HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 597 Health Care Facility Regulation
SPONSOR(S): Yarborough
TIED BILLS: **IDEN./SIM. BILLS:** SB 622

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee	12 Y, 0 N	Royal	Crosier
2) Health Care Appropriations Subcommittee	13 Y, 0 N, As CS	Clark	Pridgeon
3) Health & Human Services Committee			

SUMMARY ANALYSIS

HB 597 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 between part I of ch. 395, F.S., ch. 400, F.S., and part II of ch. 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 (ALFs) by strengthening the enforcement capabilities of AHCA.
- Defines the assistance an ALF must provide a resident under the Resident Bill of Rights.
- 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 ch. 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 ch. 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 the 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 language that prevents nurse registries from marketing their services.
- Excludes individuals from employment with licensees if they have a pending domestic violence offense and excludes providers from participation in the Medicaid program for criminal offenses including offenses related to the provision of health care services, fraud, and controlled substances.
- Establishes the authority of a county with a public health trust over the trust's facility.
- Makes necessary conforming changes throughout the statutes to reflect the changes proposed in the bill.

The bill has a negative fiscal impact on AHCA due to a decrease in revenues from the repeal of certain licensure application fees; however, regulatory trust fund revenues are sufficient to absorb this loss. In addition, AHCA should experience a positive fiscal impact due to administrative efficiencies, including a decreased need for full-time equivalent positions.

The bill has an effective date of July 1, 2018.

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 49,500 individual providers.[1] Regulated providers include:

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

Health Care Facility Licensing

Background

Certain health care providers[2] are regulated under part II of ch. 408, F.S., which is the Health Care Licensing Procedures Act (Act), or core licensing statutes. The Act provides uniform licensing procedures and standards for 29 provider types.[3] In addition to the Act, each provider type has an

[1] Agency for Health Care Administration, *Health Quality Assurance*, 2017, available at http://ahca.myflorida.com/MCHQ/ (last visited November 20, 2017).
[2] "Provider" means any activity, service, agency, or facility regulated by the agency and listed in s. 408.802, F.S.
[3] S. 408.802, F.S.

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.[4]

Relatives

The term "relative" is not currently defined in the Act. The Act makes portions of patient records that contain the name, residence or business address, telephone number, social security or other identifying number, or photograph of the patient's relative confidential and exempt from public records.[5] The Act also requires a provider furnish any relative of a person who has applied to be admitted by the provider with a copy of its last inspection report upon request.[6]

Unlicensed Activity

It is unlawful for any person or entity to own, operate, or maintain an unlicensed provider. Unlicensed activity constitutes harm that materially affects the health, safety, and welfare of clients.[7] AHCA works closely with the Department for Children and Families (DCF), The Attorney General's Medicaid Fraud Control Unit, Medicaid Program Integrity, and the Department of Elder Affairs when unlicensed activity is discovered. Currently, some cases AHCA receives from the DCF concerning a victim of unlicensed activity do not currently fall under DCF's current statutory authority for the protection of vulnerable adults[8], so the DCF does not have the authority to open a case or move residents from an unlicensed facility.

Ownership

Current law requires an application for change of ownership of a provider to comply with all aspects of an initial license application, including submitting proof of financial ability to operate.[9]

Current law requires an applicant for licensure to disclose each controlling interest.[10] A controlling interest is an applicant or licensee, a person or entity that serves as an officer or on the board of directors, or a person or entity with 5% or greater ownership interest. Overtime, organizations have reorganized to move owners outside the disclosure requirements, such as through a parent corporation that wholly owns the owner of a licensee. This arrangement enables persons with an adverse criminal or regulatory history to control health care provider operations without disclosure.

Hospice Licensure

Hospice authorizing statutes require initial and change of ownership applicants to submit a copy of the most recent profit-loss statement and licensure inspection if the applicant is an existing licensed health care provider.[11] The Act also requires certificate of need applicants that are existing licensed health care provers to submit a profit-loss statement for the two previous fiscal years' operation.[12] Hospices are subject to certificate of need review.[13] The Act also requires applicants and licensees to provide proof of financial ability to operate in order to obtain and maintain a license.[14] Applicants and licensees must submit a pro forma balance sheet, a pro forma cash flow statement and a pro forma income and

[4] S. 408.832, F.S.
[5] S. 408.061(7), F.S.
[6] S. 408.811(6)(b), F.S.
[7] S. 408.812, F.S.
[8] Ch. 415, F.S. provides DCF with authority to investigate complaints alleging abuse, neglect or exploitation of vulnerable adults and to provide protective services to vulnerable adults.
[9] S. 408.806, F.S.
[10] Id.
[11] S. 400.606. F.S.
[12] S. 408.037(1)(c), F.S.
[13] S. 408.036, F.S.
[14] S. 408.810(8), F.S.

expense statement for the first 2 years of operation that provide evidence of having sufficient assets, credit, and projected revenues to cover liabilities and expenses.[15]

Background Investigations

At the time of licensure, a level 2 background screening[16] must be conducted on the following persons:

- The licensee, if an individual;
- The administrator or similarly titled individual who is responsible for the day-to-day operation of the provider;
- The financial officer or similarly titled individual who is responsible for the financial operation of the provider;
- Any person who has a controlling interest if AHCA has reason to believe that such person has been convicted of a prohibited offense;[17] and
- Any person, as required by authorizing statutes, seeking employment with a licensee or provider and who is expected to provide personal care or services directly to clients or have access to client funds, personal property, or living areas; and any person contracting with a licensee to provide such service or have such access.

All electronically submitted fingerprints retained by the Department of Law Enforcement (FDLE) are checked against all incoming arrest fingerprints.[18] If there is a match with a retained fingerprint submission, FDLE notifies AHCA of the arrest. Currently, FDLE may only search against incoming Florida arrest fingerprints. If an arrest occurs in another state or by the federal government, the arrest will not be included in the arrest notifications. The screening is valid for 5 years, after which an individual must be re-screened.

The Federal Bureau of Investigations (FBI) provides the "Rap Back" services that allows authorized agencies to receive ongoing status notifications of any criminal history reported to the FBI on certain individuals.[19] Currently, the national background screening is a one-time snapshot of an individual's criminal history background.

Effect of the Bill – Health Care Facility Licensing

Relatives

The bill defines "relative" for purposes of the Act. The term "relative" is not currently defined in the Act. The proposed definition clarifies who qualifies as a relative for the public records exemption for information related to a patient's relative in a patient's record and for receiving a copy of facility's inspection report.

Additionally, 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.

[15] Rule 59A-35.062, F.A.C.
[16] Under s. 435.04, F.S., a level 2 screening includes fingerprinting for statewide criminal history checks through the Department of Law Enforcement and national criminal history records check through the Federal Bureau of Investigations, and may include local criminal records checks through local law enforcement agencies.
[17] S. 435.04(2), F.S., provides a list of prohibited offenses.
[18] FDLE, *Criminal History Records Checks/Background Checks Fact Sheet*, (Feb. 14, 2017), available at https://www.fdle.state.fl.us/cms/Criminal-History-Records/Documents/BackgroundChecks_FAQ.aspx (last visited November 27, 2017)
[19] FBI, "Next Generation Identification (NGI)," available at https://www.fbi.gov/services/cjis/fingerprints-and-other-biometrics/ngi (last visited November 27, 2017).

Unlicensed Activity

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.

Ownership

The bill exempts a change of ownership applicant 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 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 to exclude bad actors from owning, directly or indirectly, a licensed facility.

Hospice Licensure

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. Profit-loss statements and proof of financial ability are already required to be collected pursuant to the Act and licensure inspection reports for all health care providers are readily available via the internet.

Expiration Dates

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 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.

Background Investigations

Currently, a background screening for an employee of a licensee that is a controlling interest is only initiated if AHCA has evidence of a conviction of a disqualifying offense. This provision limits AHCA's ability to properly vet potential facility operators and conflicts with Medicaid screening requirements. The bill amends the language for background screening requirements to include background screenings for all employees of a licensee that are a controlling interest.

The bill excludes from employment with licensees persons who have been arrested for and are awaiting final disposition of domestic violence offense. Under current law, to be excluded from employment for a domestic violence offense, a person must have been found guilty of or have entered a plea of nolo contendere or guilty to such offense.[20]

[20] S. 435.04(3), F.S.

The bill also amends language to require contractors who work 20 or more hours a week and provide personal care or service and have access to client funds or personal property, or living area to have a Level 2 screening. This change allows for consistency in screening standards for contractors who are performing the same duties as employees of facilities, but are currently not required to be screened.

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.[21] Services performed in clinical labs include:

- The examination of fluids or other materials taken from the human body;[22]
- The examination of tissue taken from the human body;[23] and
- The examination of cells from individual tissues or fluid taken from the human body.[24]

Clinical laboratories are regulated under part I of ch. 483, F.S. In keeping with federal law and regulations, clinical laboratories must meet appropriate standards.[25] 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 program[26] and standards of performance in the examination of specimens for clinical laboratory proficiency testing programs using external quality control procedures.[27] AHCA may impose an administrative fine of up to $1,000 per violation of any statute or rule.[28] In determining the penalty to be imposed for a violation, AHCA must consider the following factors:

- 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.[29]

In 1993, Florida enacted legislation requiring all facilities, including doctor's offices, performing clinical laboratory testing to be licensed.[30] AHCA previously issued two types of clinical laboratory licenses: one for laboratories that only performed waived testing and one for laboratories that performed non-waived testing.[31] Waived tests are simple laboratory examinations and procedures that have an insignificant risk of erroneous result; any other tests are considered non-waived.[32] In 2009, the requirement for laboratories that performed waived testing to obtain a state license was repealed. However, 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.[33]

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[21] S. 483.041, F.S.
[22] S. 483.041(2)(a), F.S.
[23] S. 483.041(2)(b), F.S.
[24] S. 483.041(2)(c), F.S.
[25] S. 483.021, F.S.
[26] S. 483.051(2)(a), F.S.
[27] S. 483.051(2)(b), F.S.
[28] S. 483.221(1), F.S.
[29] S. 483.221(2)(a)-(d), F.S.
[30] Id.
[31] 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 visited November 20, 2017).
[32] Examples of waived tests include urine dipstick, blood glucose, etc. A full list of waived tests can be found at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm (last visited November 20, 2017).
[33] 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 visited November 20, 2017).

