases.

¹⁴⁰ S. 395.602(2)(b), F.S.

¹⁴¹ S. 395.602(2)(f), F.S.

¹⁴² Email from Tony Guzzo, Deputy Legislative Affairs Director, Agency for Health Care Administration, RE: HB 1195 (March 8, 2017) (on file with the Health Innovation Subcommittee staff).

¹⁴³ Id.

¹⁴⁴ S. 395.602(2)(c), F.S.

¹⁴⁵ Email from Tony Guzzo, Deputy Legislative Affairs Director, Agency for Health Care Administration, RE: another HB 1195 question (March 7, 2017) (on file with the Health Innovation Subcommittee staff).

Home Health Agency

Background

Home Health Agencies (HHAs) are organizations licensed AHCA to provide home health services and staffing services.¹⁴⁶ Home health services are health and medical services and medical supplies furnished to an individual in the individual's home or place of residence. These services include:

- Nursing care;
- Physical, occupational, respiratory, or speech therapy;
- Home health aide services (assistance with daily living such as bathing, dressing, eating, personal hygiene, and ambulation);
- Dietetics and nutrition practice and nutrition counseling; and
- Medical supplies, restricted to drugs and biologicals prescribed by a physician.¹⁴⁷

Staffing services are provided to health care facilities, schools, or other business entities on a temporary or school-year basis by licensed health care personnel and by certified nursing assistants and home health aides who are employed by, or work under the umbrella of, a licensed HHA.¹⁴⁸

A HHA may also provide homemaker¹⁴⁹ and companion¹⁵⁰ services without additional licensing or registration. These services do not involve hands-on personal care to a client and typically include housekeeping, meal planning and preparation, shopping assistance, routine household activities, and accompanying the client on outings. Personnel providing homemaker or companion services are employed by or under contract with a HHA.¹⁵¹

Licensure and Exceptions

Since 1975, HHAs operating in Florida have been required to obtain a state license.¹⁵² HHAs must meet the general health care licensing provisions of part II of ch. 408, F.S., the specific HHA licensure provisions in part III of ch. 400, F.S., and the minimum standards for HHAs in chapter 59A-8, F.A.C. A HHA license is valid for 2 years, unless revoked.¹⁵³ If a HHA operates related offices, each related office outside the health service planning district where the main office is located must be separately licensed.¹⁵⁴ As of March 12, 2017, there are 1,951 licensed HHAs in Florida.¹⁵⁵

A HHA may obtain an initial license by submitting to AHCA a signed, complete, and accurate application and the \$1,705 licensure fee.¹⁵⁶ The HHA must also submit the results of a survey conducted by AHCA.¹⁵⁷ The application must identify the geographic service areas¹⁵⁸ and counties in which the HHA will provide services.

An applicant for initial or renewal licensure must file with the application:

- A listing of services to be provided.

¹⁴⁶ S. 400.462(12), F.S.

¹⁴⁷ S. 400.462(14), F.S.

¹⁴⁸ S. 400.462(30), F.S.

¹⁴⁹ S. 400.462(16), F.S.

¹⁵⁰ S. 400.462(7), F.S.

¹⁵¹ S. 400.462(13), F.S.

¹⁵² SS. 36 – 51 of ch. 75-233, Laws of Fla.

¹⁵³ S. 408.808(1), F.S.

¹⁵⁴ S. 400.464(2), F.S. There are eleven health service planning districts grouped by county.

¹⁵⁵ Florida Health Finder, *Facility/Provider Search Results-Home Health Agencies*, available at <http://www.floridahealthfinder.gov/facilitylocator/ListFacilities.aspx> (report generated March 12, 2017).

¹⁵⁶ S. 400.471(5) and Rule 59A-8.003(12).

¹⁵⁷ Id.

¹⁵⁸ S. 408.032(5), F.S. lists the eleven health service planning districts grouped by county.

- The number and discipline of professional staff to be employed.
- Information concerning volume data on the renewal application, as determined by rule.
- A business plan, which details the HHAs methods to obtain patients and its plan to recruit and maintain staff.
- Evidence of contingency funding equal to one month's average operating expenses during the first year of operation.
- A balance sheet, income and expense statement, and statement of cash flow for the first two years of operation showing evidence of sufficient assets, credit, and projected revenues to cover liabilities and expenses.
- All other ownership interests in health care entities for each controlling interest, as defined in part II of chapter 408.
- For initial licensure, documentation of accreditation, or an application for accreditation, from an accrediting organization that is recognized by the agency as having standards comparable to those required by this part and part II of chapter 408.¹⁵⁹

A HHA must obtain malpractice and liability insurance for at least \$250,000 per claim, and submit proof of coverage with its initial application for renewal.¹⁶⁰

Section 400.464, F.S., exempts certain entities, individuals, and services from the HHA licensure requirements, including:

- A HHA operated by the Federal Government.
- A home health aide or certified nursing assistant who is acting in his or her individual capacity, within the definitions and standards of his or her occupation, and who provides hands-on care to patients in their homes.
- The delivery of nursing home services for which the nursing home is licensed under part II of Chapter 400, F.S., to serve its residents.
- A not-for-profit, community-based agency that provides early intervention services to infants and toddlers.¹⁶¹

For licensure renewal, the HHA must submit a signed renewal application and licensure fee.¹⁶² AHCA may not issue a renewal license to a HHA in any county where there is at least one licensed HHA and that has more than one HHA per 5,000 persons, if the applicant has been sanctioned by AHCA within two years prior to submitting the license renewal application for one or more of the following acts:

