The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Committee on Rules

BILL:	CS/CS/SB 622
INTRODUCER:	Rules Committee; Appropriations Committee (Recommended by Appropriations Subcommittee on Health and Human Services); and Senators Grimsley and Bean
SUBJECT:	Health Care Facility Regulation
DATE:	March 1, 2018 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Stovall	HP	**Favorable**
2.	Kidd	Williams	AHS	**Recommend: Fav/CS**
3.	Kidd	Hansen	AP	**Fav/CS**
4.	Looke	Phelps	RC	**Fav/CS**

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/CS/SB 622 amends numerous provisions related to the regulation of health care facilities by the Agency for Health Care Administration (AHCA or agency). The bill's provisions include, but are not limited to:

- Eliminating obsolete language and terms such as mobile surgical facility and provisions related to specialty definitions for rural hospitals, and certificate of need requirements for hospitals wanting to add adult open-heart services.
- Eliminating the requirement that health care facility risk managers be licensed by the state.
- Amending various statutes related to home health agencies, nurse registries, assisted living facilities (ALF), and general licensing requirements.
- Amending the pediatric cardiovascular technical advisory panel to add nonvoting members and to require additional reports. The bill also requires hospitals providing pediatric cardiology services meet certain guidelines.
- Requiring the AHCA to contract with certain entities to provide information about hospital's pediatric cardiac programs on AHCA's webpage.
- Exempting certain hospitals from volume requirements needed to provide Level I adult cardiovascular services (ACS).
- Specifying training that staff must have in hospitals providing ACS if the experience was not obtained in a hospital with a surgical center.

- Repealing the subscriber assistance program.
- Repealing state licensure of clinical laboratories in favor of deferring to federal requirements.
- Eliminating both statewide and district Ombudsman Committees.
- Extending from five to six years the period in which a Florida cancer center seeking NCI designation may participate in the Florida Consortium of National Cancer Institute Centers Program as a Tier 3 cancer center.

The bill will reduce state revenues by approximately $2.05 million annually as a result of the elimination of the risk manager application fees and the clinical laboratory licensing fees. This includes reductions of $1.6 million from the Health Care Trust Fund in ACHA, $0.3 million from the Grants and Donations Trust Fund in the Department of Health and $0.15 million from the General Revenue Fund.

The bill becomes effective on July 1, 2018.

II. Present Situation:

The Agency for Health Care Administration (AHCA) is created in s. 20.42, F.S, as the chief health policy and planning entity for the state and is responsible for, among other things, health facility licensure, inspection, and regulatory enforcement. AHCA licenses or certifies and regulates 40 different types of health care providers, including hospitals, nursing homes, ALFs, and home health agencies. In total, the agency licenses, certifies, regulates or provides exemptions for more than 42,000 providers. [1]

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

Due to the many diverse issues addressed by the bill, pertinent background is provided within the **Effect of Proposed Changes** portion of this analysis for the reader's convenience.

III. Effect of Proposed Changes:

This bill amends numerous statutes related to the AHCA.

Public Health Trust Facilities

Section 2 creates s. 154.13, F.S., to specify that any designated facility owned or operated by a public health trust and located within the boundaries of a municipality is under the exclusive jurisdiction of the county creating the public health trust and not within the municipality's jurisdiction. The Public Health Trust of Miami-Dade County is the only public health trust that owns/operates health care providers. Jackson Health System consists of three hospitals: Jackson Memorial, Jackson North Medical Center and Jackson South Community Hospital. These are the

[1] *See* the Agency for Health Care Administration, *Division of Health Quality Assurance*, available at: http://ahca.myflorida.com/MCHQ/index.shtml (last visited Nov. 29, 2017).
[2] *See* s. 408.802, F.S., for the health care provider types and applicable licensure statutes.

only hospitals owned by a public health trust, Public Health Trust of Miami-Dade County. According to the license information, there is also a nursing home, Jackson Memorial Perdue Medical Center and five hospital-based clinical laboratories that are part of Jackson Health System.[3]

Florida Consortium of National Cancer Institute Centers Program

A National Cancer Institute (NCI) designated center performs research related to cancer and delivers cutting-edge cancer treatments to patients.[4] NCI-designated cancer centers are recognized for their scientific leadership, resources, and the depth and breadth of their research.[5]

In 2014, the Legislature established the Florida Consortium of National Cancer Institute Centers Program to enhance the quality and competitiveness of cancer care in Florida, further a statewide biomedical research strategy directly responsive to the health needs of Florida's citizens, and capitalize on the potential educational opportunities available to students.[6] The DOH is directed to make quarterly distributions to Florida-based cancer centers that are NCI-designated cancer centers or comprehensive cancer centers, as well as cancer centers working toward achieving such designation.[7]

The law directs the DOH to calculate an allocation in combination with tier-allocated weights for distributing funds to participating cancer centers.[8] The tier-allocated weights are based on the NCI status of the center, as follows:[9]

- Tier I: NCI-designated comprehensive cancer center;
- Tier 2: NCI-designated cancer center; and
- Tier 3: Cancer center seeking designation as either an NCI-designated cancer center or NCI-designated comprehensive cancer center.

There are currently 3 participating cancer centers: H. Lee Moffitt Cancer Center, University of Florida Shands Cancer Hospital, and University of Miami Sylvester Comprehensive Cancer Center.[10] The H. Lee Moffitt Cancer Center is the only NCI-designated comprehensive cancer center in Florida and there are no NCI-designated cancer centers in the state.[11] The cancer

[3] Agency for Health Care Administration, *Senate Bill 622 Analysis* (Nov. 15, 2017) (on file with the Senate Committee on Health Policy.)
[4] National Cancer Institute, NCI-Designated Cancer Centers, available at https://www.cancer.gov/research/nci-role/cancer-centers (last visited Mar. 1, 2018).
[5] Id.
[6] Chapter 2014-165, Laws of Fla., codified at s. 381.915, F.S.
[7] Id. Such distributions are subject to an appropriation by the Legislature.
[8] Department of Health, Florida Consortium of National Cancer Institute Centers Program, Report to the Cancer Control and Research Advisory Council, p. 2, (July 1, 2017), available at http://www.floridahealth.gov/provider-and-partner-resources/research/NCI%20Report%202017.pdf (last visited Mar. 1, 2018).
[9] Section 381.915(4), F.S.
[10] Supra note 60.
[11] National Cancer Institute, Find a Cancer Center, available at https://www.cancer.gov/research/nci-role/cancer-centers/find#Florida (last visited Mar. 1, 2018).

centers at University of Florida and University of Miami are currently seeking NCI designation.[12]

To be eligible to continue receiving funding under the program, a cancer center seeking NCI-designation must:[13]

- Conduct cancer-related basic scientific research and cancer-related population scientific research;
- Offer and provide the full range of diagnostic and treatment services on site, as determined by the Commission on Cancer of the American College of Surgeons;
- Host or conduct cancer-related interventional clinical trials that are registered with the NCI's Clinical Trials Reporting Program;
- Offer degree-granting programs or affiliate with universities through degree-granting programs accredited or approved by a nationally recognized agency and offered through the center or through the center in conjunction with another institution accredited by the Commission on Colleges of the Southern Association of Colleges and Schools;
- Provide training to clinical trainees, medical trainees accredited by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association, and postdoctoral fellows recently awarded a doctorate degree; and
- Have more than $5 million in annual direct costs associated with their total NCI peer-reviewed grant funding.