Currently, all clinical laboratories performing non-waived testing in Florida must hold both a valid state license and federal CLIA certificate.[34]

Clinical Laboratory Improvement Amendments of 1988

The federal Centers for Medicare & Medicaid Services (CMS), within the United States Department of Health and Human Services, regulates all laboratory testing performed on humans in the United States through the CLIA.[35] The purpose of the CLIA program is to establish quality standards for all laboratory testing to ensure accuracy, reliability, and timeliness of test results regardless of where the test was performed.[36] The Division of Laboratory Services, within the Survey and Certification Group, under the Center for Clinical Standards and Quality in CMS has the responsibility for implementing the CLIA Program, including laboratory registration, fee collection, onsite surveys, and enforcement.[37] In total, CLIA covers approximately 254,000 laboratory entities.[38]

In 1992, the federal government required all facilities, including doctor's offices, performing clinical laboratory testing to register with the CLIA program.[39] The CLIA program issues five types of certificates:

- Certificate of Waiver – Issued to a laboratory that performs only waived tests;
- Certificate of Provider-Performed Microscopy Procedures [40] - Issued to a laboratory in which a physician, midlevel practitioner, or dentist performs specific microscopy procedures during the course of a patient's visit. This certificate permits the laboratory to also perform waived tests;
- Certificate of Registration – Issued to a laboratory to allow the laboratory to conduct nonwaived testing until the laboratory is inspected to determine its compliance with CLIA regulations;
- Certificate of Compliance - Issued to a laboratory after a survey is conducted and the laboratory is found to be in compliance with all applicable CLIA requirements; and
- Certificate of Accreditation - Issued to a laboratory on the basis of the laboratory's accreditation by an accreditation organization approved by the CMS.[41]

Alternate Site Laboratory Testing

Generally, a hospital's main or central laboratory or satellite laboratories that are licensed clinical laboratories established on the same or adjoining grounds of a hospital licensed under ch. 395, F.S., may perform clinical laboratory testing.[42] 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,

[34] Id. In an effort to streamline the licensing process, Florida enacted comprehensive basic licensure requirements under part II of ch. 408, F.S. that impacted all facilities licensed by AHCA, including clinical laboratories. Health care facility licensing procedures can also be found in Chapter 59A-35, F.A.C.
[35] 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 visited November 20, 2017).
[36] Department of Health and Human Services, Office of the Inspector General, *Enrollment and Certification Processes in the Clinical Laboratory Improvement Amendments Program*, (Aug. 2001), available at https://oig.hhs.gov/oei/reports/oei-05-00-00251.pdf (last visited November 20, 2017)
[37] Id.
[38] Supra, FN 31.
[39] Supra, FN 27.
[40] 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 visited November 20, 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.
[41] Centers for Medicare and Medicaid Services, *Clinical Laboratory Improvement Amendments (CLIA): How to Obtain a CLIA Certificate*, (March 2006), available https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/HowObtainCLIACertificate.pdf (last visited November 20, 2017). All certificates are effective for two years.
[42] Rule 59A-7.034, F.A.C.

at a nurse station, in an operating room or the emergency room, or anywhere else under the administrative control of a hospital. AHCA has 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.

Effect of the Bill – Clinical Laboratories

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. Clinical laboratories will continue to be certified by the CLIA program under federal law.[43] Such certification is required for a clinical laboratory to provide testing services in Florida.

The bill defines clinical laboratory and clinical laboratory examination for clinical laboratory personnel by relocating the existing definitions from the provisions being repealed.

The bill moves language which grants AHCA rulemaking authority to adopt criteria for alternate-site testing to be performed under the supervision of a clinical laboratory director, to s. 395.0091, F.S.

The bill moves language being struck in s. 483.245(1), F.S., prohibiting clinical laboratory rebates, to the section on general authority concerning kickbacks, s. 456.054, F.S.

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,[44] and can play a role in reducing safety, finance, and patient problems in the organization or facility.[45] Health care risk managers may perform such duties as event and incident risk management; clinical, financial, legal, and general business responsibilities; statistical analysis; and claims management.[46] However, the job description of a health care risk manager is unique to the organization at which he or she is employed.

Every hospital and ambulatory surgical center (ASC) licensed under part I of ch. 395, F.S., is required to establish and maintain an internal risk management program that is overseen by a health care risk manager.[47] The purpose of the risk management program is to control and prevent medical accidents and injuries.[48] 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;

[43] Agency for Health Care Administration, *2018 Agency Legislative Bill Analysis*, November 14, 2017 (on file with the Health and Human Services Committee).
[44] 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 November 20, 2017).
[45] Id.
[46] American Society for Healthcare Risk Management, *Overview of the Healthcare Risk Management Profession*, available at http://www.ashrm.org/about/HRM_overview.dhtml (last visited November 20, 2017).
[47] S. 395.0197(1)-(2), F.S.
[48] S. 395.10971, F.S.

- A system for informing a patient or an individual that she or he was the subject of an adverse incident; and
- An incident reporting system which allows for the reporting of adverse incidents to the risk manager within 3 business days after their occurrence.[49]

Licensure of Health Care Risk Managers

Florida is the only state to require the licensure of health care risk managers.[50] Health care risk managers are licensed by AHCA. 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; and
- Medical terminology.[51]

AHCA must issue a license to an applicant who affirmatively proves that he or she is:

- 18 years of age or over; and
- 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.[52]

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.[53] On average, for the past five years, approximately 174 initial applications for licensure are received and 181 licensees fail to renew each year.[54]

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 for various grounds, including submitting false information in a license application, unlicensed practice, various criminal disqualifications, and the following:

- 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;

[49] S. 395.0197(1)(a)-(d), F.S.
[50] 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 visited November 20, 2017).
[51] S. 395.10974(1), F.S.
[52] S. 395.10974(2). F.S.
[53] Supra, FN 39.
[54] Id.

- 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; or
- Discriminating against patients, employees, or staff on account of race, religion, color, sex, or national origin.[55]

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.[56] In the last 5 years, AHCA received three complaints against health care risk managers. The complaints involved allegations for which AHCA does not have regulatory and disciplinary authority such as practicing law without a license and activities of the individuals as claims adjusters for an insurance company not as the risk manager of a licensed facility.[57]

Health Care Risk Manager Advisory Council

Current law authorizes AHCA to establish a seven-member Health Care Risk Manager Advisory Council (Council) to advise AHCA on health care risk manager issues.[58] If the Council is established, it 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 ch. 458 or ch. 459.[59]

Currently, there are no appointed Council members and there have been no Council meetings for at least ten years.[60]

Effect of the Bill – Health Care Risk Managers

The bill repeals health care risk manager licensure requirements 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. Repeal of the Council is appropriate if the health care risk manager licensure requirements are repealed.

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.

[55] S. 395.10975(1), F.S.
[56] S. 395.0197(16), F.S.
[57] E-mail correspondence with AHCA staff (on file with the Health and Human Services Committee).
[58] S. 395.10972, F.S.
[59] S. 395.10972(1)-(5), F.S.
[60] Supra, FN 39.

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.[61] A personal service is direct physical assistance with, or supervision of, the activities of daily living and the self-administration of medication.[62] Activities of daily living include ambulation, bathing, dressing, eating, grooming, toileting, and other similar tasks.[63]

ALFs are licensed and regulated by AHCA under part I of ch. 429, F.S., and part II of ch. 408, F.S.[64] 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,[65] limited mental health services,[66] and extended congregate care services.[67] The Department of Elder Affairs (DOEA) is responsible for establishing training requirements for ALF administrators and staff.[68]

As of November 20, 2017, there are 3,108 licensed ALFs in Florida with 98,833 beds.[69]

An ALF administrator is responsible for the operation and maintenance of an ALF.[70] Administrators must meet minimum training and education requirements established by 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.[71] 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;

[61] S. 429.02(5), F.S. An ALF does not include an adult family-care home or a non-transient public lodging establishment.
[62] S. 429.02(16), F.S.
[63] S. 429.02(1), F.S.
[64] Under s. 429.04, F.S., the following are exempt from licensure: ALFs operated by an agency of the federal government; facilities licensed under ch. 393, F.S., relating to individuals with developmental disabilities; facilities licensed under ch. 394, F.S., relating to mental health; licensed adult family care homes; a person providing housing, meals, and one or more personal services on a 24-basis in the person's own home to no more than 2 adults; certain facilities that have been incorporated in this state for 50 years or more on or before July 1, 1983; certain continuing care facilities; certain retirement facilities; and residential units located within a community care facility or co-located with a nursing home or ALF in which services are provided on an outpatient basis.
[65] S. 429.07(3)(c), F.S. Limited nursing services include acts that may be performed by a person licensed nurse but are not complex enough to require 24-hour nursing supervision and may include such services as the application and care of routine dressings, and care of casts, braces, and splints (s. 429.02(13), F.S.)
[66] S. 429.075, F.S. A facility that serves one or mental health residents must obtain a licensed mental health license. A limited mental health ALF must assist a mental health patient in carrying out activities identified in the resident's community support living plan. A community support plan is written document that includes information about the supports, services, and special needs of the resident to live in the ALF and a method by which facility staff can recognize and respond to the signs and symptoms particular to that resident which indicate the need for professional services (s. 429.02(7), F.S.)
[67] S. 429.07(3)(b), F.S. Extended congregate care facilities provide services to an individual that would otherwise be ineligible for continued care in an ALF. The primary purpose is to allow a resident the option of remaining in a familiar setting from which they would otherwise be disqualified for continued residency as they become more impaired.
[68] S. 429.52, F.S.
[69] Agency for Health Care Administration, *Facility/Provider Search Results-Assisted Living Facilities*, available at http://www.floridahealthfinder.gov/facilitylocator/ListFacilities.aspx (report generated on November 20, 2017).
[70] S. 429.02(2), F.S.
[71] S. 429.52(2), F.S.

- 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; and
- Care of persons with Alzheimer's disease and related disorders.[72]

All ALF administrators and managers must successfully complete ALF core training course and pass a competency test within 3 months from the date of becoming an ALF administrator.[73] Administrators must complete at least 12 contact hours of continuing education every 2 years.[74] Effective October 1, 2015, each new ALF administrator or manager, 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.[75]

An ALF must provide appropriate care and services to meet the needs of the residents admitted to the facility.[76] The owner or facility administrator determines whether an individual is appropriate for admission to the facility based on certain criteria.[77] 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.[78]

Unlicensed Assisted Living Facilities

All facilities that meet the definition of an ALF must be licensed except:

- A facility, institution, or other place operated by the federal government;
- A facility licensed under ch. 393, F.S.,[79] or ch. 394, F.S.;[80]
- A facility licensed as an adult family-care home;
- Any person who provides housing, meals, and one or more personal services[81] on a 24-hour basis in the person's own for to not more than two adults who do not receive optional state supplementation.[82] The person providing the housing, meals, and personal services must own or rent the home and reside therein;
- Certain homes or facilities approved by the U.S. Department of Veterans Affairs;
- Certain facilities that have been incorporated in this state for 50 years or more on or before July 1, 1983;
- Any facility licensed under ch. 651, F.S., as a continuing care retirement community, or a retirement community that provide certain services to its residents who live in single-family homes, duplexes, quadraplexes, or apartments on its campus under certain conditions; and
- A residential unit for independent living located within a facility certified under ch. 651, F.S., or co-located with a licensed nursing home.[83]

[72] S. 429.52(3), F.S.
[73] Rule 58A-5.0191(a), F.A.C.
[74] S. 429.52(5), F.S.
[75] S. 429.52(1), F.S.
[76] For specific minimum standards, see Rule 58A-5.0182, F.A.C.
[77] S. 429.26, F.S., and Rule 58A-5.0181, F.A.C.
[78] S. 429.28, F.S.
[79] These include facilities licensed by the Agency for Persons with Disabilities for individuals with developmental disabilities.
[80] These include mental health facilities licensed by AHCA, in consultation with the Department of Children and Families.
[81] S. 429.02(17), F.S. defines personal services as "direct physical assistance with supervision of the activities of daily living, and the self-administration of medicine, and other similar services which the department may define by rule."
[82] Optional State Supplementation is a cash assistance program that supplements the income of eligible individuals to help them pay for room and board. The programs is funded entirely by state general revenue. In most instances, the maximum monthly payment is $78.40. AHCA, *Optional State Supplementation*, available at http://www.fdhc.state.fl.us/SCHS/ALWG/archived/docs/2011/2011-11-07_08/OSSFACT-102011.pdf (last visited November 20, 2017).
[83] S. 429.04, F.S.