- An intentional or negligent act that materially affects the health or safety of a client;
- Preparing or maintaining fraudulent patient records, such as, but not limited to, charting ahead, recording vital signs or symptoms which were not personally obtained or observed by the HHA's staff at the time indicated, borrowing patients or patient records from other HHAs to pass a survey or inspection, or falsifying signatures;
- Demonstrating a pattern of falsifying documents relating to the training of home health aides or certified nursing assistants or demonstrating a pattern of falsifying health statements for staff who provide direct care to patients; and
- Giving cash, or its equivalent, to a Medicare or Medicaid beneficiary.¹⁶³

AHCA conducts unannounced licensure surveys every 36.9 months, unless a HHA has requested an exemption from such surveys based on accreditation by an approved accrediting organization.¹⁶⁴ The Home Health Agency State Regulation Set that is used in conducting surveys contains over 100

¹⁵⁹ S. 400.471(2), F.S.

¹⁶⁰ S. 400.471(3), F.S.

¹⁶¹ S. 400.464(5)(a)-(n), F.S.

¹⁶² Rules 59A-8.003(2) and (12), F.A.C.

¹⁶³ S. 400.471(10), F.S.

¹⁶⁴ Rule 59A-8.003(3)(a), F.A.C.

standards and surveyor guidelines, which are based on regulations found in Chapter 59A-8, F.A.C.¹⁶⁵ AHCA also conducts inspections related to complaints.¹⁶⁶

Each HHA is required to employ an administrator.¹⁶⁷ The administrator¹⁶⁸ must be a licensed physician, physician assistant, or registered nurse licensed to practice in this state or an individual having at least one year of supervisory or administrative experience in home health care in a facility licensed under ch. 395, F.S.,¹⁶⁹ part II of ch. 400, F.S.,¹⁷⁰ or part I of ch. 429, F.S.¹⁷¹ The administrator may manage a maximum of five licensed HHAs if the HHAs have identical controlling interests and are located within one geographic service area or within an immediately contiguous county.¹⁷² An employee of a retirement community that provides multiple levels of care may administer a HHA and up to a maximum of four entities licensed under ch. 400, F.S.,¹⁷³ or ch. 429, F.S.,¹⁷⁴ if they are owned, operated, or managed by the same corporate entity. The administrator must designate an alternate administrator to serve during the administrator's absence.¹⁷⁵

A HHA providing skilled nursing services for more than 30 days is required to employ a director of nursing¹⁷⁶ who is a Florida licensed registered nurse with at least one year of supervisory experience.¹⁷⁷ The director of nursing is responsible for overseeing the delivery of professional nursing and home health aide services¹⁷⁸ and must be readily available at the HHA or by phone for any eight consecutive hours between 7 a.m. to 6 p.m.¹⁷⁹ The director of nursing is also responsible for establishing and conducting an ongoing quality assurance program for services provided by the HHA.¹⁸⁰

A director of nursing may be the director for a maximum of five licensed HHAs if the HHAs have identical controlling interests, are located within one geographic service area or within an immediately contiguous county, and each HHA has a registered nurse who meets the qualifications of a director of nursing and has been delegated by the director of nursing to serve in the stead of the director. An employee of a retirement community that provides multiple levels of care may serve as the director of nursing of a HHA and of up to four entities licensed under ch. 400, F.S., or ch. 429, F.S., if they are owned, operated, or managed by the same corporate entity.¹⁸¹

Effect of Proposed Changes

The bill requires that any HHA license obtained after June 30, 2017, must specify the home health services the HHA is authorized to perform and must indicate whether the specified services are considered "skilled care." In addition, the bill permits any person or HHA providing home health services that is exempt from licensure to apply for a certificate of exemption. The proposed changes to s. 400.464, F.S., will simplify existing licensure requirements and should not have an adverse effect on AHCA or HHA licensees.

¹⁶⁵ Agency for Health Care Administration, *ASPEN: Regulation Set (RS): Home Health Agencies*, available at, http://ahca.myflorida.com/MCHQ/Current_Reg_Files/Home_Health_Agencies_ST_H.pdf (last viewed March 1, 2017).

¹⁶⁶ Rule 59A-8.003(4), F.A.C.

¹⁶⁷ S. 400.476(1)(a), F.S.

¹⁶⁸ S. 400.462(1), F.S.

¹⁶⁹ Facilities licensed under ch. 395, F.S., include hospitals, ambulatory surgical centers, and mobile surgical facilities.

¹⁷⁰ Facilities licensed under part II of ch. 400, F.S., include nursing homes.

¹⁷¹ Facilities licensed under part I of ch. 429, F.S., include assisted living facilities.

¹⁷² S. 400.476(1), F.S.

¹⁷³ Entities licensed under ch. 400, F.S., include nursing homes, home health agencies, nurse registries, hospices, intermediate care facilities, homes for special services, transitional living facilities, prescribed pediatric extended care centers, home medical equipment providers, intermediate care facilities for developmentally disabled persons, health care services pools, and health care clinics.

¹⁷⁴ Entities licensed under ch. 429, F.S., include assisted living facilities, adult family care homes, and adult day care centers.

¹⁷⁵ S. 400.476(1)(a), F.S.

¹⁷⁶ S. 400.462(10), F.S.

¹⁷⁷ S. 400.476(2), F.S.

¹⁷⁸ S. 400.462(10), F.S.

¹⁷⁹ Rule 59A-8.003(11)(a), F.A.C.

¹⁸⁰ Rule 59A-8.0095(2)(e), F.A.C.

¹⁸¹ S. 400.476(2), F.S.