A cancer center may only participate in Tier 3 for 5 years.[14]

Section 10 amends s. 381.915, F.S., to allow a cancer center to participate in Tier 3 for six years, rather than five years.

Birth Centers

Section 17 amends s. 383.313, F.S., to require that any birthing center that performs laboratory tests on its patients must be federally certified by the Federal Centers for Medicare and Medicaid Services (CMS) under the federal Clinical Laboratory Improvement Amendments (CLIA) and federal rules adopted thereunder. Currently, birthing centers are exempt from the requirement to be licensed as a clinical laboratory under part I of ch. 483, F.S.,[15] if the birth center has no more than five physicians and the tests are conducted exclusively for the diagnosis and treatment of clients of the birth center.

Section 18 repeals s. 383.335, F.S., which provides obsolete exemptions to certain rules related to birth centers. Currently, no providers meet these exemptions.[16]

[12] Supra note 60.
[13] Section 381.915(4)(c), F.S.
[14] Id.
[15] Part I of ch. 483, F.S., is repealed in this bill.
[16] Supra note 3

Mobile Surgical Facilities

Sections 23, 24, 25, 28, 29, 61, and 124 amend ss. 395.001, 395.002, 395.003, 395.0161, 395.0163, 408.036, and 766.118, F.S., respectively, to repeal obsolete provisions related to mobile surgical facilities. No license has been issued for a mobile surgical facility and none are anticipated. The Florida Department of Corrections operates one hospital: Reception and Medical Center Hospital in Lake Butler. The hospital does not offer surgical services directly to its inmates, but contracts with U.S. Medical Group, Inc., via its licensed Ambulatory Surgical Center, Modular Freestanding Surgery Center. This Ambulatory Surgical Center has been licensed since September 24, 2002, and is stationary on the premises of the correctional facility. A separate license type is not needed in order to meet the surgical needs of the inmate population.[17]

Alternate-Site Testing

Section 27 creates s. 395.0091, F.S., to define the term "alternate-site testing" to mean any laboratory testing done under the administrative control of a hospital, but performed out the of physical or administrative confines of the hospital's central laboratory. This section also requires the AHCA, in consultation with the Board of Clinical Laboratory Personnel, to adopt rules for criteria for alternate-site testing. The section establishes minimum criteria the rules must address and requires alternate-site testing locations to register when the associated hospital applies to renew its license. This change will keep the requirements in place for alternate-site testing after the repeal of provisions related to clinical laboratory state licensure.[18]

Deregulation of Risk Managers

Current law requires every hospital, ambulatory surgical center, and Health Maintenance Organization providing direct services to employ a state licensed health care risk manager to oversee the facility's risk management program. No other state requires licensure of risk managers. Other Florida licensed facilities such as nursing homes are not required to employ a licensed risk manager and can employ anyone meeting the facility's qualifications for their risk manager positions.

The health care risk manager licensure requirements have multiple pathways, including being licensed as a health care professional such as a nurse, respiratory therapist, physical therapist or emergency medical technician. Physician assistants and other professions licensed by the Florida Department of Health may not qualify unless they also meet another pathway. There are no licensure examinations, no continuing education requirements, and no method for the agency to determine a licensee's continued competency in health care risk management. Licensees are required to renew their license biennially. As there are no requalification requirements to renew a license, the process involves verification of contact information, employment, if applicable, and background screening status. Professional certification is available through the American Society for Healthcare Risk Management, but is not required for licensure.

[17] Supra note 3
[18] Supra note 3

The agency currently licenses 2,458 health care risk managers, of which only 602 (24.5 percent) report working in a licensed capacity for at least one hospital or ambulatory surgical center. A licensed health care risk manager may also appoint an unlicensed delegate to assist with risk management functions. On-the-job training is a common pathway to licensure. On average for the past 5 years, approximately 174 initial applications are received and 181 licensees fail to renew each year. Roughly 50 of the 1,200 applications (initial and renewal) reviewed each year are withdrawn from consideration because the applicant does not submit all of the required documentation.[19]

Sections 30, 35, 94, and 117 amend ss. 395.0197, 395.10973, 458.307, and 641.55, F.S., respectively and **sections 33, 34, 36, and 37** repeal ss. 395.10971, 395.10972, 395.10974, and 395.10975, F.S., respectively, to eliminate the requirement that health care facility risk managers be licensed by the state. The bill continues to require risk managers and that risk managers demonstrate competence in specified areas, as determined by each health care facility. The bill eliminates all provisions related to licensure of risk managers by the AHCA but continues to require the AHCA to develop a model risk management program for health care facilities that will satisfy the requirements of s. 395.0197, F.S.

Complaint Investigation Procedures

Section 31 repeals s. 395.1046, F.S., relating to the complaint investigation procedures for alleged violation of the emergency access to care provisions found in s. 395.1041, F.S. The state's emergency access to care provisions are similar to the federal Emergency Medical Treatment and Labor Act, commonly known as EMTALA.[20] The agency enforces the emergency access to care requirements through the uniform complaint investigation procedure used for all license types and these complaints are given top priority. Section 395.1046, F.S., duplicates the complaint investigation procedures found in the general licensing provisions in part II of ch. 408, F.S. Also, s. 395.1046, F.S., provides confidentiality protections and a public records exemption for the results in the investigation report, which the agency proposes is an unnecessary level of confidentiality.[21]

AHCA Rules for Certain Healthcare Services

Section 32 amends s. 395.1055, F.S., to require the agency to adopt rules to ensure that all hospitals providing organ transplantation, neonatal intensive care services, inpatient psychiatric services, inpatient substance abuse services, or comprehensive medical rehabilitation meet the minimum licensure requirements adopted by the agency. The licensure requirement must include quality of care, nurse staffing, physician staffing, physical plant, equipment, emergency

[19] Supra note 3

[20] EMTALA, also known as the patient antidumping statute, was passed in 1986 as part of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA), Public Law 99–272. Section 1867 of the Act sets forth requirements for medical screening examinations for individuals who come to the emergency department of a hospital and request examination or treatment for an emergency medical condition, regardless of ability to pay. The statute further provides that, if a hospital finds that such an individual has an emergency medical condition, it is obligated to provide that individual with either necessary stabilizing treatment or an appropriate transfer to another medical facility. *See* the CMS.gov website at: https://www.cms.gov/Regulations-and-Guidance/Legislation/EMTALA/index.html (last visited Dec. 1, 2017).