A person who owns, operates, or maintains an unlicensed ALF commits a felony of the third degree.[84] Any person found guilty of operating an unlicensed ALF a second or subsequent time commits a felony of the second degree.[85] Health care practitioners must report an unlicensed ALF to AHCA.[86] Any provider who knowingly discharges a patient to an unlicensed ALF is subject to sanction by AHCA.[87] AHCA works with the Department of Children and Families, the Attorney General's Medicaid Fraud Control Unit,[88] Medicaid Program Integrity, and DOEA when unlicensed activity is discovered.[89]

If a person operates an unlicensed ALF due to a change in the law or rules adopted thereunder within 6 months after the effective date of the change, a facility must apply for a license or cease operation within 10 working days of receiving notification from AHCA.[90] Failure to comply is a felony of the third degree.[91] Each day of continued operation is considered a separate offense.[92]

In the last 5 years, AHCA received 765 complaints involving unlicensed ALFs, 281 of which were substantiated.[93]

Inspections, Surveys and Monitoring Visits

Current law authorizes AHCA to inspect each licensed ALF at least once every 24 months to determine compliance with statutes and rules. Section 408.813, F.S. categorizes violations into four classes according to the nature and gravity of its probable effect on residents. 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.[94] Similarly, the Resident Bill of Rights requires AHCA to perform a biennial survey to determine whether a facility is adequately protecting residents' rights.[95]

During any calendar year in which no survey is performed, AHCA may conduct at least one monitoring visit of a facility, as necessary, to ensure compliance of a facility with a history of certain violations that threaten the health, safety, or security of residents. If warranted, AHCA will perform an inspection as a part of a complaint investigation of alleged noncompliance with the Resident Bill of Rights.[96]

Facilities with limited nursing services (LNS) or extended congregate care (ECC) licenses are subject to monitoring visits by AHCA to inspect 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

[84] S. 429.08(1)(b), F.S.
[85] S. 429.08(1)(c), F.S.
[86] S. 429.08(2)(a), F.S.
[87] S. 429.08(2)(b), F.S.
[88] The Medicaid Fraud Control Unit investigates and prosecutes Medicaid provider fraud, as well as allegations of patient, abuse, neglect, and exploitation in facilities receiving payments under the Medicaid program, such as nursing homes and assisted living facilities. Office of the Attorney General, *Medicaid Fraud Control Unit,* available at http://www.myfloridalegal.com/pages.nsf/Main/EBC480598BBF32D885256CC6005B54D1 (last visited November 20, 2017).
[89] Supra, FN 39.
[90] S. 429.08, F.S.
[91] Id. A felony in the third degree is punishable by a term of imprisonment of up to 5 years (s. 775.082, F.S.), and a fine of up to $5,000 (s. 775.083, F.S.)
[92] Supra, FN 86.
[93] Supra, FN 53.
[94] S. 429.34(2), F.S.
[95] S. 429.28(3), F.S.
[96] Id.

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.

Penalties

Under s. 408.813, F.S., ALFs are subject to administrative fines imposed by AHCA for certain types of violations. In addition, 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 must deny or revoke the license of an ALF with 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.[97] 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.[98] AHCA is required to publicly post notification of a license suspension or revocation, or denial of a license renewal, at the facility.[99] Finally, ch. 825, F.S., provides criminal penalties for the abuse, neglect, and exploitation of elderly persons[100] and disabled adults.[101]

Resident Contracts

All residents of an ALF must be covered by a contract, executed at or before the time of admission, between the resident and the ALF.[102] Each contract must specifically describe the services and accommodations to be provided by the facility, along with the charges and rates. The contract must also include provision that requires the ALF to give at least 30 days written notice of a rate increase.

Assistance to Residents

An ALF may provide assistance to a resident who is medically stable with self-administration of a routine, regularly scheduled medication that is intended to be self-administered if there is a documented request by and the written informed consent of the resident.[103] This assistance includes, among other things:

- Taking a medication from where it is stored and bring it to the resident;
- In the presence of the resident, reading the label, opening the container, removing the prescribed amount from the container, and closing the container;
- Placing the dosage in the resident's hand or in another container and lifting the container to the resident's mouth;
- Returning medication to proper storage; and
- Maintaining a record of when a resident receives assistance with self-administration.[104]

[97] S. 429.14(4), F.S.
[98] S. 408.814(1), F.S.
[99] S. 429.14(7), F.S.
[100] "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 ch. 825, F.S., that the accused did not know the age of the victim. S. 825.104, F.S.
[101] "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.
[102] S. 429.24, F.S.
[103] S. 429.256(2), F.S.
[104] S. 429.256(3)(a), F.S. A resident may also receive assistance with applying topical medications, using a nebulizer, using a glucometer to perform blood-glucose level checks, putting on and taking off anti-embolism stockings, applying and removing an oxygen cannula, the use of a continuous airway pressure device, measuring vital signs, and colostomy bags.

Under the Resident's Bill of Rights, the ALF must provide its residents with access to adequate and appropriate health care. An ALF may not be able to provide all health care needed for a resident but may facilitate the provision of such health care services.

Effect of the Bill – Assisted Living Facilities.

ALF Licensure Compliance

Currently, a facility administrator must complete core educational requirements prior to or within a reasonable time of assuming his or her position. The bill requires administrators complete the core educational requirements within 90 days of the date of employment at an ALF. The bill prohibits a facility from operating for more than 120 consecutive days without an administrator who has completed core educational requirements.

Current law exempts from ALF licensure an individual who provides housing, meals, and one or more personal services on a 24-hour basis in the individual's own home to two or more adults who do not receive optional state supplementation.[105] The bill requires that the individual must establish the home as his or her permanent residence. The bill establishes a presumption that if the individual asserts a homestead exemption at an address other than the address used for the exemption from licensure, that the address is not his or her permanent residence. This exemption does not apply to an individual or entity that previously held a license that was revoked, denied renewal, or voluntarily relinquished during an enforcement proceeding.

ALF Unlicensed Activity

Under current law, there are several exemptions from ALF licensure. The bill creates additional exemptions:

- Hospitals licensed under ch. 395, F.S.;
- Nursing homes licensed under part II of ch. 400, F.S.;
- Inpatient hospices licensed under part IV of ch. 400, F.S.;
- Homes for special services licensed under part V of ch. 400, F.S.;
- Intermediate care facilities licensed under part VIII of ch. 400, F.S.; and
- Transitional living facilities licensed under part XI of ch. 400, F.S.

In an AHCA investigation of a complaint of unlicensed activity, the bill places the burden of proving that an individual or entity is exempt from licensure on the individual or entity claiming the exemption.

The bill makes it a third degree felony to own, operate, or maintain an unlicensed ALF after receiving notice from AHCA. Under current law, a person has 10 days from the date of notification to apply for a license or cease operations before he or she is regarded as committing a felony of the third degree. The bill eliminates the 10-day waiting period.

The bill modifies the definition of "personal services" to close loopholes taken advantage of by unlicensed providers. Because s. 429.02(17), F.S., defines personal services as "direct physical assistance with supervision of the activities of daily living, *and* the self-administration of medicine, *and* other similar services which the department may define by rule," the statute could be interpreted to require all of the criteria be met in order to meet the definition of personal services. As an example, an unlicensed provider giving multiple patients assistance with medication would not meet the definition because the unlicensed provider was also not giving direct physical assistance with the activities of daily living. The bill changes the definition of "personal services" to direct physical assistance with supervision of the activities of daily living, *or* the self-administration of medicine, *or* other similar services which the department may define by rule." The change allows AHCA to prosecute unlicensed

[105] S. 429.04(1)(d), F.S.

providers who meet any of the criteria in the definition rather than only providers that meet all of the criteria.

ALF Inspections and Surveys

Currently, AHCA must inspect an ALF every 24 months. The bill aligns the inspection schedule with the core licensing statute (ch. 408, F.S.), by requiring that re-licensure inspections be conducted biennially. This will provide AHCA with more flexibility in scheduling inspections. The bill retains and relocates the authority to conduct monitoring visits in calendar years in which a survey is not performed from the Resident Bill of Rights to the statutory section on inspections.

ALF Resident Contracts

Current law requires an ALF to provide a resident a 30-day written notice of a rate increase; however, it is unclear whether the notice requirement also applies to service changes. Under the bill, a facility does not have to provide a resident 30-day written notice if it offers a new service or if an accommodation is amended or implemented in a resident's contract for which the ALF did not previously charge the resident. For example, if a resident returns from a hospital stay with a new need for wound care, the resident's personal services plan would be amended immediately and the resident would begin receiving the new care immediately, while the assisted living facility would be able to begin charging immediately.

ALF Assistance to Residents

Current law governing assistance with self-administered medications requires that the ALF employee to read the medication label every time the assistance is provided. The bill authorizes an ALF resident to decline the reading of a label at each time of assistance.

Currently, the Resident Bill of Rights states that a resident has the right to assistance from the ALF in obtaining access to adequate and appropriate health care. The bill clarifies this right by defining such assistance as the management of medication, assistance in making appointments for health care services, providing transportation to health care appointments, and performing certain other health care services by appropriately licensed personnel or volunteers, including:

- Taking resident vital signs;
- Managing pill organizers for residents who self-administer medication;
- Give prepackaged enemas ordered by a physician;
- Observe and document residents and report such observations to the resident's physician;
- In an emergency, exercise professional duties until emergency medical personnel assume responsibility for care; and
- For facilities with 17 or more beds, have a functioning automated external defibrillator on the premises at all times.

Current law requires an ALF to provide a copy of the resident's complete records within 10 days, upon the request of a resident or his or her representative. The bill requires an ALF to respond to such requests in the same timeframe as required for nursing homes, which is within 14 working days of a request for a current resident and within 30 days for a request relating to a former resident.[106]

Mobile Surgical Facilities

Background

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

[106] S. 400.145, F.S.