The bill requires a HHA that provides skilled nursing care to have a director of nursing. The provision ensures that skilled nursing care services are overseen by a registered nurse, and ensures recipients of such services are receiving appropriate care.

The bill removes the definitions of Class I, II, III, and IV violations from s. 400.484(2), F.S., and instead references the definitions of the violations found in s. 408.813, F.S. This change eliminates any conflicts between part II of ch. 408, F.S., and part III of ch. 400, F.S.

The bill deletes the federal certification requirement from the home health licensure statute. The proposed changes should eliminate confusion among providers and consumers, and should not have an adverse effect on AHCA or home health agency licensees.

The bill repeals the requirement that a HHA, for purpose of license renewal, report the volume of patients serviced during the previous licensure period. The repeal will ease the administrative burden for HHA associated with applying for license renewal.

The bill provides that any HHA which provides skilled nursing services to any patient for any amount of time must have a director of nursing. The 30-day threshold for providing such services before a HHA must hire a director of nursing is eliminated.

The bill also makes conforming changes to s. 400.497(4), F.S., to reflect the provisions of the bill.

Health Care Facility Licensing

Health Care Licensing Procedures Act

Certain health care providers¹⁸² are regulated under Part II of chapter 408, F.S., which is the Health Care Licensing Procedures Act (Act). The Act provides uniform licensing procedures and standards applicable to most AHCA-regulated entities. The Act contains basic licensing standards for 29 provider types, such as birth centers, abortion clinics, crisis stabilization units, and short-term residential treatment facilities.¹⁸³ In addition to the Act, each provider type has an authorizing statute which includes unique provisions for licensure beyond the uniform criteria. In the case of conflict between the Act and an individual authorizing statute, the Act prevails.¹⁸⁴

Effect of Proposed Changes

The bill defines “relative” for purposes of the Act as any individual who is related to a patient or client in the following manner:

[f]ather, mother, stepfather, stepmother, son, daughter, brother, sister, grandmother, grandfather, great-grandmother, great-grandfather, grandson, granddaughter, uncle, aunt, first cousin, nephew, niece, husband, wife, father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, sister-in-law, stepson, stepdaughter, stepbrother, stepsister, half-brother, or half-sister.

The term “relative” is not currently defined in the Act, and the proposed definition clarifies who qualifies as a relative for certain purposes. For example, the bill grants AHCA rule-making authority to govern the circumstances under which a controlling interest of a licensed facility, an administrator, an employee, a contractor, or a representative thereof, who is not a relative of the patient or client, can act as the patient’s or client’s legal representative, agent, health care surrogate, power of attorney, or guardian. The bill requires the rules to include disclosure requirements, bonding, restrictions, and patient or client protections.

¹⁸² “Provider” means any activity, service, agency, or facility regulated by the agency and listed in s. 408.802, F.S.

¹⁸³ S. 408.802, F.S.

¹⁸⁴ S. 408.832, F.S.

The bill deems any unlicensed activity, which constitutes harm that materially affects the health, safety, and welfare of clients, as abuse and neglect as defined under ch. 415, F.S. The change allows vulnerable adults receiving health or custodial care from an unlicensed provider to be eligible for adult protective services from DCF.

The bill exempts an applicant seeking a change of ownership license from demonstrating proof of financial ability to operate if the current licensee has been operational for five years and:

- Due to a corporate reorganization, the controlling interest does not change, or
- Due to the death of a controlling interest, the licensee changes but the remaining ownership holds more than 51 percent after the change.

The bill removes the requirement for an existing licensed health care provider to provide a copy of the most recent profit-loss statement and licensure inspection report with his or her application for hospice licensure. Such information is collected at other steps in the application process and does not need to be collected again.

The bill allows a licensee that holds a license for multiple providers to request alignment of all license expiration dates. AHCA is permitted to prorate a licensure fee for an abbreviated licensure period resulting from the alignment. AHCA and licensees with multiple provider licenses should realize greater efficiency in the licensure process.

The bill requires a licensee, during the license application process, to ensure that no person applying for a license has held or currently holds ownership interest in another licensed provider that has had a license or change of ownership application denied, revoked, or excluded. This patient safety provision allows AHCA exclude bad actors from owning, directly or indirectly, a licensed facility.

The bill makes conforming changes to ss. 400.933 and 400.980, F.S., to reflect the new requirements of health care facility licensing proposed by the bill.

Statewide Managed Care Ombudsman Committee

Background

The Statewide Managed Care Ombudsman Committee (Committee) is established by s. 641.60, F.S., and was created to serve as a consumer protection and advocacy organization on behalf of health care consumers receiving services through managed care organizations.¹⁸⁵ In addition to the statewide Committee, district committees are established to protect consumers receiving managed care services at a more local level. The districts are established by each health service planning district, composed of the following counties:

- District 1—Escambia, Santa Rosa, Okaloosa, and Walton Counties.
- District 2—Holmes, Washington, Bay, Jackson, Franklin, Gulf, Gadsden, Liberty, Calhoun, Leon, Wakulla, Jefferson, Madison, and Taylor Counties.
- District 3—Hamilton, Suwannee, Lafayette, Dixie, Columbia, Gilchrist, Levy, Union, Bradford, Putnam, Alachua, Marion, Citrus, Hernando, Sumter, and Lake Counties.
- District 4—Baker, Nassau, Duval, Clay, St. Johns, Flagler, and Volusia Counties.
- District 5—Pasco and Pinellas Counties.
- District 6—Hillsborough, Manatee, Polk, Hardee, and Highlands Counties.
- District 7—Seminole, Orange, Osceola, and Brevard Counties.
- District 8—Sarasota, DeSoto, Charlotte, Lee, Glades, Hendry, and Collier Counties.
- District 9—Indian River, Okeechobee, St. Lucie, Martin, and Palm Beach Counties.