[21] Supra note 3

transportation, and data reporting standards. The section also requires the AHCA to mandate level 2 background screening for personnel of distinct part nursing units of hospitals.

Pediatric Cardiovascular Technical Advisory Panel

Prior to the 2001 Regular Session, a Cardiac Advisory Council existed in the Division of Children's Medical Services.[22] The Cardiac Advisory Council was appointed by the secretary of the department and included eight members with technical expertise in cardiac medicine who were charged with:

- Recommending standards for personnel and facilities rendering cardiac services;
- Receiving reports of the periodic review of cardiac personnel and facilities to determine if established standards for cardiac care are met;
- Making recommendations to the director as to the approval or disapproval of reviewed personnel and facilities; and
- Providing input on all aspects of the Children's Medical Services cardiac program, including the rulemaking process.[23]

The statute was repealed effective June 30, 2001, as part of an exhaustive review of more than three dozen boards, committees, commissions, and councils to determine whether to continue or abolish each entity.[24] The department recommended the repeal of the Cardiac Advisory Council and indicated it would absorb the functions of the Cardiac Advisory Council in 2001.[25]

Chapter 2017-151, L.O.F., reestablished a technical advisory panel on pediatric cardiovascular procedures. The law provided for the membership of the panel and required the AHCA to adopt rules based on the recommendations of the panel.

Section 32 amends s. 395.1055, F.S., to revise the requirement that the AHCA establish a technical advisory panel to develop procedures and standards for measuring outcomes of pediatric cardiac catheterization programs and pediatric cardiovascular surgery programs. The bill requires members of the panel to have expertise in pediatric cardiac medicine and to serve without compensation, including without reimbursement for per diem or travel expenses.

The bill also requires that each of the ten voting members, appointed by the ten children's hospitals statewide, have an alternate member appointed and that if the appointing hospital fails to maintain its pediatric certificate of need (CON) or fails to meet required standards that hospital's member may only serve as a nonvoting member until the hospital restores its certificate and compliance with the required standards.

The bill allows the Secretary of the AHCA to appoint nonvoting members to the panel including:

- The Secretary of Health Care Administration.
- The Surgeon General.

[22] *See* s. 391.222, F.S. (2000).
[23] *Id.*
[24] Chapter 2001-89, s. 27, Laws of Fla.
[25] Senate Committee on Governmental Oversight and Productivity, *CS/SB 1410 Staff Analysis and Economic Impact*, p. 9 (Mar. 28, 2001) *available at* http://archive.flsenate.gov/data/session/2001/Senate/bills/analysis/pdf/2001s1410.go.pdf (last visited Jan. 31, 2018).

- The Deputy Secretary of Children's Medical Services.
- Any current or past Division Director of Children's Medical Services.
- A parent of a child with congenital heart disease.
- An adult with congenital heart disease.
- A representative from each of the following organizations:
  - The Florida Chapter of the American Academy of Pediatrics;
  - The Florida Chapter of the American College of Cardiology;
  - The Greater Southeast Affiliate of the American Heart Association;
  - The Adult Congenital Heart Association;
  - The March of Dimes;
  - The Florida Association of Children's Hospitals; and
  - The Florida Society of Thoracic and Cardiovascular Surgeons.

The panel is required to meet at least biannually or upon the call of the Secretary of AHCA and meetings can be held telephonically or electronically. The panel is tasked with recommending to the AHCA standards for quality of care, personnel, physical plant, equipment, emergency transportation, and data reporting for hospitals that provide pediatric cardiac services. Starting on January 1, 2020, and annually thereafter the panel must submit a report to the Governor, the Legislature, the Secretary of AHCA, and the State Surgeon General summarizing the panel's activities during the preceding year and including data and performance measures on surgical morbidity and mortality for all pediatric cardiac programs.

The bill revises the rules the AHCA is required to adopt based on the recommendations of the panel to include:

- Standards for pediatric cardiac catheterization services and pediatric cardiovascular surgery including quality of care, personnel, physical plant, equipment, emergency transportation, data reporting, and appropriate operating hours and timeframes for mobilization for emergency procedures.
- Outcome standards consistent with nationally established levels of performance in pediatric cardiac programs.
- Specific steps to be taken by the agency and licensed facilities when the facilities do not meet the outcome standards within a specified time, including time required for detailed case reviews and development and implementation of corrective action plans.

The bill also requires that a pediatric cardiac program:

- Be located in a hospital licensed under this chapter and include the following co-located components: a pediatric cardiology clinic, a pediatric cardiac catheterization laboratory, and a pediatric cardiovascular surgery program.
- Have a risk adjustment surgical procedure protocol following the guidelines established by the Society of Thoracic Surgeons.
- Have quality assurance and quality improvement processes in place to enhance clinical operation and patient satisfaction with services.
- Participate in the clinical outcome reporting systems operated by the Society of Thoracic Surgeons and the American College of Cardiology.

Section 63 amends s. 408.05, F.S. to require the AHCA contract with the Society of Thoracic Surgeons and the American college of Cardiology to obtain data reported pursuant to s. 395.1055 for publication on the AHCA's website in a manner that will allow consumers to be informed of the aggregate data and to compare pediatric cardiac programs.

Repealing Obsolete Provisions Relating to Rural Hospitals

Section 38 amends s. 395.602, F.S., relating to rural hospitals, to remove the definitions of "emergency care hospital," "essential access community hospital," "inactive rural hospital bed," and "rural primary care hospital." These definitions relate to obsolete rural hospital programs that are no longer available or applicable to rural hospitals. Hospitals are authorized to make changes to their bed inventory at will so there is no longer a need to maintain an inventory of inactive rural hospital beds for CON purposes.[26] Current law classifies a sole community hospital as a rural hospital regardless of the number of beds.[27]

Section 39 amends s. 395.603, F.S., to remove provisions relating to the deactivation of general hospital beds in order to seek licensure for programs that are now obsolete.

Section 40 repeals s. 395.604, F.S., relating to licensing hospitals for these obsolete programs.

Section 41 repeals s. 395.605, F.S., relating to licensing emergency care hospitals, which is now an obsolete program.

Hospital Annual Assessments

Sections 42 and 66 amend ss. 395.701 and 408.20, F.S., relating to hospital assessments on inpatient and outpatient services. Current law excludes hospitals operated by the agency or the DOC. The bill expands the exclusion to any hospital operated by a state agency, to specifically exclude hospitals operated by the Department of Children and Families.[28]

Nursing Homes

Section 44 amends s. 400.0625, F.S., to delete language that required a nursing home to accept clinical laboratory tests performed by a clinical laboratory prior to admission in lieu of routine examinations and any clinical laboratory tests ordered by a physician as required upon admission. This section also conforms provisions to the repeal of part I of ch. 483, F.S.

Section 45 amends s. 400.191, F.S., to require the AHCA to post nursing home survey and deficiency information that is older than 30 months in its nursing home guide.