> [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 ch. 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 ch. 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 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.[107] 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.[108]

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

- The governing board bylaws, rules and regulations, or other written organizational plan;
- A roster of medical staff members;
- A 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.[109]

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.[110] Upon receipt of the required information, AHCA will conduct a licensure inspection to determine compliance with the applicable statutes

[107] S. 395.003, F.S. and Rule 59A-5.003, F.A.C., contain the licensure provisions for mobile surgical facilities.
[108] Rule 59A-5.003(4)(a)-(c), F.A.C.
[109] Rule 59A-5.003(5), F.A.C.
[110] Rule 59A-5.003(7), F.A.C.

and rules.[111] 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.[112] AHCA may revoke or deny a license if it there has been substantial failure to comply with the applicable statutes and rules.[113]

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.

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.[114]

Effect of the Bill – Mobile Surgical Facilities

The bill eliminates the "mobile surgical facility" license from statute by deleting the definition of mobile surgical facility and all other references to such a facility.

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.

Hospital Regulation

Background

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.

State-Operated Hospitals

State-operated hospitals are subject to the same licensure and reporting requirements as other licensed hospitals in the state, except hospitals operated by AHCA and the Department of Corrections are exempt from the requirement to file an annual financial statement. Hospitals operated by the Department of Children and Families (DCF) are not exempt. A primary purpose of the financial statement is to determine the payment each hospital must pay to the Public Medical Assistance Trust Fund (PMATF), which is used to fund health care services to indigent persons.[115] An assessment of 1.5% of the annual net operating revenue for inpatient services and 1% for outpatient services is collected.[116] Hospitals operated by AHCA and the Department of Corrections are exempt from paying this tax.[117]

DCF operates seven hospitals and treatment centers statewide:

- Florida State Hospital in Chattahoochee;

[111] Rule 59A-5.003(12), F.A.C.
[112] Rule 59A-5.003(13), F.A.C.
[113] 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.
[114] Supra, FN 39.
[115] S. 409.918, F.S.
[116] S. 395.701, F.S.
[117] Id.

- 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.[118]

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.[119]

Complaint Investigation Procedures

Under the core licensing statute (ch. 408, F.S.), AHCA may inspect or investigate a facility to determine the state of compliance with the core licensing statute, the facility authorizing statutes, and applicable rules.[120] Inspections must be unannounced, except for those performed pursuant to initial licensure and license renewal. If at the time of the inspection, AHCA identifies a deficiency, the facility must file a plan of correction within 10 calendar days of notification, unless an alternative timeframe is required.

For any violation of the core licensing statute, the facility authorizing statutes, or applicable rules, AHCA may impose administrative fines.[121] Violations are classified according to the nature of the violation and the gravity of its probable effect on clients:

- Class I violations are those conditions that AHCA determines presents an immediate danger to clients or there is a substantial probability of death or serious physical or emotional harm. These violations must be abated or eliminated within 24 hours unless a fixed period is required for correction.
- Class II violations are those conditions that AHCA determines directly threaten the physical and emotional health, safety, or security of clients.
- Class III violations are those conditions that AHCA determines indirectly or potentially threaten the physical or emotional health, safety, or security of clients.
- Class IV violations are those conditions that do not have the potential of negatively affecting clients.

AHCA may also impose an administrative fine for a violation that is not designated in one of the classes listed above.

Emergency Services

The federal Emergency Medical Treatment and Labor Act (EMTALA)[122] 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.[123] In 1987, Florida enacted the first statute requiring some degree of emergency services to be provided to a patient regardless of the patient's ability to pay.[124]

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[118] Department of Children and Families, *State Mental Health Treatment Facilities*, available at http://www.myflfamilies.com/service-programs/mental-health/state-mental-health-treatment-facilities (last visited November 20, 2017).
[119] Department of Corrections, *Reception and Medical Center (RMC)*, 2014, available at http://www.dc.state.fl.us/facilities/region2/209.html (last visited November 20, 2017).
[120] S. 408.811, F.S.
[121] S. 408.813, F.S.
[122] 42 U.S.C. §1395
[123] Richard E. Mills, *Access to Emergency Services and Care in Florida*, The Florida Bar Journal, January 1998, available at https://www.floridabar.org/news/tfb-journal/?durl=/DIVCOM/JN/jnjournal01.nsf/cb53c80c8fabd49d85256b5900678f6c/1C3429F6216E4EA985256ADB005D6190!opendocument (last viewed November 20, 2017).
[124] Id.

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.[125]

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.[126] Each hospital must retain records of each transfer made or received for a period of five years.[127] 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.[128]

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.[129]

Section 395.1046, F.S., provides the procedures for complaints against hospitals regarding emergency access issues, such as a person being denied emergency services and care.[130] 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.[131] AHCA may investigate emergency access complaints even if the complaint is withdrawn.[132] When the investigation is complete, AHCA prepares a report making a probable cause determination.[133]

Section 408.811, F.S. in the licensure act also provides procedures for investigating complaints and applies to all AHCA-regulated facilities. The investigative procedures in s. 395.1046, F.S. are the same as those in s. 408.811, F.S. However, s. 408.811, F.S. provides broader authority to AHCA to open an investigation whenever the agency deems necessary to determine compliance with the Act, authorizing statutes, and applicable rules, whereas s. 395.1046, F.S. provides authority for only complaint-based investigations.

[125] S. 395.1041(3)(a), F.S.
[126] S. 395.1041(3)(e), F.S.
[127] S. 395.1041(4)(a)1., F.S.
[128] S. 395.1041(3)(f), F.S.
[129] S. 395.1041(5)(a), F.S.
[130] S. 395.1041(1), F.S.
[131] S. 395.1046(1), F.S.
[132] Id.
[133] S. 395.1046(2), F.S.

Adult Cardiovascular Services

Section 408.0361, F.S., establishes two levels of hospital program licensure for Adult Cardiovascular Services (ACS). A Level I program is authorized to perform adult percutaneous cardiac intervention (PCI)[134] without onsite cardiac surgery and a Level II program is authorized to perform PCI with onsite cardiac surgery.[135]

Level I ACS Programs

Licensed Level I ACS programs provide diagnostic and therapeutic cardiac catheterization services, including PCI, on a routine and emergency basis, but do not have on-site open-heart surgery capability.[136] For a hospital seeking a Level I ACS program license, it must demonstrate that, for the most recent 12-month period as reported to AHCA, it has:

- Provided a minimum of 300 adult inpatient and outpatient diagnostic cardiac catheterizations; or
- Discharged or transferred at least 300 inpatients with the principal diagnosis of ischemic heart disease;[137] and that it has formalized, written transfer agreement with a hospital that has a Level II program.[138]

Licensed Level I ACS programs must comply with the guidelines that apply to diagnostic cardiac catheterization services[139] and PCI, including guidelines for staffing, physician training and experience, operating procedures, equipment, physical plant, and patient selection criteria to ensure patient quality and safety.[140] Additionally, they must comply with the reporting requirements of the ACC-National Cardiovascular Data Registry.[141]

Level I ACS programs must meet the following staffing requirements:

- Each cardiologist shall be an experienced physician who has performed a minimum of 75 interventional cardiology procedures, exclusive of fellowship training, within the previous 12 months from the date of the Level I ACS application or renewal application.
- Physicians with less than 12 months experience shall fulfill applicable training requirements prior to being allowed to perform emergency PCI in a hospital that is not licensed for a Level II ACS program.
- Nursing and technical catheterization laboratory staff must:
    - Be experienced in handling acutely ill patients requiring intervention or balloon pump;
    - Have at least 500 hours of previous experience in dedicated cardiac interventional laboratories at a hospital with a Level II adult cardiovascular services program;

[134] Percutaneous cardiac intervention (PCI), commonly known as coronary angioplasty or angioplasty, is a nonsurgical technique for treating obstructive coronary artery disease.
[135] S. 408.0361(3)(a), F.S.
[136] Rule 59A-3.2085(16)(a), F.A.C. Level I programs are prohibited from performing any therapeutic procedure requiring trans-septal puncture, any lead extraction for a pacemaker, biventricular pacer or implanted cardioverter defibrillator.
[137] Heart condition caused by narrowed heart arteries. This is also called "coronary artery disease" and "coronary heart disease."
[138] S. 408.0361(3)(b), F.S.
[139] Rule 59A-3.2085(16)(a)5., F.A.C.
[140] Rule 59A-3.2085(16)(a)2., F.A.C., requires compliance with the American College of Cardiology/Society for Cardiac Angiography and Interventions Clinical Expert Consensus Document on Cardiac Catheterization Laboratory Standards: Bashore, et al., *ACC/SCA&I Clinical Expert Consensus Document on Catheterization Laboratory Standards*, Journal of the American College of Cardiology, Vol. 37, No. 8, June 2001: 2170-214. The rule also requires compliance the *ACC/AHA/SCAI 2005 Guideline Update for Percutaneous Coronary Intervention A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/SCAI Writing Committee to Update the 2001 Guidelines for Percutaneous Coronary Intervention)* available at http://circ.ahajournals.org/content/113/1/156.full.pdf+html (last visited November 20, 2017), which revises the guidelines for procedural complications, quality assurance, volume of elective procedures, the role of on-site cardiac surgical back-up, treatment of patients with certain diagnoses or medical history, the use of specified procedures and devices, and the use of certain drugs.
[141] Rule 59A-3.2085(16)(a)8., F.A.C. The reporting requirements include patient demographics; provider and facility characteristics; history/risk factors, cardiac status, treated lesions; intracoronary device utilization and adverse event rates; appropriate use criteria for coronary revascularization; and compliance with ACC/AHA clinical guideline recommendations.