¹⁸⁵ S. 641.60(2), F.S.

- District 10—Broward County.
- District 11—Miami-Dade and Monroe Counties.¹⁸⁶

Each district committee must have at least nine members and no more than 16 members,¹⁸⁷ with the AHCA secretary appointing the first three committee members in each district.¹⁸⁸ Each committee is required to have:

- Multiple licensed physicians:
 - one physician licensed under chapter 458;
 - one osteopathic physician licensed under chapter 459;
 - one chiropractor licensed under chapter 460; and
 - one podiatrist licensed under chapter 461;
- One licensed psychologist;
- One registered nurse;
- One clinical social worker;
- One attorney; and
- One consumer.¹⁸⁹

Each district committee or member of the committee:

- Must serve to protect the health, safety, and rights of all enrollees participating in managed care programs in this state.
- Must receive complaints regarding quality of care from the agency, and may assist the agency with the resolution of complaints.
- May conduct site visits with the agency, as the agency determines is appropriate.
- Must submit an annual report to the statewide committee concerning activities, recommendations, and complaints reviewed or developed by the district committee during the year.
- Must conduct meetings as required at the call of its chairperson, the call of the agency director, the call of the statewide committee, or by written request of a majority of the district committee members.¹⁹⁰

Effect of Proposed Changes

The bill repeals the Statewide Managed Care Ombudsman Committee. Due to the very stringent committee requirements, the Committee could not meet the requirements in the majority of the districts and the program was never fully implemented. The last activity on record was in 2010, and there are currently no active committees.¹⁹¹

The bill makes conforming changes to the following statutes to reflect the repeal of the Statewide Managed Care Ombudsman Committee: ss. 408.20, 641.70, and 641.75, F.S.

¹⁸⁶ S. 408.032(5), F.S.

¹⁸⁷ S. 641.65(2), F.S.

¹⁸⁸ S. 641.65(3)(a), F.S.

¹⁸⁹ S. 641.65(2), F.S.

¹⁹⁰ S. 641.65(6), F.S.

¹⁹¹ Supra, FN 25 at pg. 6.

Hospital Regulation

Background

Licensure

Hospitals in Florida must be licensed by AHCA. Hospital licensure is governed by part II of ch. 408, F.S., part I of ch. 395, F.S., and associated rules. An application for hospital licensure must include:

- The name, address, and social security number of the applicant, the administrator, the financial officer, and each controlling interest.
- The name, address, and federal employer identification number or taxpayer identification number of the applicant and each controlling interest.
- The name by which the provider is to be known.
- The total number of beds or capacity requested, as applicable.
- The name of the person or persons under whose management or supervision the provider will operate and the name of the administrator.
- Proof that the applicant has obtained a certificate of authority if the applicant offers continuing care agreements.
- Other information, including satisfactory inspection results that the agency finds necessary to determine the ability of the applicant to carry out its responsibilities.
- An attestation, under penalty of perjury, stating compliance with AHCA's provisions.¹⁹²

AHCA has thirty days, from receipt of an application for a license, to examine the application and notify the applicant, in writing, of any apparent errors or omissions, and request any additional information required.¹⁹³ AHCA will then conduct an initial inspection.¹⁹⁴

AHCA licenses four classes of hospital.¹⁹⁵ Class I hospitals are general hospitals.¹⁹⁶ Class II hospitals are specialty hospitals offering the same range of medical services offered by general hospitals, but restricted to a defined age or gender group.¹⁹⁷ Class III hospitals are specialty hospitals offering a restricted range of services appropriate to the diagnosis, care, and treatment of patients with specific categories of medical or psychiatric illness or disorders.¹⁹⁸ Class IV hospitals are specialty hospitals restricted to offering Intensive Residential Treatment Programs for Children and Adolescents.¹⁹⁹

All licensed hospitals must have:

- Inpatient beds;
- A governing authority legally responsible for the conduct of the hospital;
- A chief executive officer or others similarly titled official to whom the governing authority delegates the full-time authority for the operation of the hospital in accordance with the established policy of the governing authority;
- An organized medical staff to which the governing authority delegates responsibility for maintaining proper standards for medical and other health care;
- A current and complete medical record for each patient admitted to the hospital;
- A policy requiring that all patients be admitted on the authority of and under the care of a member of the organized medical staff;

¹⁹² S. 408.806(1), F.S.

¹⁹³ S. 408.806(3)(a), F.S.

¹⁹⁴ S. 408.806(7)(a), F.S.

¹⁹⁵ Rule 59A-3.252(1), F.A.C.

¹⁹⁶ Rule 59A-3.252(1)(a), F.A.C.

¹⁹⁷ Rule 59A-3.252(1)(b), F.A.C.

¹⁹⁸ Rule 59A-3.252(1)(c), F.A.C.

¹⁹⁹ Rule 59A-3.252(1)(d), F.A.C.

- Facilities and professional staff available to provide food to patients to meet their nutritional needs;
- A procedure for providing care in emergency cases;
- A method and policy for infection control; and
- An on-going organized program to enhance the quality of patient care and review the appropriateness of utilization of services.²⁰⁰

State-Operated Hospitals

DCF operates seven hospitals and treatment centers statewide:

- Florida State Hospital in Chattahoochee;
- Northeast Florida State Hospital in Macclenny;
- South Florida State Hospital in Pembroke Pines;
- North Florida Evaluation and Treatment Center in Gainesville;
- South Florida Evaluation and Treatment Center in Florida City;
- Treasure Coast Forensic Treatment Center in Indiantown; and
- West Florida Community Care Center in Milton.²⁰¹

The Department of Corrections (DOC) operates the Reception and Medical Center in Lake Butler, where newly committed male inmates are processed into the corrections system and medical care is provided to inmates.²⁰² Every state hospital is subject to the same licensure and reporting requirements as other licensed hospitals in the state.