[26] Supra note 3
[27] Currently, no rural hospital has over 100 beds. See Florida Health Finder list of rural hospitals, available at http://www.floridahealthfinder.gov/facilitylocator/ListFacilities.aspx, (last visited on Dec. 1, 2017).
[28] Supra note 3.

Home Health Agencies

Home health agencies are health care providers that provide skilled services (by nurses, therapists, and social workers) and/or unskilled services (by home health aides, certified nursing assistants, homemaker, and companions) to patients in their homes. A home health agency may also provide staffing to health care facilities on a temporary basis.[29]

Section 46 amends s. 400.464, F.S., to require that any license issued for a home health agency on or after July 1, 2018, must specify the services that the home health agency is authorized to perform. Any advertising or provision of services by the home health agency that the home health agency is not licensed to perform constitutes unlicensed activity. The section eliminates a 10-day grace period for the cessation of unlicensed activity after receiving notification of such from the AHCA and ties penalties for unlicensed activity to s. 408.812, F.S.[30] The section also authorizes a voluntary process for applying for a certificate of exemption from licensure for a person providing home health services who is exempt from licensure as a home health agency. The agency may charge a fee of $100 or the actual cost of processing this certificate. The certificate of exemption is valid for up to 2 years.

Section 47 amends s. 400.471, F.S., to require application for a change of ownership or for the addition of skilled services. Applicants for license renewal no longer need to provide volume data. Under this section, evidence of contingency funding refers to the general licensing provisions in part II of ch. 408, F.S., to eliminate an inconsistency between the two chapters. Under current law, a home health agency that is not Medicare or Medicaid certified and does not provide skilled care is exempt from providing proof of accreditation. This section provides the exemption only if the home health agency does not provide skilled care. The section further clarifies that the accrediting organization must be recognized by the agency, the survey must demonstrate compliance with Florida laws pertaining to home health agencies and must be continuously maintained.

Sections 47 and 48 amend ss. 400.471 and 400.474, F.S., respectively, to clarify that a licensed home health agency must provide the services specified in the written agreement with the patient except in emergency situations that are beyond the provider's control that make it impossible to provide the services.

Section 49 amends s. 400.476, F.S., to require a home health agency that provides skilled nursing care to have a director of nursing. Current law exempts a home health agency from this requirement if it is Medicare or Medicaid certified or provides only physical, occupational, or speech therapy. This exemption is repealed.

Section 50 amends s. 400.484, F.S., renaming deficiencies as violations with respect to providing care by home health agencies and tying these violations to the general licensing provisions for health care facilities in part II of ch. 408, F.S.

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[29] Home Health Agencies, AHCA webpage, available at http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Home_Care/HHA/index.shtml, (last visited on Nov. 29, 2017).

[30] Section 408.812, F.S., prohibits unlicensed activity and provides penalties for violations including fines of up to $1,000 a day, injunctive relief, and potential application of licensure violations as if the operator were licensed.

Nurse Registries

As of October 1, 2017, there were 593 nurse registries licensed by the agency responsible for securing health-care-related contracts for private duty (in home) or health care facility staffing services by independently contracted caregivers within Florida.

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 fine for each day of continued non-compliance. While it does not make unlicensed activity a criminal offense, the Health Care Licensing Procedures Act of Chapter 408, Part II, F.S., prevails over s. 400.506, F.S., and authorizes the agency to impose a $1000 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. Upon investigation, 11 of the complaints were substantiated. Of the 11 substantiated complaints, the agency imposed an administrative fine of $46,000 for one unlicensed nurse registry that failed to discontinue operations after notification.

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. Currently, s. 400.506, F.S., specifically prohibits licensed nurse registries who bill Florida Medicaid or the Medicare program from giving remuneration to certain named parties who are involved in the discharge of patients from health care facilities such as hospitals and nursing homes from which the registry receives referrals. Likewise, a nurse registry is prohibited from giving remuneration to physicians, physicians' office staff members, and immediate family members of physicians if the nurse registry received a referral from the physician or his or her office within the previous 12 months.[31]

Section 52 amends s. 400.506, F.S., to eliminate a 10-day grace period for the cessation of unlicensed activity after receiving notification of such from the AHCA, and ties penalties for unlicensed activity to s. 408.812, F.S.[32] In addition, the section removes the prohibitions on a nurse registry providing remuneration to a case manager, discharge planner, facility based staff member, third party vendor, physician, member of the physician's office staff, or an immediate family member of a physician for referrals. Current law exempts nurse registries from this prohibition if they do not bill Medicare or Medicaid or share a controlling interest with any entity that bills Medicare or Medicaid. In addition to s. 400.506, F.S., s. 817.505(1)(a), F.S., makes it unlawful for any health care provider or health care facility, including nurse registries, to "offer or pay a commission, benefit, bonus, rebate, kickback, or bribe, directly or indirectly, in cash or in kind, or engage in any split-fee arrangement whatsoever, to induce the referral of a patient or patronage to or from a health care provider or health care facility."[33] The bill also clarifies that a

[31] Supra note 3
[32] Supra note 3
[33] Supra note 3

nurse registry may not monitor, supervise, manage or train a caregiver or a registered nurse, licensed practical nurse, certified nursing assistant, companion or homemaker or home health aide referred for contract under this chapter. The bill also restricts nurse registries from monitoring, supervising, managing, or training a caregiver and specifies that a caregiver referred by a nurse registry is not considered an employee of the nurse registry under any chapter.

Hospices

Section 53 amends s. 400.606, F.S., to eliminate the requirement that applicants for hospice licensure that are existing health care providers submit a profit-loss statement and the most recent licensure inspection report. The requirement to provide a profit-loss statement is duplicative of general health care licensing statutes that require uniform proof of financial ability to operate and the requirement to provide an inspection report is unnecessary since all inspection reports are available to the public online.[34]

Home Medical Equipment Providers

Section 54 amends s. 400.925, F.S., to make technical clarifying changes to the definition of home medical equipment.

Section 55 amends s. 400.931, F.S., to require a licensed home medical equipment provider to notify the AHCA of a change in the general manager within the timeframes established in part II of ch. 408, F.S., which is 21 days, rather than the 45-day timeframe provided in this section of law.

Health Care Service Pools

Section 57 amends s. 400.980, F.S., to require changes of information contained on the original registration application to be submitted to the agency within the timeframes established in part II of ch. 408, F.S., rather than 14 days prior to the change as required in this section of law.

Health Care Clinic Exemptions

Section 59 amends s. 400.9935, F.S., to make certificates of exemption from licensure valid for up to 2 years. Currently, such exemptions are valid indefinitely. This change is intended to improve the integrity of the exemption process.[35]

Adult Cardiovascular Services

Hospitals are regulated by the AHCA under ch. 395, F.S., and the general licensure provisions of part II of ch. 408, F.S. Hospitals are subject to the certificate of need (CON) provisions in part I of ch. 408, F.S. A CON is a written statement issued by the AHCA evidencing community need for a new, converted, expanded, or otherwise significantly modified health care facility or health service.[36]

[34] Supra note 3
[35] Supra note 3
[36] Section 408.032(3), F.S.