    - Be skilled in all aspects of interventional cardiology equipment; and
    - Participate in a 24-hour-per-day, 365 day-per-year call schedule.
- A member of the cardiac care nursing staff who is adept in hemodynamic monitoring and Intra-aortic Balloon Pump management shall be in the hospital at all times.[142]

As of October 1, 2017, there are 56 general acute care hospitals with a Level I ACS program in Florida.[143]

Level II ACS Programs

Licensed Level II ACS programs provide diagnostic and therapeutic cardiac catheterization services on a routine and emergency basis, but have on-site open-heart surgery capability.[144] For a hospital seeking a Level II program license, it must demonstrate that, for the most recent 12-month period as reported to AHCA, it has:

- Performed a minimum of 1,100 adult inpatient and outpatient cardiac catheterizations, of which at least 400 must be therapeutic catheterizations; or
- Discharged at least 800 patients with the principal diagnosis of ischemic heart disease.[145]

In addition to the licensure requirements for a Level I ACS program, Level II ACS programs must also comply with the ACC/AHA 2004 Guideline Update for Coronary Artery Bypass Graft Surgery: A Report of the ACC/AHA Task Force on Practice Guidelines (Committee to Update the 1999 Guidelines for Coronary Artery Bypass Graft Surgery) Developed in Collaboration With the American Association for Thoracic Surgery and the Society of Thoracic Surgeons, which includes standards regarding staffing, physician training and experience, operating procedures, equipment, physical plant, and patient selection criteria to ensure patient quality and safety.[146] Level II ACS programs must also document an ongoing quality improvement plan to ensure that their cardiac catheterization, PCI, and cardiac surgical programs meet or exceed national quality and outcome benchmarks reported by the ACC-National Cardiovascular Data Registry and the Society of Thoracic Surgeons.[147] In addition to the reporting requirements for Level I ACS Programs, Level II ACS programs must meet the reporting requirements for the Society of Thoracic Surgeons National Database.[148]

As of October 1, 2017, there are 79 general acute care hospitals[149] with a Level II ACS program in Florida.[150]

Background Screening - Distinct Part Nursing Units

Some hospitals operate distinct part nursing units that provide long-term care. A distinct part nursing unit is a unit of a hospital certified for participation in the Medicare and Medicaid nursing facility program.[151] Skilled nursing units operate under the hospital's license and are not currently subject to

[142] Rule 59A-3.2085(16)(b), F.A.C.
[143] Supra FN 39.
[144] Rule 59A-3.2085(17)(a), F.A.C.
[145] S. 408.0361(3)(c), F.S.
[146] Rule 59A-3.2085(16)(a)5., F.A.C.
[147] Id. Eligible professionals must satisfactorily report 50 percent performance on at least nine quality measures for the annual reporting period. The measures address topics such as preoperative screenings, length of postoperative intubation, and length of postoperative stay.
[148] Rule 59A-3.2085(16)(a)5., F.A.C. The data collection form is available at https://www.ncdr.com/WebNCDR/docs/default-source/tvt-public-page-documents/tvt-registry_2_0_tavr_data-collection-form.pdf (last visited February 7, 2017).
[149] 64 Level II ACS programs were licensed pursuant to the grandfathering provisions of Chapters 2004-382 and 2004-383, Laws of Fla.; Agency for Health Care Administration, *Agency Analysis of SB 58 2017 Legislative Session*, Nov. 28, 2016 (on file with Health Innovation Subcommittee staff).
[150] Supra, FN 39.
[151] A distinct part nursing unit is a unit of a hospital certified for participation in the Medicare and Medicaid nursing facility program (s. 395.1055(3), F.S. A distinct part must be physically distinguishable from the larger institution and fiscally separate for cost reporting

the background screening requirements of nursing homes even though they provide skilled nursing care.

Standards for Tertiary Services

Certain tertiary health services provided by hospitals are subject to certificate of need review.[152] The following tertiary health services must undergo certificate of need review:

- Pediatric cardiac catheterization;
- Pediatric open-heart surgery;
- Neonatal intensive care units;
- Adult open heart surgery;
- Comprehensive medical rehab (CMR) services; and
- Organ transplantation, including
    - Heart;
    - Kidney;
    - Liver;
    - Bone marrow;
    - Lung; and
    - Pancreas.[153]

The certificate of need process includes standards for pediatric cardiovascular, neonatal intensive care units (NICU), transplant, psychiatric and comprehensive medical rehab services. Current licensure statutes, as opposed to certificate of need statutes, do not contain specific authority for AHCA to adopt or enforce through the facility's license on an ongoing basis. Additionally, licensure requirements are included in the survey process whereas certificate of need requirements are not.

Effect of the Bill – Hospital Regulation

Emergency Access Complaints

The bill eliminates redundant 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. Section 408.811, F.S., authorizes AHCA to inspect or investigate a licensed facility to ensure compliance with licensing requirements.

State-Operated Hospitals

The bill exempts all state-operated hospitals from the requirement to pay the annual assessment to the PMATF and to file an annual financial statement.

Adult Cardiovascular Services

The bill provides an exception to the qualifications for a Level I ASC program, which will allow the Lower Keys Medical Center to become a Level I ACS provider. The facility would have to meet the physician qualification requirements for Level I ACS providers currently in rule, and meet lower annual volume requirements. Currently, Level I ACS providers must provide a minimum of 300 adult inpatient and outpatient diagnostic cardiac catheterizations. The facility must provide a minimum of 100 adult

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purposes. *Medicare Provider Reimbursement Manual (2000)* available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R418PR1.pdf (last visited December 14, 2017).

[152] S. 408.032, F.S.

[153] Id.

inpatient and outpatient diagnostic cardiac catheterizations. The facility will not have to meet the transfer time requirements to a Level II hospital.

Additionally, the bill adds an option for meeting staffing qualifications for all ASC providers. Nurses working in a Level I hospital will be able to obtain the required training and experience within their hospital instead of training at a Level II hospital if the hospital has an annual volume of 500 or more percutaneous coronary interventions in which balloon angioplasty, stenting, rotational atherectomy, cutting balloon atheroma remodeling, and procedures relating to left ventricular support are performed with a 95% or more success rate and less than 5% complication rate.

Background Screening - Distinct Part Nursing Units

The bill requires level 2 background screenings for personnel of a distinct part nursing unit of a hospital. This is consistent with the requirement for nursing facilities personnel in long-term care units in s. 400.215, F.S.

Standards for Tertiary Services

The bill directs AHCA to implement minimum standards for neonatal intensive care units, transplant, psychiatric, and comprehensive medical rehab services. The Agency has rulemaking authority to implement the certificate of need review process for those services but does not currently have rulemaking authority under licensure standards for those services. The addition of these rules will require facilities who obtain a certificate of need to provide these services to continue to meet the licensure standards adopted by rule.

Rural Hospitals

Background

A rural hospital is an acute care hospital that has 100 or fewer licensed beds and an emergency room that is:[154]

- The sole provider within a county with a population density of up to 100 persons per square mile;[155]
- 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;[156]
- A hospital supported by a tax district or subdistrict whose boundaries encompass a population of up to 100 persons per square mile;[157]
- A hospital classified as a sole community hospital under 42 C.F.R. § 412.92 regardless of the number of licensed beds;[158]
- A hospital with a service area that has a population of up to 100 persons per square mile;[159] or
- A hospital designated as a critical access hospital, as defined in s. 408.07.[160]

[154] S. 395.602(2)(e), F.S.
[155] S. 395.602(2)(e)1., F.S.
[156] S. 395.602(2)(e)2., F.S.
[157] S. 395.602(2)(e)3., F.S.
[158] S. 395.602(2)(e)4., F.S.
[159] 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.
[160] S. 395.602(2)(e)6., F.S.

Special Designations for Rural Hospitals

AHCA licenses four classes of hospital.[161] Class I licenses include rural hospitals.[162] 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 who 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.[163]

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.[164]

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
- Inpatient medical care to persons needing such care up to 96 hours.[165]

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;[166]
- Is part of a network that includes rural primary care hospitals;

[161] Rule 59A-3.252(1), F.A.C.
[162] Rule 59A-3.252(1)(a)3., F.A.C.
[163] Rule 59A-3.252(2), F.A.C.
[164] Rule 59A-3.252(3), F.A.C.
[165] S. 395.602(2)(a), F.S.
[166] Rural Referral Centers are high-volume acute care rural hospitals that treat a large number of complicated cases.

- 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.[167]

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.[168]

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.[169] The designations of "emergency care hospital," "essential access community hospital," and "rural primary care hospital are redundant or obsolete since the implementation of the Critical Access Hospital program.[170]

Effect of the Bill – Rural Hospitals

The bill repeals the emergency care hospital, essential access community hospital, and rural primary care hospital designations. 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. A hospital currently meeting the definition of rural hospital will continue to be classified as a rural hospital.

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.[171] 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 Certificate of Need (CON) program.[172]

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.

Home Health Agencies

Background

Home health agencies (HHAs) are organizations licensed by AHCA to provide home health and staffing services.[173] 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;

[167] S. 395.602(2)(b), F.S.
[168] S. 395.602(2)(f), F.S.
[169] Medicare and Medicaid Programs; Reform of Hospital and Critical Access Hospital Conditions of Participation; Final Rule. 77 Fed. Reg. 95 (May 16, 2012). *Federal Register: The Daily Journal of the United States*, available at: https://www.gpo.gov/fdsys/pkg/FR-2012-05-16/pdf/2012-11548.pdf (last visited December 14, 2017). The Critical Access Hospital program is a federal program that pays certain state-designated rural hospitals an enhanced, cost-based rate for Medicare services. See, 42 U.S.C. 1395i-4; 42 U.S.C. 1395x; et al; and ss. 395.002, 395.602, 408.07, F.S.
[170] Supra, FN 161.
[171] S. 395.602(2)(c), F.S.
[172] Supra, FN 39.
[173] S. 400.462(12), F.S.

- 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.[174]

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.[175]

A HHA may also provide homemaker[176] and companion[177] 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.[178]

Licensure and Exceptions

Since 1975, HHAs operating in Florida have been required to obtain a state license.[179] HHAs must meet the general health care licensing provisions[180] and specific HHA licensure provisions and standards.[181] A HHA license is valid for 2 years, unless revoked.[182] 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.[183] As of November 20, 2017, there are 1,917 licensed HHAs in Florida.[184]

A HHA may obtain an initial license by submitting to AHCA a signed, complete, and accurate application and the $1,705 licensure fee.[185] The HHA must also submit the results of a survey conducted by AHCA.[186] The application must identify the geographic service areas[187] and counties in which the HHA will provide services. An initial licensure applicant must be fully accredited to obtain a license to provide skilled nursing services, however, accreditation is not required if, after initial licensure, a home health agency requests to begin providing skilled nursing services.

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 ch. 400, F.S., to serve its residents; and

[174] S. 400.462(14), F.S.
[175] S. 400.462(30), F.S.
[176] S. 400.462(16), F.S.
[177] S. 400.462(7), F.S.
[178] S. 400.462(13), F.S.
[179] SS. 36 – 51 of ch. 75-233, Laws of Fla.
[180] Part II of ch. 408, F.S.
[181] Part III of ch. 400, F.S., and Rule 59A-8, F.A.C.
[182] S. 408.808(1), F.S.
[183] S. 400.464(2), F.S. There are eleven health service planning districts grouped by county.
[184] Florida Health Finder, *Facility/Provider Search Results-Home Health Agencies*, available at http://www.floridahealthfinder.gov/facilitylocator/ListFacilities.aspx (report generated April 2, 2017).
[185] S. 400.471(5) and Rule 59A-8.003(12).
[186] Id.
[187] S. 408.032(5), F.S. lists the eleven health service planning districts grouped by county.

- A not-for-profit, community-based agency that provides early intervention services to infants and toddlers.[188]

For licensure renewal, the HHA must submit a signed renewal application, licensure fee and report the volume of patients serviced during the previous licensure period.[189] The requirement to report patient volume is found in both ss. 400.474(7), F.S. and 400.471(2)(c), F.S.