Emergency Services

The federal Emergency Medical Treatment and Labor Act (EMTALA)²⁰³ passed in 1986 after “patient dumping,” the practice of refusing to treat uninsured patients in need of emergency care, came to the attention of the U.S. Congress.²⁰⁴ Effective January 1, 1987, the Florida Legislature enacted the first statute requiring some degree of emergency services to be provided to a patient regardless of the patient’s ability to pay.²⁰⁵

Currently, in Florida, every general hospital which has an emergency department must provide emergency services and care for any emergency medical condition when:

- A person requests emergency services and care; or
- Emergency services and care are requested on behalf of a person by:
 - An emergency medical services provider who is rendering care to or transporting the person; or
 - Another hospital, when such hospital is seeking a medically necessary transfer.²⁰⁶

If a medically necessary transfer is made, it must be made to the geographically closest hospital with the service capability, unless another prior arrangement is in place or the geographically closest hospital is at service capacity.²⁰⁷ Each hospital must retain records of each transfer made or received

²⁰⁰ Rule 59A-3.252(2), F.A.C.

²⁰¹ Department of Children and Families, *State Mental Health Treatment Facilities*, 2014, available at <http://www.myflfamilies.com/service-programs/mental-health/state-mental-health-treatment-facilities> (last viewed March 15, 2017).

²⁰² Department of Corrections, *Reception and Medical Center (RMC)*, 2014, available at <http://www.dc.state.fl.us/facilities/region2/209.html> (last viewed March 15, 2017).

²⁰³ 42 U.S.C. §1395

²⁰⁴ Richard E. Mills, *Access to Emergency Services and Care in Florida*, The Florida Bar Journal, January 1998, available at <http://www.floridabar.org/divcom/jn/jnjournal01.nsf/Author/1C3429F6216E4EA985256ADB005D6190> (last viewed March 8, 2017).

²⁰⁵ Id.

²⁰⁶ S. 395.1041(3)(a), F.S.

²⁰⁷ S. 395.1041(3)(e), F.S.

for a period of five years.²⁰⁸ Decisions about services and care provided to an individual cannot be based upon the individual's:

- Race;
- Ethnicity;
- Religion;
- National origin;
- Citizenship;
- Age;
- Sex;
- Preexisting medical condition;
- Physical or mental handicap;
- Insurance status;
- Economic status; or
- Ability to pay for medical services.²⁰⁹

AHCA may deny, revoke, or suspend a hospital's license or impose an administrative fine, not to exceed \$10,000 per violation, for any violation of access to emergency service and care laws.²¹⁰

Complaint Investigation Procedures

Section 395.1046, F.S., provides special procedures for complaints against hospitals regarding emergency access issues, such as a person being denied emergency services and care.²¹¹ AHCA must investigate any complaint against a hospital for any violation which AHCA reasonably believes to be legally sufficient. A complaint is legally sufficient if it contains facts showing that a violation of ch. 395, F.S., or any rule adopted under ch. 395, F.S., has occurred.²¹² AHCA may investigate emergency access complaints even if the complaint is withdrawn.²¹³ When the investigation is complete, AHCA prepares a report making a probable cause determination.²¹⁴

Effect of Proposed Changes

The bill eliminates the special procedures for investigating hospital emergency access complaints and allows AHCA to employ existing hospital complaint investigation procedures used for all other types of complaints. Section 395.1046, F.S., duplicates the complaint investigation procedure found in s. 408.811, F.S. The elimination of the special procedures for investigating hospital emergency access complaints should not cause an adverse effect on patients or AHCA.

The bill amends the definition of "hospital" in s. 395.701, F.S., by removing the specific references to AHCA and DOC and replacing them with "a state agency." State agencies that run hospitals will be exempt from filing their financial experience for the fiscal year and from making AHCA's annual assessment payment. The provision will ease an unnecessary administrative burden for hospitals operated by state agencies.

The bill adds language to s. 395.1055(2), F.S. directing AHCA to implement standards for pediatric cardiovascular, neonatal intensive care units, transplant, psychiatric, and comprehensive medical rehab services. This rulemaking authority exists elsewhere in statute, but the bill consolidates the authority in the hospital licensure statute.

²⁰⁸ S. 395.1041(4)(a)1., F.S.

²⁰⁹ S. 395.1041(3)(f), F.S.

²¹⁰ S. 395.1041(5)(a), F.S.

²¹¹ S. 395.1041(1), F.S.

²¹² S. 395.1046(1), F.S.

²¹³ Id.

²¹⁴ S. 395.1046(2), F.S.

Birth Centers

Background

A birth center is any facility, institution, or place, which is not an ASC, a hospital or in a hospital, in which births are planned to occur away from the mother's usual residence following a normal, uncomplicated, low-risk pregnancy.²¹⁵ A birth center must include:

- Birthing rooms;
- Bath and toilet facilities;
- Storage areas for supplies and equipment;
- Examination areas; and
- Reception or family areas.²¹⁶

A birth center shall be equipped with those items needed to provide low-risk maternity care and readily available equipment to initiate emergency procedures in life-threatening events to mother and baby, as defined by rule.²¹⁷

Effect of Proposed Changes

The bill repeals an exemption to birth center licensure for any facility that was providing obstetrical and gynecological surgical services and was owned and operated by a board-certified obstetrician on June 15, 1984. There are currently no providers who meet these criteria in s. 383.335, F.S.