Adult cardiovascular services (ACS), including percutaneous coronary intervention (PCI), were previously regulated through the CON program.[37] However, in 2004, the Legislature established a licensure process for adult interventional cardiology services (the predecessor terminology for ACS), dependent upon rulemaking, in lieu of the CON procedure.[38] Among other things, that law required the rules to establish two hospital program licensure levels: a Level I program authorizing the performance of adult primary PCI for emergency patients without onsite cardiac surgery, and a Level II program authorizing the performance of PCI with onsite cardiac surgery.[39] Additionally the rules must require compliance with the most recent guidelines of the American College of Cardiology and American Heart Association guidelines for staffing, physician training and experience, operating procedures, equipment, physical plant, and patient-selection criteria to ensure quality and safety.[40] Current law requires that a hospital seeking a Level I program must demonstrate that it has, in the most recent 12-month period, provided a minimum of 300 adult inpatient and outpatient diagnostic cardiac catheterizations or discharged at least 300 patients with the principal diagnosis of ischemic heart disease and has a transfer agreement with a Level II hospital within 60 minutes transfer time.

The AHCA adopted rules for Level I ACS[41] and Level II ACS.[42] Staffing rules for both levels require the nursing and technical catheterization laboratory staff to meet the following:

- 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 ACS program;[43]
- Be skilled in all aspects of interventional cardiology equipment; and
- Participate in a 24-hour-per-day, 365 day-per-year call schedule.

One of the authoritative sources referenced in the AHCA's rulemaking is The American College of Cardiology/American Heart Association Task Force on Practice Guidelines' report: ACC/AHA/SCAI 2005 Guideline Update for PCI.[44] Table 15 in that report provides criteria for the performance of primary PCI at hospitals without onsite cardiac surgery. It states:

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[37] *See* s. 408.036(3)(m) and (n), F.S., allowing for an exemption from the full review process for certain adult open-heart services and PCI services.
[38] Chapter 2004-383, s. 7, Laws of Fla.
[39] Level I and Level II ACS programs may also perform adult diagnostic cardiac catheterization in accordance with Rule 59A-3.2085(13), F.A.C. Adult diagnostic cardiac catheterization involves the insertion of a catheter into one or more heart chambers for the purpose of diagnosing cardiovascular diseases.
[40] *See* s. 408.0361(3), F.S.
[41] Rule 59A-3.2085(16), F.A.C.
[42] Rule 59A-3.2085(17), F.A.C.
[43] The standard in the CON exemption in s. 408.036(3)(n), F.S., for providing PCI in a hospital without an approved adult open-heart-surgery program required previous experience in dedicated interventional laboratories or surgical centers.
[44] Smith SC Jr, Feldman TE, Hirshfeld JW Jr, Jacobs AK, Kern MJ, King SB III, Morrison DA, O'Neill WW, Schaff HV, Whitlow PL, Williams DO. *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). the Society for Cardiovascular Angiography and Interventions* (2005), *available at* http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=3&ved=0ahUKEwizrYy2zubKAhUBfSYKHafZCiAQFggvMAI&url=http%3A%2F%2Fwww.scai.org%2Fasset.axd%3Fid%3Da1d96b40-b6c7-42e7-9b71-1090e581b58c%26t%3D634128854999430000&usg=AFQjCNF0t0334L9yMm_XLA5rl0pXoCvPDw (last visited Nov. 29, 2017).

> The nursing and technical catheterization laboratory staff must be experienced in handling acutely ill patients and must be comfortable with interventional equipment. They must have acquired experience in dedicated interventional laboratories at a surgical center.

In 2014, the Society for Cardiovascular Angiography and Interventions, the American College of Cardiology Foundation, and the American Heart Association, Inc., issued the SCAI/ACC/AHA Expert Consensus Document: 2014 Update on PCI Without On-Site Surgical Backup.[45] That report acknowledged advances and best practices in PCI performed in hospitals without onsite surgery. Table IV in that report addresses personnel requirements for PCI programs without onsite surgery. It recommends the program have experienced nursing and technical laboratory staff with training in interventional laboratories. The report does not reference a requirement that the training or experience should occur in a dedicated interventional laboratory at a surgical center.

As of October 31, 2017, there are 56 Florida hospitals providing Level I ACS services and 79 Florida hospitals providing Level II ACS services.[46]

Section 61 amends s. 408.036, F.S., to remove the exemption from certificate of need for hospitals wanting to add adult open-heart services. This exemption is no longer necessary due to the creation of licensure standards in 2004.

Section 62 amends s. 408.0361, F.S., to exempt a hospital located more than 100 road miles from the closest Level II ACS from the requirement to meet ischemic heart disease diagnosis volume requirements if the hospital demonstrates that it has, for the most recent 12-month period as reported to the agency, provided a minimum of 100 adult inpatient and outpatient diagnostic cardiac catheterizations or that, for the most recent 12-month period, it has discharged or transferred at least 300 patients with the principal diagnosis of ischemic heart disease. This change will allow Lower Keys Medical Center to become a Level I provider.[47]

The section also requires AHCA licensure rules for hospitals providing ACS to include, at a minimum, a requirement that all nursing and technical staff have demonstrated experience in handling acutely ill patients requiring PCI in dedicated cardiac interventional laboratories or surgical centers. Currently, pursuant to AHCA rules, the experience must have been acquired in a hospital with a surgical center. The section states that, if a staff member's previous experience was in a dedicated cardiac interventional laboratory at a hospital that did not have an approved adult open-heart-surgery program, the laboratory must meet the following criteria in order for the staff member's experience to qualify. The laboratory must have:

- Had an annual volume of 500 or more PCI procedures;
- Achieved a demonstrated success rate of 95 percent or higher for PCI;
- Experienced a complication rate of less than 5 percent for PCI; and

[45] Gregory J. Dehmer, et.al, *available at* http://circ.ahajournals.org/content/129/24/2610.full.pdf+html (last visited Nov. 29, 2017).
[46] *See* The AHCA FloridaHealthFinder.gov *available at* http://www.floridahealthfinder.gov/facilitylocator/FacilitySearch.aspx, (last visited Nov. 29, 2017).
[47] Id.

- Performed diverse cardiac procedures, including, but not limited to, balloon angioplasty and stenting, rotational atherectomy, cutting balloon atheroma remodeling, and procedures relating to left ventricular support capability.