In addition to the requirements of the core licensing statute in s. 408.813, F.S.,[190] a HHA is also subject to inspections and investigations under its authorizing statute, s. 400.484, F.S. In conducting an inspection or investigation, AHCA may cite an HHA for violations of laws and rules and may impose administrative fines. Both s. 408.813, F.S., and s. 400.484, F.S., categorize violations into four defined classes according to the nature of the violation. Section 408.813, F.S., authorizes AHCA to impose fines for those violations "as provided by law", referring to s. 400.484, F.S., which specifies the fines AHCA may impose.

Sections 400.484 and 408.813, F.S., although quite similar, have a few slight differences and redundancies. For example, under s. 408.813, F.S., a Class I deficiency presents an imminent danger or a substantial probability of harm, and must be corrected within 24 hours (or within some other timeframe determined by AHCA). A Class I deficiency under s. 400.484, F.S., is one that results in *actual* harm *or* presents a *risk* of harm, and that section is silent on the timeframe in which a Class I deficiency must be corrected. Similarly, a Class II violation in s. 408.813, F.S., threatens physical and emotional health, while a Class II violation in s. 400.484, F.S., merely refers to "health". The definitions for Class III and Class IV violations appear to be largely redundant.

A HHA providing skilled nursing services for more than 30 days is required to employ a director of nursing[191] who is a Florida licensed registered nurse with at least one year of supervisory experience.[192] However, HHAs that are not Medicaid or Medicare certified and do not provide skilled care, or provide only physical, occupational, or speech therapy are not required to employ a director of nursing.

The director of nursing is responsible for overseeing the delivery of professional nursing and home health aide services[193] and must be readily available at the HHA or by phone for any eight consecutive hours between 7 a.m. to 6 p.m.[194] The director of nursing is also responsible for establishing and conducting an ongoing quality assurance program for services provided by the HHA.[195]

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.[196]

Effect of the Bill – Home Health Agencies

The bill requires that any HHA license issued on or after July 1, 2018, must specify the home health services the HHA is authorized to perform and whether such services are considered "skilled care." Currently, an initial licensure applicant must be fully accredited to obtain a license to provide skilled

[188] S. 400.464(5)(a)-(n), F.S.
[189] Ss. 400.474(7), F.S. and 400.471(2)(c), F.S. Rules 59A-8.003(2) and (12), F.A.C.
[190] S. 408.813, F.S.
[191] S. 400.462(10), F.S.
[192] S. 400.476(2), F.S.
[193] S. 400.462(10), F.S.
[194] Rule 59A-8.003(11)(a), F.A.C.
[195] Rule 59A-8.0095(2)(e), F.A.C.
[196] S. 400.476(2), F.S.

nursing services, however, accreditation is not required if, after initial licensure, a home health agency requests to begin providing skilled nursing services. The bill closes the loophole by which a home health agency could forgo full accreditation after initial licensure by requiring proof of accreditation when seeking approval to begin providing skilled nursing services.

In addition, the bill authorizes AHCA to issue a certificate of exemption to any person or HHA providing home health services that is exempt. The certificate of exemption is voluntary and expires after two years, at which time the exempt HHA may voluntarily reapply for a certificate. AHCA is authorized to charge $100 or the actual cost to process the certificate. This provides the industry an option for demonstrating to clients and payor sources that they are exempt from licensure.

The bill removes the exemption for HHAs that are not Medicaid or Medicare certified and do not provide skilled care, or provide only physical, occupational, or speech therapy 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 eliminates redundancy and resolves differences between the two sections of law. The bill retains the specified administrative fines that may be charged for each class of violations.

An HHA that wishes to provide services to Medicare or Medicaid patients must meet the certification standards for each program. However, if a home health agency does not provide services to Medicare or Medicaid patients, it does not need to meet the certification standards. Currently, AHCA lists a HHA as Medicare-certified or Medicaid-certified on the HHA's license. The bill deletes the requirement that a home health license states that if it is Medicare-certified or Medicaid-certified. According to ACHA, the proposed changes should eliminate confusion among providers and consumers, and should not have an adverse effect on AHCA or home health agency licensees.[197]

The bill repeals duplicative language that a HHA, for purpose of license renewal, report the volume of patients serviced during the previous licensure period.

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

Birth Centers

Background

A birth center is any facility, institution, or place, which is not an ambulatory surgical center, 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.[198] A birth center must include:

- Birthing rooms;
- Bath and toilet facilities;
- Storage areas for supplies and equipment;
- Examination areas; and
- Reception or family areas.[199]

A birth center must 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 a mother and baby.[200]

[197] Supra, FN 39.
[198] S. 383.302(2), F.S.
[199] S. 383.308(1), F.S.

Current law provides 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.[201] According to AHCA, there are currently no providers who meet these criteria.[202]

Effect of the Bill – Birth Centers

The bill repeals the 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.

Nurse Registries

Background

A nurse registry refers to 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 hospitals, nursing homes, hospices, ALFs, and other business entities.[203] A nurse registry is exempt from the licensing requirements of a HHA, but must be licensed as a nurse registry.[204]

A nurse registry is prohibited from providing remuneration to health care providers, health care provider office staff, immediate family members of a health care providers, and vendors for patient referrals.[205] The nurse registry is also prohibited from providing remuneration to a case manager, discharge planner, facility-based staff, or other third-party vendor who is involved in the discharge planning process.[206] However, if a nurse registry does not bill the Medicaid or Medicare programs or does not share a controlling interest in a licensed entity or facility that bills Medicaid or Medicare, this provision does not apply. Nurse registries are not eligible for participation in the Medicare program and are only authorized to participate in Florida Medicaid through the Long Term Care Waiver program. AHCA has received three complaints in the last 5 years against nurse registries for providing remuneration in violation of law. [207] However, the complaints were not substantiated and AHCA did not take any disciplinary action.

In accordance with s. 400.506(5)(a), F.S., the continued operation of an unlicensed nurse registry for more than 10 days after Agency notification is considered a second degree misdemeanor. Each day of continued non-compliance is considered a separate offense, with each offense carrying the potential for imprisonment of up to 60 days. In addition to the criminal actions, s. 400.506(5)(b), F.S., authorizes the Agency to impose a $500.00 fine for each day of continued non-compliance. However, s. 408.812, F.S., authorizes the Agency to impose a $1000.00 per day fine for each day of continued operation after Agency notification.

Agency records show that 37 complaints alleging nurse registry unlicensed activity were filed between January 1, 2012, and present and upon investigation, only 11 of the complaints were substantiated.[208] Of the 11 substantiated complaints, the Agency imposed an administrative fine of $46,000.00 for one unlicensed nurse registry who failed to discontinue operations after notification.

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[200] S. 383.308(2)(a), F.S.
[201] S. 383.335, F.S
[202] Supra, FN 39.
[203] S. 400.462(21), F.S.
[204] S. 400.506(1)(a), F.S. A licensed nurse registry may operate a satellite office.
[205] S. 400.506(15)(a)4., F.S.
[206] S. 400.506(15)(a)5., F.S.
[207] Supra, FN 39.
[208] Id.

Effect of the Bill – Nurse Registries

The bill repeals the two prohibitions on nurse registries that relate to remuneration by the registry to health care providers, facility staff, or third party vendors. However, nurse registries will continue to be subject to criminal penalties for patient brokering as provided for in s. 817.505, F.S.

Additionally, the bill resolves the conflict between ss. 400.606 and 408.812, F.S., for penalties of unlicensed facilities, referring to provisions in s. 408.812, F.S., so all licensed facilities will be subject to the same penalties. Unlicensed nurse registries will be subject to criminal penalties and administrative fines of $1000.00 per day for each day of continued operation after Agency notification.

Home Medical Equipment

A home medical equipment provider sells or rents, or offers to sell or rent, home medical equipment[209] and services or home medical equipment services[210] to or for a consumer. A home medical equipment provider must be licensed by AHCA.[211] Medical oxygen is defined as oxygen USP[212] which must be labeled in compliance with labeling requirements for oxygen under the federal act.[213] The Department of Business and Professional Regulation (DBPR) regulates medical equipment, including medical oxygen.[214] In 2014, part III of ch. 499, F.S., was created to regulate of medical gas, including medical oxygen, separate from other drugs and medical equipment.

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.

The bill modifies the definition of home medical equipment in s. 400.925(6), F.S., by restructuring and providing clarification of which items require home medical equipment licensure in order to sell and/or rent those items. The placement of the semi-colons in the current statutory definition is often misinterpreted to mean none of the items that are listed after “but does not include” are considered home medical equipment.[215]

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.[216] Registration or a license issued by AHCA is required for the operation of a health care services

[209] 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.
[210] 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.
[211] See generally s. 400.931, F.S.
[212] 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.
[213] S. 499.82(10), F.S.
[214] Ch. 499, F.S.
[215] Supra, FN 39.
[216] S. 400.980(1), F.S.

pool.[217] Currently, if a health care services pool must change information contained its original registration application, it must notify AHCA 14 days prior to the change.[218]

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.

Health Care Clinics

Health care clinics are licensed by AHCA under the Health Care Clinic Act (Act), ss. 400.990 - 400.995, F.S. [219] The Act creates many exceptions to this requirement.[220] Health care clinics exempt from licensure include:

- Entities owned, operated, or licensed by certain licensed facilities, licensed health care practitioners; and certain non-profit entities;
- Clinical facilities affiliated with an accredited medical school or an accredited college of chiropractic;
- Clinical
- Entities that only provide oncology or radiation therapy services by licensed physicians which are owned by a publicly-traded corporation;
- Entities that provide licensed practitioners to staff emergency room departments or to deliver anesthesia services in hospitals and derive at least 90 percent of their gross annual revenues from the provision of those services;
- Orthotic, prosthetic, pediatric cardiology, or perinatology clinical facilities or anesthesia clinical facilities that are not otherwise exempt and are a publicly-traded company or wholly owned by a publicly-traded company;
- Entities owned by certain corporations that have $250 million or more in total annual sales of health care services provided by licensed health care practitioners; and
- Certain entities that employ 50 or more licensed health care practitioners billing for medical services under a single tax identification number.[221]

A health care clinic may voluntarily apply for a certificate of exemption, and the fee for issuance of the certificate is $100.[222] There are currently 10,239 entities with certificates of exemption[223] under the Health Care Clinic Act. Certificates of exemption have no expiration date, and AHCA does not know if all of these entities still qualify for an exemption or whether the entity still exists.

The bill limits the health care clinic license exemption to two years. Therefore, an entity holding a voluntary certificate of exemption would need to renew the exemption biennially.

Nursing Home Guide

Under the §1864 Agreement of the Social Security Act, the Agency serves as an agent of the federal Centers for Medicare and Medicaid Services to provide regulatory oversight and perform certification functions for nursing homes in the state of Florida. Nursing homes are subject to a standard survey that is completed no later than 15.9 months after the previous survey. The Agency typically combines

[217] S. 400.980(2), F.S.
[218] Id.
[219] The Health Care Clinic Act was enacted in 2003 to reduce fraud and abuse in the personal injury protection insurance system. A health care clinic is an entity where health care services are provided to individuals and which tenders charges for reimbursement of such services (s. 400.9905(4), F.S.)
[220] Section 400.9905(4), F.S.
[221] S. 400.9905(4), F.S.
[222] Rule 59A-33.006, F.A.C.
[223] Supra, FN 39.

the standard federal survey with the standard state licensure survey, and many surveys may occur well before the 15.9-month mark.