Nurse Registries

Background

A nurse registry is defined in s. 400.462(21), F.S., as any person that procures, offers, promises, or attempts to secure healthcare-related contracts for registered nurses, licensed practical nurses, certified nursing assistants, home health aides, companions, or homemakers, who are compensated by fees as independent contractors, including, but not limited to, contracts for the provision of services to patients and contracts to provide private duty or staffing services to health care facilities licensed under ch. 395, F.S., ch. 400, F.S., or ch. 429, F.S., or other business entities. A nurse registry is exempt from the licensing requirements of a HHA, but must be licensed as a nurse registry.²¹⁸ A licensed nurse registry may operate a satellite office.²¹⁹ The application for licensure must be filed with AHCA along with a \$2,000 licensure fee.²²⁰ A license will not be granted to anyone less than 18 years of age,²²¹ and evidence of financial ability to operate for initial licensure and change of ownership must be submitted with the application.²²²

A nurse registry administrator must be available to the public for eight consecutive hours between 7:00 a.m. and 6:00 p.m., Monday through Friday of each week, excluding legal and religious holidays.²²³

The nurse registry must provide to the patient a list of telephone numbers to be called if a replacement caregiver is needed, along with local emergency numbers.²²⁴

²¹⁵ S. 383.302(2), F.S.

²¹⁶ S. 383.308(1), F.S.

²¹⁷ S. 383.308(2)(a), F.S.

²¹⁸ S. 400.506(1)(a), F.S.

²¹⁹ S. 400.506(1)(b), F.S.

²²⁰ Rule 59A-18.004(1), F.A.C.

²²¹ Rule 59A-18.004(3), F.A.C.

²²² Rule 59A-18.004(4), F.A.C.

²²³ Rule 59A-18.004(9)(a), F.A.C.

²²⁴ Rule 59A-18.004(9)(d), F.A.C.

Any person who owns, operates, or maintains an unlicensed nurse registry and does not cease operation and apply for a license, within ten working days after receiving notification from AHCA, can be criminally charged.²²⁵

Effect of Proposed Changes

The bill repeals two grounds upon which AHCA may base the denial, suspension, or revocation of the license of a nurse registry, both of which relate to remuneration by the registry to health care providers, facility staff, or third party vendors. These grounds are broad and prevent nurse registries from marketing their business. Additionally, the bill clarifies language for penalties of unlicensed facilities, referring to provisions in s. 408.812, F.S., so that there is no contradicting language between part II of ch. 408, F.S., and the nurse registry provision in ch. 400, F.S. Lastly, the bill replaces the phrase “it is not the obligation,” or “has no obligation” with the phrase “is not permitted” to clarify the actions a nurse registry cannot take, so as to avoid misperception by clients seeking or obtaining services from a nurse referred by a nurse registry.

Miscellaneous

Home Medical Equipment

A home medical equipment provider sells or rents, or offers to sell or rent, home medical equipment²²⁶ and services or home medical equipment services²²⁷ to or for a consumer. A home medical equipment provider must be licensed by AHCA.²²⁸ Medical oxygen is defined as oxygen USP²²⁹ which must be labeled in compliance with labeling requirements for oxygen under the federal act.²³⁰ The Department of Business and Professional Regulation (DBPR) regulates medical equipment, including medical oxygen.²³¹ In 2014, Part III of ch. 499, F.S., was created for the regulation of medical gas, including medical oxygen, separate from other drugs and medical equipment.

Effect of Proposed Changes

The bill requires a licensee to notify AHCA within 21 days, rather than 45 days, when a change in the general manager of a home medical equipment provider occurs. The reduced notification timeframe matches other notification provision timeframes in Part II of ch. 408, F.S., resulting in regulatory uniformity. The bill makes changes to the home medical equipment exemption for a medical oxygen permit by correcting the reference in s. 400.933, F.S., from Department of Health (DOH) to DBPR, which is now responsible for such regulation.

Health Care Service Pools

A health care services pool is any person, firm, corporation, partnership, or association which provides temporary employment in health care facilities, residential facilities, and agencies for licensed, certified, or trained health care personnel, including nursing assistants, nurses' aides, and orderlies.²³²

²²⁵ S. 400.506(5)(a), F.S.

²²⁶ S. 400.925(6), F.S., defines home medical equipment as any product as defined by the Federal Drug Administration, any products reimbursed under the Medicare Part B Durable Medical Equipment benefits or the Florida Medicaid durable medical equipment program. Such equipment includes oxygen and related respiratory equipment, wheelchairs and related seating and positioning, but does not include motorized scooters, personal transfer systems, specialty beds, prosthetics, orthotics, or custom-fabricated splints, braces, or aids.

²²⁷ S. 400.925(9), F.S., defined home medical equipment services as equipment management and consumer instruction, including selection, delivery, setup, and maintenance of equipment, and other related services for the use of home medical equipment in the consumer's place of residence.

²²⁸ See generally s. 400.931, F.S.

²²⁹ The United States Pharmacopoeia (USP) is a list of drugs licensed for use in the U.S. with standards necessary to determine purity suitable for persons.

²³⁰ S. 499.82(10), F.S.

²³¹ Chapter 499, F.S.

²³² S. 400.980(1), F.S.