Subscriber Assistance Program

The subscriber assistance panel (SAP) was created in 1985 to assist members of managed care entities whose grievances or appeals were not satisfactorily resolved by the managed care entity upon exhaustion of the managed care entity's internal grievance and appeal process. Under the federal Patient Protection and Affordable Care Act (PPACA),[48] managed care entities were given an option to either comply with the state's external review requirement or opt-out and participate in the federal external review program. The majority of health plans in Florida elected to use the federal program and the SAP program experienced a significant decrease in the number of cases being reviewed by the panel.[49]

The SAP is currently available to members of managed care entities with coverage by: Statewide Medicaid Managed Care, Healthy Kids, Prepaid Health Clinics, or grandfathered policies[50] that have not elected to have all of their health insurance policies subject to an external review process by independent review organization(s). Medicaid recipients in managed care can file for an external review through a Medicaid Fair Hearing and members with grandfathered commercial policies may appeal through independent review organizations.[51]

Repeal of the SAP eliminates this program as an external appeal option for members in Healthy Kids and Prepaid Health Clinics, although according to the agency, no Prepaid Health Clinic members have used the SAP. At this time, these members do not have another avenue in which to file an external appeal.[52]

Section 67 repeals s. 408.7056, F.S., relating to the subscriber assistance program.

General Licensing Provisions

Section 69 amends s. 408.803, F.S., to add a definition of "relative." This addition is to clarify the meaning of the term when used in the newly created s. 408.810(1), F.S., (see Section 70, below).

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[48] Pub. Law No. 111-148 (Mar. 23, 2010) amended by Pub. Law. No. 111-152 (Mar. 30, 2010).

[49] According to the agency, between FY 2011-2012 and FY 2012-2013, when the majority of plans opted to use the federal external review program, the number of cases received by the SAP dropped from 415 to 213. The number of cases heard by the SAP dropped from 74 to 17. There was an uptick in both number of cases received by the subscriber assistance program and the number of cases heard by the panel for FY 2014-2015 and FY 2015-2016; however, FY 2016-2017 showed a decline in the number of cases received and heard from 350 to 253 and 53 to 28, respectively. The predominant outcome of the cases in FY 2016-2017 was a determination of non-jurisdiction (165), followed by submission of an incomplete application (24) and resolved prior to panel hearing (26). *See* the chart prepared by the agency for activity since FY 2009-2010 at supra note 1.

[50] A grandfathered health plan is a plan that existed on March 23, 2010, the date that the PPACA was enacted, and that at least one person had been continuously covered for 1 year. Plans or policies may lose their "grandfathered" status if they make certain significant changes that reduce benefits or increase costs to consumers. *See* Healthcare.gov, *Grandfathered Health Plans*, https://www.healthcare.gov/glossary/grandfathered-health-plan/ (last visited Nov. 28, 2017).

[51] Supra note 3.

[52] *Id.*

Section 70 amends s. 408.806, F.S., to authorize a licensee that holds a license for multiple providers licensed by the agency to request alignment of all license expiration dates. In order to accomplish this, the agency is authorized to issue a license for an abbreviated licensure period with a prorated licensure fee.

Section 71 amends s. 408.809, F.S., to apply background screening provisions to all controlling interests in a health care facility. Current law only requires background screening of controlling interests if the AHCA has reason to believe that such a person has been convicted of a prohibited offense. The section also requires background screening for contractors with a licensee or provider who work for 20 hours or more per week and have access to client funds, personal property, or living areas.

Section 72 amends s. 408.810, F.S., to exempt an applicant for a change of ownership from submitting proof of financial ability to operate, if the provider has been licensed for at least 5 years and the change is the result of a corporate reorganization under which the controlling interest is unchanged or solely due to the death of a controlling interest, and the surviving controlling interest continue to hold at least 51 percent of the ownership.

The agency is authorized to adopt rules to address the circumstances under which a controlling interest, an administrator, an employee, a contractor, or a representative thereof who is not a relative of the patient or client may act as a legal representative, agent, health care surrogate, power of attorney, or guardian of a patient or client. According to the agency, licensure regulations are currently inconsistent in this area. Due to the vulnerability of persons receiving health or custodial care, allowing the paid caregiver to control finances or health care decisions of the patient can result in exploitation or abuse. In some cases, the facility has a surety bond, but this is not required for all provider types.[53]

The section also requires that the licensee must ensure that no person holds any ownership interest who has a disqualifying offense[54] or who holds any ownership interest in a provider that had a license revoked or application denied. This provision does not apply to shareholders in a publicly traded corporation.

Section 73 amends s. 408.812, F.S., relating to unlicensed activity, to specify that unlicensed activity constitutes abuse and neglect, as defined in s. 415.102, F.S.[55] The section removes the requirement that a person or entity must apply for a license after receiving notification from the agency that the person or entity is engaging in unlicensed activity. If a controlling interest or licensee has more than one provider and fails to license all providers that require licensure, the agency may impose a fine, regardless of correction, as one of the authorized sanctions.

[53] Supra note 1.
[54] Pursuant to s. 408.809, F.S.
[55] In summary, s. 415.102, F.S., defines "abuse" as any willful act or threatened act by a relative, caregiver, or household member which causes or is likely to cause significant impairment to a vulnerable adult's physical, mental, or emotional health; and that abuse includes acts and omissions. "Neglect" is defined as the failure or omission on the part of the caregiver or vulnerable adult to provide the care, supervision, and services necessary to maintain the physical and mental health of the vulnerable adult. Refer to s. 415.102(16), F.S., for additional acts that constitute neglect.

Background Screening

Sections 76 and 89 amend ss. 409.907 and 435.04, F.S., respectively, to move certain disqualifying offenses from the Medicaid requirements into background screening standards. This move allows Medicaid applicants to apply for an exemption to a disqualifying offense in the same manner as other persons required to be screened under these provisions.[56] The section also provides more specificity as to which offenses are disqualifying.

Section 89 also amends s. 435.04, F.S., to disqualify persons from employment as a health care worker who have been arrested for and are awaiting final disposition of an offense related to domestic violence. This change conforms to the language used in subsection (2) disqualifying persons from employment for all other enumerated offenses.

Assisted Living Facilities

ALFs provide full-time living arrangements in the least restrictive and most home-like setting. Facilities can include individual apartments or rooms that a resident has alone or shares with another person. These facilities can also range in size from one resident to several hundred residents.

The basic services provided by an ALF include, but are not limited to:
- Housing, nutritional meals, and special diets;
- Personal care (help with bathing, dressing, eating, walking, physical transfer);
- Give medications (by a nurse employed at the facility or arranged by contract) or help residents give themselves medications;
- Supervise residents;
- Arrange for health care services;
- Provide or arrange for transportation to health care services;
- Health monitoring;
- Respite care;
- Social and leisure activities; and
- Mental Health services.

Section 80 amends s. 429.04, F.S., relating to exemptions from licensure, to clarify and expand the exemptions to include facilities licensed by the Agency for Persons with Disabilities, mental health facilities, licensed hospitals, nursing homes, inpatient hospices, homes for special services,[57] intermediate care facilities, or transitional living facilities. Additionally, the section assigns the burden of providing documentation substantiating an exemption to the person or entity asserting an exemption in response to an agency investigation of unlicensed activity.