Section 400.191, F.S. requires AHCA to publish a quarterly Nursing Home Guide in electronic form to assist consumers and their families in comparing and evaluating nursing home facilities. The Nursing Home Guide that includes survey and deficiency information, including federal and state recertification, licensure, revisit, and complaint survey information for the past 30 months.

However, if a provider's survey period were to be extended beyond the 15-month window, but still within the permissible 15.9-month window, it could possibly place them outside of the 30-month period preceding the release of the publication of the Guide. As a result, the provider could potentially be impacted with a rating of "NR" (Not Rated). According to the Nursing Home Guide Methodology[224], the deficiencies cited on an inspection are used to compute a score for the nursing home. The Nursing Home Guide was intended to consider at least two standard surveys and the loss of 1.8 months of data may result in the unintentional exclusion of some providers from being rated in the Nursing Home Guide.

The bill removes the 30-month time-frame for surveys to be included in the guide. The change would afford providers whose survey period may have exceeded 15 months the opportunity to receive a rating in the Nursing Home Guide.

Public Health Trusts

Current law authorizes each county to create a public corporate body known as a public health trust.[225] A public health trust may only be created if the governing body of the county of a public health trust declares that there is a need for the trust to function.[226] The governing body of the county must then designate health care facilities to be operated and governed by the trust and appoint a board of trustees (board).[227]

The purpose of a public health trust is to exercise supervisory control over the operation, maintenance, and governance of the designated health care facilities. A designated facility is any county-owned or county-operated facility used in connection with the delivery of health care.[228] Designated facilities include: [229]

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

[224] AHCA, *Nursing Home Guide Methodology*, available at: http://www.floridahealthfinder.gov/CompareCare/MethodologyNH.aspx (last visited December 14, 2017).
[225] Section 154.07, F.S.
[226] Id.
[227] Section 154.08, F.S., and s. 154.09, F.S.
[228] Section 154.08, F.S.
[229] Id.

- Parking facilities and areas serving health care facilities.

Current law authorizes the board of each public health trust to be the operator of, and governing body for, any designated facility.[230] The governing body of the county where the trust is located selects the board, which consists of between 7 and 21 members.[231] The members must be residents of the county in which the trust is located and are appointed on staggered terms which may not exceed 4 years.[232] The members serve without compensation, but are entitled to necessary expenses incurred in the discharge of their duties.[233]

The board's authority is subject to the limitation of the governing body of the county where the trust is located and includes the authority to: [234]

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

Miami-Dade County is the only county to have created a public health trust, Public Health Trust of Miami-Dade County (Trust), created in 1973.[235] The Trust's designated facilities include Jackson Memorial Hospital and all related facilities and real and personal property.

The bill grants a county with a public health trust exclusive jurisdiction over a designated facility owned or operated by that public health trust if it is located within the boundaries of a municipality.

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 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.[236]

[230] Id.
[231] Section 154.09, F.S.
[232] Id.
[233] Id.
[234] Id.
[235] Chapter 25A of the Miami-Dade County Code.
[236] 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 visited November 27, 2017).

Since 1973, under federal law,[237] 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.[238]

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.[239] The types of disputes that regulators consider relate to decisions to deny or limit coverage and judgments about medical necessity or appropriateness of care.[240]

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 Subscriber Assistance Program (SAP).[241]

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).[242]

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.[243]

The panel must consist of:

- Members employed by AHCA and members employed by the Office of Insurance Regulation (OIR), chosen by their respective agencies;
- 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.[244]

[237] Health Maintenance Organization Act of 1973, Title 42, Sec. 300e, et seq.
[238] Id.
[239] 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.
[240] Supra, FN 233.
[241] Id.
[242] Id.
[243] Id.
[244] S. 408.7056(11), F.S

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.[245]

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.[246] 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.[247] 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.

SAP Cases FY 2009-2010 through FY 2016-2017 (YTD)[248]

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
Total Number of Cases Received by SAP (MCD - # Medicaid cases)	498 (70 MCD)	506 (75 MCD)	415 (50 MCD)	213 (57 MCD)	160 (50 MCD)	238 (114 MCD)	350 (204 MCD)	253 (101 MCD)
Total Number of Cases Heard by The Panel (MCD - # Medicaid cases)	124 (7 MCD)	96 (9 MCD)	74 (3 MCD)	17 (2 MCD)	19 (8 MCD)	29 (12 MCD)	53 (37 MCD)	28 (12 MCD)
Outcomes of Cases								
Determined Non-jurisdictional	246	260	224	145	115	166	221	165
Incomplete Application	39	37	40	24	11	27	31	24
Request Withdrawn	27	21	20	9	6	11	26	10
Resolved Prior to Panel Hearing	68	82	55	18	9	7	19	26
Panel Found in Favor of Subscriber	23	23	19	5	7	7	27	6
Panel Found in Favor of Plan	95	83	57	12	12	17	25	22

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.[249] 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. Insurance companies may choose to participate in a process administered by the federal Department of Health and Human Services (HHS) or contract with independent review organizations in states where the federal government oversees the process.[250]

[245] S. 408.7056(11)(a), F.S.
[246] S. 408.7056(14)(b), F.S.
[247] Supra, FN 249.
[248] Supra, FN 39.
[249] 42 U.S.C. 300gg-19.
[250] What are my rights in an external review, Department of Health and Human Services. Available at: https://www.healthcare.gov/appeal-insurance-company-decision/external-review/ (last visited January 3, 2018).

Managed care plans that elected to participate in the federal program established by PPACA are no longer required to participate in the SAP.[251] 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.[252]

Effect of the Bill – Subscriber Assistance Program

The bill repeals s. 408.7056, F.S. that 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, consumers have access to the grievance resolution program provided by PPACA, through either the federally administered process or independent contractor review. Further, 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. 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.

Medicaid Provider Background Investigations

Current law excludes from participation in the Medicaid program, providers who have been convicted of a federal or state criminal offense relating to[253]:

- The delivery of goods or services under Medicare, Medicaid, or any other public or private health care or insurance program;
- Neglect or abuse of a patient in connection to the delivery of any health care good or service;
- Unlawful manufacture, distribution, prescription, or dispensing of a controlled substance;
- Fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct;
- Moral turpitude, if punishable by imprisonment by a year or more;
- Criminal use of a public record or public records information;
- Unlawful compensation of reward for official behavior;
- Corruption by threat against a public servant;
- Official misconduct;
- Bid tampering;
- Falsifying records;
- Misuse of confidential information; or
- Interfering with or obstructing an investigation into any of the above-listed criminal offenses.

Current law does not provide those who have a disqualifying offense the ability to request an exemption from disqualification.

Effect of the bill – Medicaid Provider Background Investigations

The bill moves the disqualifying offenses for Medicaid providers from s. 409.907(10), F.S., to ch. 435, F.S., which provides those who have a disqualifying offense the ability to request an exemption from disqualification.

[251] Centers for Medicaid and Medicare Services, *The Center for Consumer Information & Insurance Oversight*, available at https://www.cms.gov/cciio/Programs-and-Initiatives/Consumer-Support-and-Information/External-Appeals.html (last visited November 20, 2017).
[252] Supra, FN 39.
[253] s. 409.907(10), F.S.

Managed Care Ombudsman Committees

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.[254] 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.
- District 10—Broward County.
- District 11—Miami-Dade and Monroe Counties.[255]

Each district committee must have at least nine members and no more than 16 members,[256] with the AHCA secretary appointing the first three committee members in each district.[257] Each committee is required to have:

- Multiple licensed physicians:
    - one physician licensed under ch. 458;
    - one osteopathic physician licensed under ch. 459;
    - one chiropractor licensed under ch. 460; and
    - one podiatrist licensed under ch. 461;
- One licensed psychologist;
- One registered nurse;
- One clinical social worker;
- One attorney; and
- One consumer.[258]

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.

[254] S. 641.60(2), F.S.
[255] S. 408.032(5), F.S.
[256] S. 641.65(2), F.S.
[257] S. 641.65(3)(a), F.S.
[258] S. 641.65(2), F.S.

- 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.[259]

Effect of the Bill - Managed Care Ombudsman Committees

The bill repeals the Statewide Managed Care Ombudsman Committee and district managed care ombudsman committees. 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.[260]

The bill provides an effective date of July 1, 2018.

B. SECTION DIRECTORY:

Section 1: Amends s. 20.43, F.S., relating to Department of Health.
Section 2: Creates s. 154.13, F.S.; relating to designated facilities; jurisdiction.
Section 3: Amends s. 220.1845, F.S., relating to contaminated site rehabilitation tax credit.
Section 4: Amends s. 376.30781, F.S., relating to tax credits for rehabilitation of drycleaning-solvent-contaminated sites and brownfield sites in in designated brownfield areas; application process; rulemaking authority; revocation authority.
Section 5: Amends s. 376.86, F.S., relating to Brownfield Areas Loan Guarantee Program.
Section 6: Amends s. 381.0031, F.S., relating to epidemiological research; report of diseases of public health significance to department.
Section 7: Amends s. 381.0034, F.S., relating to requirement for instruction on HIV and AIDS.
Section 8: Amends s. 381.004, F.S., relating to HIV testing.
Section 9: Amends s. 381.0405, F.S., relating to Office of Rural Health.
Section 10: Amends s. 381.14, F.S. relating to screening for metabolic disorders, other hereditary and congenital disorders, and environmental risk factors.
Section 11: Amends s. 383.30, F.S., relating to Birth Center Licensure Act; short title.
Section 12: Amends s. 383.301, F.S., relating to licensure and regulation of birth centers.
Section 13: Amends s. 383.302, F.S., relating to definitions of terms used in ss. 383.30-383.335.
Section 14: Amends s. 383.305, F.S., relating to licensure; fees.
Section 15: Amends s. 383.309, F.S., relating to minimum standards for birth centers; rules and enforcement.
Section 16: Amends s. 383.313, F.S., relating to performance of laboratory and surgical services; use of anesthetic and chemical agents.
Section 17: Amends s. 383.33, F.S., relating to administrative penalties; moratorium on admissions.
Section 18: Repeals s. 383.335, F.S., relating to partial exemptions.
Section 19: Amends s. 384.31, F.S., relating to testing of pregnant women; duty of the attendant.
Section 20: Amends s. 385.211, F.S., relating to refractory and intractable epilepsy treatment and research at recognized medical centers.
Section 21: Amends s. 394.4787, F.S., relating to definitions; ss. 394-4786, 394.4787, 394.4788, and 394.4789.
Section 22: Amends s. 395.001, F.S., relating to legislative intent.
Section 23: Amends s. 395.002, F.S., relating to definitions
Section 24: Amends s. 395.003, F.S., relating to licensure; denial, suspension, and revocation.
Section 25: 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 26: Creates s. 395.0091, F.S., relating to alternate-site testing.

[259] S. 641.65(6), F.S.
[260] Supra, FN 39.

Section 27: Amends s. 395.0161, F.S., relating to licensure inspection.
Section 28: Amends s. 395.0163, F.S., relating to construction inspections; plan submission and approval; fees.
Section 29: Amends s. 395.0197, F.S., relating to internal risk management program.
Section 30: Repeals s. 395.1046, F.S., relating to complaint investigation procedures.
Section 31: Amends s. 395.1055, F.S., relating to rules and enforcement.
Section 32: Repeals s. 395.10971, F.S., relating to purpose.
Section 33: Repeals s. 395.10972, F.S., relating to Health Care Risk Manager Advisory Council.
Section 34: Amends s. 395.10973, F.S., relating to powers and duties of the agency.
Section 35: Repeals s. 395.10974, F.S., relating to health care risk managers; qualifications, licensure, fees.
Section 36: 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 37: Amends s. 395.602, F.S., relating to rural hospitals.
Section 38: Amends s. 395.603, F.S., relating to deactivation of general hospital beds; rural hospital impact statement.
Section 39: Repeals s. 395.604, F.S., relating to other rural hospital programs.
Section 40: Repeals s. 395.605, F.S., relating to emergency care hospitals.
Section 41: 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 42: Amends s. 395.7015, F.S., relating to annual assessment on health care entities.
Section 43: Amends s. 400.0625, F.S. relating to minimum standards for clinical laboratory test results and diagnostic X-ray results.
Section 44: Amends s. 400.191, F.S., relating to availability, distribution, and posting of reports and records.
Section 45: Amends s. 400.464, F.S., relating to home health agencies to be licensed; expiration of license; exemptions; unlawful acts; penalties.
Section 46: Amends s. 400.471, F.S., relating to application for license; fee.
Section 47: Amends s. 400.474, F.S., relating to administrative penalties.
Section 48: Amends s. 400.476, F.S., relating to staffing requirements; notifications; limitations on staffing services.
Section 49: Amends s. 400.484, F.S., relating to right of inspection; deficiencies; fines.
Section 50: Amends s. 400.497, F.S., relating to rules establishing minimum standards.
Section 51: Amends s. 400.506, F.S., relating to licensure of nurse registries; requirements; penalties.
Section 52: Amends s. 400.606, F.S., relating to license; application; renewal; conditional license or permit; certificate of need.
Section 53: Amends s. 400.925, F.S. relating to definitions.
Section 54: Amends s. 400.931, F.S., relating to application for license; fee.
Section 55: Amends s. 400.933, F.S., relating to licensure inspections and investigations.
Section 56: Amends s. 400.980, F.S., relating to health care services pools.
Section 57: Amends s. 400.9905, F.S., relating to definitions.
Section 58: Amends s. 400.9935, F.S., relating to clinic responsibilities.
Section 59: Amends s. 408.033, F.S., relating to local and state health planning.
Section 60: Amends s. 408.036, F.S., relating to projects subject to review; exemptions.
Section 61: Amends s. 408.0361, F.S., relating to cardiovascular services and burn unit licensure.
Section 62: Amends s. 408.061, F.S., relating to data collection; uniform systems of financial reporting; information relating to physician charges; confidential information; immunity.
Section 63: Amends s. 408.07, F.S., relating to definitions.
Section 64: Amends s. 408.20, F.S., relating to assessments; Health Care Trust Fund.
Section 65: Repeals s. 408.7056, F.S., relating to Subscriber Assistance Program.
Section 66: Amends s. 408.802, F.S., relating to applicability.
Section 67: Creates s. 408.803, F.S., relating to definitions.
Section 68: Amends s. 408.806, F.S., relating to license application process.
Section 69: Amends s. 408.809, F.S., relating to background screening; prohibited offenses.

Section 70: Amends s. 408.810, F.S., relating to minimum licensure requirements.
Section 71: Amends s. 408.812, F.S., relating to unlicensed activity.
Section 72: Amends s. 408.820, F.S., relating to exemptions.
Section 73: Amends s. 409.905, F.S., relating to mandatory Medicaid services.
Section 74: Amends s. 409.907, F.S., relating to Medicaid provider agreements.
Section 75: Amends s. 409.9116, F.S., relating to disproportionate share/financial assistance program for rural hospitals.
Section 76: Amends s. 409.975, F.S., relating to managed care plan accountability.
Section 77: Amends s. 429.02, F.S., relating to definitions.
Section 78: Amends s. 429.04, F.S. relating to facilities to be licensed; exemptions.
Section 79: Amends s. 429.08, F.S., relating to unlicensed facilities; referral of person for residency to unlicensed facility; penalties.
Section 80: Amends s. 429.176, F.S., relating to notice of change of administrator.
Section 81: Amends s. 429.19, F.S., relating to violations; imposition of administrative fines; grounds.
Section 82: Amends s. 429.24, F.S., relating to contracts.
Section 83: Amends s. 429.28, F.S., relating to Resident Bill of Rights.
Section 84: Amends s. 429.294, F.S., relating to availability of facility records for investigation of resident's rights violations and defenses; penalty.
Section 85: Amends s. 429.34, F.S., relating to right of entry and inspection.
Section 86: Amends s. 429.52, F.S., relating to staff training and educational programs; core educational requirements.
Section 87: Amends s. 435.04, F.S., relating to level 2 screening standards.
Section 88: Amends s. 456.001, F.S., relating to definitions.
Section 89: Amends s. 456.054, F.S., relating to kickbacks prohibited.
Section 90: 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 91: Amends s. 456.076, F.S., relating to impaired practitioner programs.
Section 92: Amends s. 458.307, F.S., relating to Board of Medicine.
Section 93: 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 94: Amends s. 459.021, F.S., relating to registration of resident physicians, interns, and fellows; list of hospital employees; penalty.
Section 95: Repeals part I of ch. 483, F.S., relating to clinical laboratories.
Section 96: Amends s. 483.294, F.S., relating to inspection of centers.
Section 97: Amends s. 483.801, F.S., relating to exemptions.
Section 98: Amends s. 483.803, F.S., relating to definitions.
Section 99: Amends s. 483.813, F.S., relating to clinical laboratory personnel license.
Section 100: Amends s. 483.823, F.S., relating to qualifications of clinical laboratory personnel.
Section 101: Amends s. 491.003, F.S., relating to definitions.
Section 102: Amends s. 627.351, F.S., relating to insurance risk apportionment plans.
Section 103: Amends s. 627.602, F.S., relating to scope, format of policy.
Section 104: Amends s. 627.6406, F.S., relating to maternity care.
Section 105: Amends s. 627.64194, F.S., relating to coverage requirements for services provided by nonparticipating providers; payment collection limitations.
Section 106: Amends s. 627.6513, F.S., relating to scope.
Section 107: Amends s. 627.6574, F.S., relating to maternity care.
Section 108: Amends s. 641.185, F.S., relating to health maintenance organization subscriber protections.
Section 109: Amends s. 641.31, F.S., relating to health maintenance contracts.
Section 110: Amends s. 641.312, F.S., relating to scope.
Section 111: Amends s. 641.3154, F.S., relating to organization liability; provider billing prohibited.
Section 112: Amends s. 641.51, F.S., relating to quality assurance program; second medical opinion requirement.
Section 113: Amends s. 641.511, F.S., relating to subscriber grievance reporting and resolution requirements.

Section 114: Amends s. 641.515, F.S., relating to investigation by the agency.
Section 115: Amends s. 641.55, F.S., relating to internal risk management program.
Section 116: Repeals s. 641.60, F.S., relating to Statewide Managed Care Ombudsman Committee.
Section 117: Repeals s. 641.65, F.S., relating to district managed care ombudsman committees.
Section 118: Repeals s. 641.67, F.S., relating to district managed care ombudsman committees; exemption from public records requirements; exceptions.
Section 119: Repeals s. 641.68, F.S., relating to district managed care ombudsman committees; exemption from public meeting requirements.
Section 120: Repeals 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 121: Repeals s. 641.75, F.S., relating to immunity from liability; limitation on testimony.
Section 122: Amends s. 766.118, F.S., relating to determination of noneconomic damages.
Section 123: Amends s. 766.202, F.S., relating to definitions; ss. 766.201-766.212.
Section 124: 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 125: Amends s. 1009.65, F.S., relating to Medical Education Reimbursement and Loan Repayment Program.
Section 126: Amends s. 1011.52, F.S., relating to appropriation to first accredited medical school.
Section 127: Provides an effective date of July 1, 2018.

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 $1,540,000 from the repeal of AHCA's clinical laboratory licensure requirement and subsequent licensure application fees.[261]

2. Expenditures:

AHCA will no longer expend funds to administer the SAP, health care risk manager licensure, and clinical laboratory licensure programs. AHCA will see an increased workload due to the new background screening requirements for distinct part nursing units and enforcement, issuance of certificates of exemption for health care clinics and home health agencies, and enforcement of rules regarding NICU, transplant, psychiatric and CMR services. However, AHCA will be able to absorb these costs and employees from the eliminated SAP, health care risk manager licensure, and clinical laboratory licensure programs will be reassigned to handle the increased workload.[262] The chart below shows the decreased need in FTEs, as well as the decrease in the number of licensure application reviews that will take place due to the elimination of the programs. Conversely, the chart also shows the new need for FTEs and the increased licensure application reviews due to the new programs that will be added.

[261] Supra, FN 39.
[262] E-mail correspondence with AHCA staff (on file with the Health and Human Services Committee).

PROGRAMS BEING ELIMINATED			
Program	**Portion of FTE Time on Project**	**Application Reduction**	**Application Increase**
SAP Program	-1.10		
Health Care Risk Manager Program	-1.00	-600/year	
Clinical Laboratory Program	-2.75	-2,200/year	
Totals	**-4.85**	**-2,800/year**	

PROGRAMS TO BE ADDED			
Health Care Clinic Exemption Applications	2.04		5,000/year
Home Health Agency Exemption Application	2.25		1,500/year
Totals	**4.29**		**6,500/year**

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill will have a positive economic impact to certain providers, including clinical laboratories 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.

To the extent that health care clinics and home health agencies apply for voluntary certificates of exemption, these entities will have to pay biennial renewal fees.

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:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On January 23, 2018, the Health Care Appropriations Subcommittee adopted two amendments to the bill. The first amendment revised language relating to the licensed bed capacity required to be classified as a sole community hospital. The second amendment eliminated the requirement that the Florida Department of Law Enforcement retain fingerprints of individuals screened until January 1, 2021, and eliminated the requirement to extend the fingerprint retention timeframe for individuals who passed a level 2 screening after December 31, 2012.

The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute as passed by the Health Care Appropriations Subcommittee.