Registration or a license issued by AHCA is required for the operation of a health care services pool.²³³ Currently, if a health care services pool must change information contained in its original registration application, it must notify AHCA 14 days prior to the change.²³⁴

Effect of Proposed Changes

The bill requires a health care services pool to notify AHCA of a change of ownership at least 60 days before the effective date of the change. For any other change of information contained in a registration application, AHCA must be notified at least 60 days, but no more than 120 days, before the requested effective date. Health care service pools will be subject to the same reporting timeframe for these changes as other health care facilities licensed by AHCA.

B. SECTION DIRECTORY:

Section 1: Amends s. 20.43, F.S., relating to Department of Health.

Section 2: Amends s. 220.1845, F.S., relating to contaminated site rehabilitation tax credit.

Section 3: Amends s. 376.30781, F.S., relating to tax credits for rehabilitation of drycleaning-solvent-contaminated sites and brownfield sites in designated brownfield areas; application process; rulemaking authority; revocation authority.

Section 4: Amends s. 376.86, F.S., relating to Brownfield Areas Loan Guarantee Program.

Section 5: Amends s. 381.0031, F.S., relating to epidemiological research; report of diseases of public health significance to department.

Section 6: Amends s. 381.0034, F.S., relating to requirement for instruction on HIV and AIDS.

Section 7: Amends s. 381.004, F.S., relating to HIV testing.

Section 8: Amends s. 383.313, F.S., relating to performance of laboratory and surgical services; use of anesthetic and chemical agents.

Section 9: Repeals s. 383.335, F.S., relating to partial exemptions.

Section 10: Amends s. 384.31, F.S., relating to testing of pregnant women; duty of the attendant.

Section 11: Amends s. 385.211, F.S., relating to refractory and intractable epilepsy treatment and research at recognized medical centers.

Section 12: Amends s. 394.4787, F.S., relating to definitions; ss. 394-4786, 394.4787, 394.4788, and 394.4789.

Section 13: Amends s. 395.001, F.S., relating to legislative intent.

Section 14: Amends s. 395.002, F.S., relating to definitions

Section 15: Amends s. 395.003, F.S., relating to licensure; denial, suspension, and revocation.

Section 16: Amends s. 395.009, F.S., relating to minimum standards for clinical laboratory test results and diagnostic X-ray results; prerequisite for issuance or renewal of license.

Section 17: Creates s. 395.0091, F.S., relating to alternate-site testing.

Section 18: Amends s. 395.0161, F.S., relating to licensure inspection.

Section 19: Amends s. 395.0163, F.S., relating to construction inspections; plan submission and approval; fees.

Section 20: Amends s. 395.0197, F.S., relating to internal risk management program.

Section 21: Repeals s. 395.1046, F.S., relating to complaint investigation procedures.

Section 22: Amends s. 395.1055, F.S., relating to rules and enforcement.

Section 23: Repeals s. 395.10971, F.S., relating to purpose.

Section 24: Repeals s. 395.10972, F.S., relating to Health Care Risk Manager Advisory Council.

Section 25: Amends s. 395.10973, F.S., relating to powers and duties of the agency.

Section 26: Repeals s. 395.10974, F.S., relating to health care risk managers; qualifications, licensure, fees.

Section 27: Repeals s. 395.10975, F.S., relating to grounds for denial, suspension, or revocation of a health care risk manager's license; administrative fine.

Section 28: Amends s. 395.602, F.S., relating to rural hospitals.

²³³ S. 400.980(2), F.S.

²³⁴ Id.

- Section 29:** Amends s. 395.603, F.S., relating to deactivation of general hospital beds; rural hospital impact statement.
- Section 30:** Repeals s. 395.604, F.S., relating to other rural hospital programs.
- Section 31:** Repeals s. 395.605, F.S., relating to emergency care hospitals.
- Section 32:** Amends s. 395.701, F.S., relating to annual assessments on net operating revenues for inpatient and outpatient services to fund public medical assistance; administrative fines for failure to pay assessments when due; exemption.
- Section 33:** Amends s. 395.7015, F.S., relating to annual assessment on health care entities.
- Section 34:** Amends s. 400.0625, F.S. relating to minimum standards for clinical laboratory test results and diagnostic X-ray results.
- Section 35:** Amends s. 400.464, F.S., relating to home health agencies to be licensed; expiration of license; exemptions; unlawful acts; penalties.
- Section 36:** Amends s. 400.471, F.S., relating to application for license; fee.
- Section 37:** Amends s. 400.474, F.S., relating to administrative penalties.
- Section 38:** Amends s. 400.476, F.S., relating to staffing requirements; notifications; limitations on staffing services.
- Section 39:** Amends s. 400.484, F.S., relating to right of inspection; deficiencies; fines.
- Section 40:** Amends s. 400.497, F.S., relating to rules establishing minimum standards.
- Section 41:** Amends 400.506, F.S., relating to licensure of nurse registries; requirements; penalties.
- Section 42:** Amends s. 400.606, F.S., relating to license; application; renewal; conditional license or permit; certificate of need.
- Section 43:** Amends s. 400.925, F.S. relating to definitions.
- Section 44:** Amends s. 400.931, F.S., relating to application for license; fee.
- Section 45:** Amends s. 400.933, F.S., relating to licensure inspections and investigations.
- Section 46:** Amends s. 400.980, F.S., relating to health care services pools.
- Section 47:** Amends s. 400.9905, F.S., relating to definitions.
- Section 48:** Amends s. 408.033, F.S., relating to local and state health planning.
- Section 49:** Amends s. 408.036, F.S., relating to projects subject to review; exemptions.
- Section 50:** Amends s. 408.061, F.S., relating to data collection; uniform systems of financial reporting; information relating to physician charges; confidential information; immunity.
- Section 51:** Amends s. 408.07, F.S., relating to definitions.
- Section 52:** Amends s. 408.20, F.S., relating to assessments; Health Care Trust Fund.
- Section 53:** Repeals s. 408.7056, F.S., relating to Subscriber Assistance Program.
- Section 54:** Amends s. 408.802, F.S., relating to applicability.
- Section 55:** Creates s. 408.803, F.S., relating to definitions.
- Section 56:** Amends s. 408.806, F.S., relating to license application process.
- Section 57:** Amends s. 408.810, F.S., relating to minimum licensure requirements.
- Section 58:** Amends s. 408.812, F.S., relating to unlicensed activity.
- Section 59:** Amends s. 408.820, F.S., relating to exemptions.
- Section 60:** Amends s. 409.905, F.S., relating to mandatory Medicaid services.
- Section 61:** Amends s. 409.9116, F.S., relating to disproportionate share/financial assistance program for rural hospitals.
- Section 62:** Amends s. 409.975, F.S., relating to managed care plan accountability.
- Section 63:** Amends s. 429.02, F.S., relating to definitions.
- Section 64:** Amends s. 429.04, F.S. relating to facilities to be licensed; exemptions.
- Section 65:** Amends s. 429.08, F.S., relating to unlicensed facilities; referral of person for residency to unlicensed facility; penalties.
- Section 66:** Amends s. 429.176, F.S., relating to notice of change of administrator.
- Section 67:** Amends s. 429.41, F.S., relating to rules establishing standards.
- Section 68:** Amends s. 456.001, F.S., relating to definitions.
- Section 69:** Amends s. 456.057, F.S., relating to ownership and control of patient records; report or copies of records to be furnished; disclosure of information.
- Section 70:** Amends s. 458.307, F.S., relating to Board of Medicine.
- Section 71:** Amends s. 458.345, F.S., relating to registration of resident physicians, interns, and fellows; list of hospital employees; prescribing of medicinal drugs; penalty.