A current exemption includes any person who provides housing, meals, or one or more personal services on a 24-hour basis in the person's own home to not more than two adults who do not receive optional state supplementation. The section specifies that in addition to owning or renting

[56] Supra n. 3
[57] Homes for special services is defined in s. 400.801, F.S., as a site licensed by the agency prior to January 1, 2006, where specialized health care services are provided, including personal and custodial care, but not continuous nursing services.

the home, the person who provides these services must have established the home as the person's permanent residence. If the person holds a homestead exemption at a different address, a presumption exists that the person has not established permanent residence as required by this section. Furthermore, the section provides that the exemption does not apply to a person or entity who previously held licensure issued by the agency and such license was revoked or licensure renewal was denied by final order, or when the license was voluntarily relinquished during agency enforcement proceedings.

Section 81 amends s. 429.08, F.S., relating to unlicensed facilities, to clarify and create a felony of the third degree penalty for renting or otherwise maintaining a building or property that operates or maintains an unlicensed ALF. This section now provides that any person who owns, operates, or maintains an unlicensed ALF after receiving notice from the agency that licensure is required and to cease such operation commits a felony of the third degree. Current law provides a 6-month window after a statutory or rule change takes place if the change placed the person in the position of violating this provision before the violation occurs. This 6-month timeframe is repealed in the bill.

Section 82 amends s. 429.176, F.S., to prohibit an ALF from operating for more than 120 consecutive days without an administrator who has completed the core educational requirements.

Section 84 amends s. 429.24, F.S., to specify that new services added to a resident's contract for which the resident was not previously charged do not require a 30-day written notice of rate increase.

Section 85 amends s. 429.28, F.S., to specify that residents in an ALF have the right to "assistance with" obtaining access to adequate and appropriate health care. Current law provides the resident with the right to "access to adequate and appropriate health care." The section further specifies that "adequate and appropriate health care" includes management of medications, assistance in making appointments for health care services, the provision of or arrangement of transportation to health care appointments, and the performance of health care services in accordance with s. 429.255, F.S.[58]

Sections 85 and 87 amend ss. 429.28 and 429.34, F.S., to strike provisions from the "resident's bill of rights" section that are related to AHCA inspections of ALFs and move the provisions into the section related to AHCA right of entry and inspection powers.

Section 86 amends s. 429.294, F.S., to conform the requirement that ALFs provide copies of medical records to the provisions requiring nursing homes to provide such records. Current law requires ALFs to provide the records within 10 days while nursing homes have 30 days to provide the records.[59]

[58] Section 429.255, F.S., specifies the types of care that may be provided by various staff in an ALF, including nursing and medical staff, and includes provisions for emergency situations.
[59] See s. 400.145, F.S.

Section 88 amends s. 429.52, F.S., to specify that an ALF administrator must complete staff training, including passing the competency test, within 90 days of the date of employment.

Clinical Laboratories

The CMS regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA).[60] Facilities that provide clinical laboratory services are required to be certified by the CMS CLIA laboratory certification program, which operates in conjunction with the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). Certain laboratories may qualify as a waived testing laboratory and receive a CLIA Certificate of Waiver.[61]

Clinical laboratories in the state performing non-waived tests must also obtain a state license from the AHCA and comply with part I of ch. 483, F.S., relating to clinical laboratories, and the general licensing provisions in part II of ch. 408, F.S. This requirement also applies to a clinical laboratory operated by one or more practitioners such as physicians, chiropractors, podiatrists, optometrists, or dentists, exclusively in connection with the diagnosis and treatment of their own patients.[62]

As of July 1, 2017, the agency licenses 3,904 clinical laboratories and collects an average of $1,540,000 per year in recurring licensure fees and an average of $321,900 per year in recurring biennial assessments required by s. 408.033, F.S. In addition, the CLIA program certifies another 18,446 Florida based laboratories that only perform "waived" testing and therefore, are exempt from state licensure requirements.[63]

Section 91 amends s. 456.054, F.S., to move anti-kickback language for clinical laboratories from s. 483.245, F.S., which is being repealed, into the general provisions for healthcare practitioners.

Section 97 repeals part I of ch. 483, F.S., relating to the licensure and regulation of clinical laboratories by the agency. Part I includes ss. 483.011 - 483.26, F.S. Laboratories will continue to be certified by, or receive a certificate of waiver from, the CMS under the CLIA. Included within the repeal is a requirement that laboratory results must be reported directly to the licensed practitioner or other authorized person who requested it, and the authorization for a laboratory to disclose the results without a patient's consent to other health care practitioners and providers involved in the care or treatment of the patient as specified in s. 456.057(7)(a), F.S.

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[60] CMS.gov, *Clinical Laboratory Improvement Amendments (CLIA)* (April 5, 2017) https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/CLIA (last visited Nov. 29, 2017).

[61] Waived testing laboratories: employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible, pose no reasonable risk of harm to the patient if the test is performed incorrectly, use tests that are cleared by the FDA for home use, and conduct testing that is considered non-technical requiring little or no difficulty. *See* Agency for Health Care Administration, Waived Laboratories: http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Laboratory_Licensure/waived_apps.shtml (last visited Nov. 29, 2017).

[62] Section 483.035(1), F.S.

[63] Supra note 3.

Section 99 amends s. 483.801, F.S., to exempt from licensure persons engaged in testing performed by laboratories that are wholly owned and operated by one or more practitioners who are licensed under Florida law as allopathic or osteopathic physicians, chiropractors, podiatrists, optometrists, or dentists and who practice in the same group practice, and in which no clinical laboratory work is performed for patients referred by a health care provider who is not a member of the same group.

Managed Care Ombudsman Committees

The Statewide Managed Care Ombudsman Committee (statewide committee) and the district managed care ombudsman committees (district committees) were established in 1996.[64] The statewide committee is created within the agency as a consumer protection and advocacy organization on behalf of managed care subscribers. The statewide committee has administrative authority over the district committees and consists of the chairpersons of the district committees.

A district committee is created in s. 641.65, F.S., in each district of the agency that has staff assigned for the regulation of managed care programs. Each district committee must have no fewer than nine members or more than 16 members, including at least four physicians, one licensed under each of chs. 458, 459, 460, and 461; one psychologist; one registered nurse; one clinical social worker; one attorney; and one consumer.[65]

According to the agency, due to the very stringent committee composition requirements, the majority of districts could not form district committees. The first committee was established in 1999 and only three other districts were able to meet committee requirements. The last activity on record was in 2010, and there are currently no active committees.[66]

Sections 118-123 repeal ss. 641.60, 641.65, 641.67, 641.68, 641.70, and 641.75, F.S., to eliminate the statewide and district Managed Care Ombudsman Committees.

Miscellaneous Provision

Section 64 amends s. 408.061, F.S., relating to data collection by the agency from health care facilities, to conform cross-references and to exclude hospitals operated by state agencies from the requirement to submit certain financial reports.

Technical and Conforming Sections

The following sections make technical changes to the Florida statutes to conform its provisions to other changes made by this bill:

Section 56 amends s. 400.933, F.S., to make a technical change specifying that it is the Department of Business and Professional Regulation, not the DOH, that issues medical oxygen retail establishment permits.

[64] Chapter 96-391, Laws of Fla.
[65] Section 641.65(2), F.S.
[66] Supra note 3

Section 79 amends s. 492.02, F.S., to make technical grammatical changes to the section.

Sections 1, 3-9, 11-16, 18, 20, 21-23, 26, 41, 51, 58, 60, 65, 68, 74, 75, 77-78, 83, 90, 92-96, 98, 100-117, and 124-128

These sections amend ss. 20.43, 220.1845, 376.30781, 376.86, 381.0031, 381.0034, 381.004, 381.0405, 383.14, 383.30, 383.301, 383.302, 383.305, 383.309, 383.33, 384.31, 385.211, 394.4787, 395.001, 395.009, 395.7015, 400.497, 400.9905, 408.033, 408.07, 408.802, 408.820, 409.905, 409.9116, 409.975, 429.19, 456.001, 456.057, 456.076, 458.307, 458.345, 459.021, 483.294, 483.803, 483.813, 483.823, 491.003, 627.351, 627.602, 627.6406, 627.64194, 627.6513, 627.6574, 641.185, 641.31, 641.312, 641.3154, 641.51, 641.511, 641.515, 641.55, 766.118, 766.202, 945.36, 1009.65, and 1011.52, F.S., respectively.

Effective Date

Section 129 provides the bill takes effect July 1, 2018.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Repealing the licensure requirement for health care risk managers will save each risk manager the cost of the licensure fee, which is $104.54 for initial applicants and $52.78 for renewal applicants.[67]

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

[67] *See* the Application checklist available at: http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/risk_manager.shtml (last visited Nov. 29, 2017).

between $400 - $3,919 biennially, depending upon the annual volume of non-waived tests performed.[68]

Allowing cancer centers seeking NCI designation to participate in the Florida Consortium of National Cancer Institute Centers Program as a Tier 3 cancer center for an additional year may have an indeterminate positive fiscal impact on such cancer centers.

C. Government Sector Impact:

State Revenues

With the elimination of the risk manager application fees and the laboratory licensure application fees, overall revenue to the state will decrease by approximately $2.05 million annually. This includes reductions of $1.6 million from the Health Care Trust Fund in ACHA, $0.3 million from the Grants and Donations Trust Fund in the Department of Health and $0.15 million from the General Revenue Fund.

Of the $2.05 million reductions noted above, $64,866 per year is attributable to the elimination of the risk manager application fees and $1,540,000 per year is attributable to the laboratory licensure application fees.[69] The AHCA collects assessments pursuant to s. 408.033, F.S., and transfers these assessments to the Grants and Donations Trust Fund within the Department of Health (DOH) to fund the Local Health Councils. The estimated reduction to the transfer to DOH associated with the laboratory assessments is $304,950. The estimated reduction to General Revenue is $152,785 relating to the General Revenue surcharge in s. 215.20, F.S.

State Expenditures

The bill reduces the workload on AHCA staff relating to the licensure of clinical laboratories. The AHCA anticipates reallocating such resources to other areas of AHCA providing regulatory functions.

VI. Technical Deficiencies:

The title of the bill does not include language stricken from s. 400.0625, F.S., on lines 1182-1186.

The bill amends s. 408.0361, F.S., to mandate the establishment of rules to require nursing and technical staff in hospitals performing adult cardiovascular services to have specified experience. This change appears to apply to both hospitals providing Level I and Level II services, however, this is placed within a statutory paragraph only relating to a hospital seeking a Level I program license. As such, it is unclear whether the staff training requirement applies to both hospitals providing Level I and Level II services or only to hospitals providing Level I services. The bill may need to be amended to clearly indicate to which hospitals the requirement applies.

[68] *See* AHCA Clinical laboratory fees, available at: http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Laboratory_Licensure/fees.shtml (last visited Nov. 29, 2017).
[69] Supra n. 3

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 20.43, 220.1845, 376.30781, 376.86, 381.0031, 381.0034, 381.004, 381.0405, 381.915, 383.14, 383.30, 383.301, 383.302, 383.305, 383.309, 383.313, 383.33, 384.31, 385.211, 394.4787, 395.001, 395.002, 395.003, 395.009, 395.0161, 395.0163, 395.0197, 395.1055, 395.10973, 395.602, 395.603, 395.701, 395.7015, 400.0625, 400.191, 400.464, 400.471, 400.474, 400.476, 400.484, 400.497, 400.506, 400.606, 400.925, 400.931, 400.933, 400.980, 400.9905, 400.9935, 408.033, 408.036, 408.0361, 408.05. 408.061, 408.07, 408.20, 408.7056, 408.802, 408.803, 408.806, 408.809, 408.810, 408.812, 408.820, 409.905, 409.907, 409.9116, 409.975, 429.02, 429.04, 429.08, 429.176, 429.19, 429.24, 429.28, 429.294, 429.34, 429.52, 435.04, 456.001, 456.054, 456.057, 456.076, 458.307, 458.345, 459.021, 483.294, 483.801, 483.803, 483.813, 483.823, 491.003, 627.351, 627.602, 627.6406, 627.64194, 627.6513, 627.6574, 641.185, 641.31, 641.312, 641.3154, 641.51, 641.511, 641.515, 641.55, 766.118, 766.202, 945.36, 1009.65, and 1011.52.

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

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

IX. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS/CS by Rules on March 1, 2018:
The committee substitute amends s. 381.915, F.S., to allow a Florida cancer center seeking NCI designation to participate in the Florida Consortium of National Cancer Institute Centers Program as a Tier 3 cancer center for six years, rather than for five years.

CS by Appropriations on January 31, 2018:
The committee substitute:

- Clarifies the duties of nurse registries.
- Removes obsolete language related to adult open-heart surgery certificate of need requirements.
- Removes section 88 of the bill relating to background screening.
- Revises the pediatric cardiac technical advisory panel in s. 396.1055, F.S., to:
  - Require that hospitals appointing members maintain a CON and licensure criteria;
  - Allow the Secretary of the AHCA to appoint nonvoting members;
  - Revise the requirements for the panel to create and submit reports;

  - Revise requirements for the AHCA to adopt rules based on the panel's reports; and
  - Require hospitals providing pediatric cardiology services meet certain guidelines.
- Requires the AHCA to contract with certain groups to provide information regarding pediatric cardiac programs at hospitals on the AHCA's webpage.
- Specifies that caregivers referred by a nurse registry are not employees of the nurse registry.

B. Amendments:

None.