- Section 72:** Repeals Part I of ch. 483, F.S., relating to clinical laboratories.
- Section 73:** Amends s. 483.294, F.S., relating to inspection of centers.
- Section 74:** Amends s. 483.801, F.S., relating to exemptions.
- Section 75:** Amends s. 483.803, F.S., relating to definitions.
- Section 76:** Amends s. 483.813, F.S., relating to clinical laboratory personnel license.
- Section 77:** Amends s. 491.003, F.S., relating to definitions.
- Section 78:** Amends s. 627.351, F.S., relating to insurance risk apportionment plans.
- Section 79:** Amends s. 627.602, F.S., relating to scope, format of policy.
- Section 80:** Amends s. 627.64194, F.S., relating to coverage requirements for services provided by nonparticipating providers; payment collection limitations.
- Section 81:** Amends s. 627.6513, F.S., relating to scope.
- Section 82:** Effective January 1, 2018, amends s. 641.185, F.S., relating to health maintenance organization subscriber protections.
- Section 83:** Effective January 1, 2018, amends s. 641.312, F.S., relating to scope.
- Section 84:** Effective January 1, 2018, amends s. 641.3154, F.S., relating to organization liability; provider billing prohibited.
- Section 85:** Effective January 1, 2018, amends s. 641.51, F.S., relating to quality assurance program; second medical opinion requirement.
- Section 86:** Effective January 1, 2018, amends s. 641.511, F.S., relating to subscriber grievance reporting and resolution requirements.
- Section 87:** Effective January 1, 2018, amends s. 641.515, F.S., relating to investigation by the agency.
- Section 88:** Effective January 1, 2018, amends s. 641.55, F.S., relating to internal risk management program.
- Section 89:** Repeals s. 641.60, F.S., relating to Statewide Managed Care Ombudsman Committee.
- Section 90:** Amends s. 641.70, F.S., relating to agency duties relating to the Statewide Managed Care Ombudsman Committee and the district managed care ombudsman committees.
- Section 91:** Amends s. 641.75, F.S., relating to immunity from liability; limitation on testimony.
- Section 92:** Amends s. 766.118, F.S., relating to determination of noneconomic damages.
- Section 93:** Amends s. 766.202, F.S., relating to definitions; ss. 766.201-766.212.
- Section 94:** Amends s. 945.36, F.S., relating to exemption from health testing regulations for law enforcement personnel conducting drug tests on inmates and releasees.
- Section 95:** Amends s. 1009.65, F.S., relating to Medical Education Reimbursement and Loan Repayment Program.
- Section 96:** Provides an effective date of July 1, 2017, except as otherwise expressly provided in the act.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

AHCA will realize an annual decrease in revenue of approximately \$64,866 from the repeal of the risk manager application licensure and licensure fees. There will be an annual decrease in revenue of approximately \$1,383,400 from the repeal of AHCA's clinical laboratory licensure requirement and subsequent licensure application fees. Three FTEs currently assigned to the Laboratory Licensure Unit within the Bureau of Health Facility Regulations will be repurposed.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

There appears to be a potential for economic impact to certain providers, including clinical labs and health care risk managers that no longer need to be licensed by the state or pay state licensure fees. Also, provisions in the bill that streamline the licensure process for various providers should ease the administrative burden on those providers to comply with licensing laws.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

AHCA has sufficient rulemaking authority necessary to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

At lines 214-215, the bill repeals the Board of Clinical Laboratory Personnel in part III of chapter 483, F.S. The repeal appears to be a scrivener's error as there was no intention to repeal the board, only to make a conforming change following the repeal of part I of chapter 483, F.S. The language should be revised to read:

22. The Board of Clinical Laboratory Personnel, created under part II ~~III~~ of chapter 483.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES