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 Health Policy

BILL:	SB 622
INTRODUCER:	Senator Grimsley
SUBJECT:	Health Care Facility Regulation
DATE:	December 4, 2017
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Stovall	HP	**Favorable**
2.			AHS	
3.			AP	
4.			RC	

I. Summary:

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.
- 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.
- 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.

II. Present Situation:

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

[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).

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 within the bill, pertinent background is provided within the effect of proposed changes for the reader's convenience.

III. Effect of Proposed Changes:

SB 622 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 which 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 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 labs.[3]

Birth Centers

Section 16 amends s. 383.313, F.S., to require that all birthing centers that perform laboratory tests on their patients be federally certified by the Federal Centers for Medicare and Medicaid Services (CMS) under the federal Clinical Laboratory Improvement Amendments 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.,[4] 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.[5]

Mobile Surgical Facilities

Sections 22, 23, 24, 27, 28, 60, and 123 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

[2] *See* s. 408.802, F.S., for the health care provider types and applicable licensure statutes.
[3] Agency for Health Care Administration, *Senate Bill 622 Analysis* (Nov. 15, 2017) (on file with the Senate Committee on Health Policy.)
[4] Part I of ch. 483, F.S., is repealed in this bill.
[5] Supra note 3

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 ASC, 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.[6]

Alternate-Site Testing

Section 26 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 bill 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.[7]

Deregulation of Risk Managers

Current law requires every hospital, ambulatory surgical center, and HMO 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.

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.[8]

[6] Supra note 3
[7] Supra note 3
[8] Supra note 3

Sections 29, 34, 93, and 116 amend ss. 395.0197, 395.10973, 458.307, and 641.55, F.S., respectively and **sections 32, 33, 35, and 36** 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 30 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.[9] 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.[10]

AHCA Rules for Certain Healthcare Services

Section 31 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 transportation, and data reporting standards. The bill also requires the AHCA to mandate level 2 background screening for personnel of distinct part nursing units of hospitals.

Repealing Obsolete Provisions Relating to Rural Hospitals

Section 37 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.[11] Additionally, this section amends the definition

[9] 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).

[10] Supra note 3

[11] Supra note 3

of "rural hospital" to limit the number of beds to 175 that a hospital classified as a sole community hospital under 42 C.F.R. s. 412.92 may have in order to be considered a rural hospital. Current law classifies a sole community hospital as a rural hospital regardless of the number of beds.[12]

Section 38 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 39 repeals s. 395.604, F.S., relating to licensing hospitals for these obsolete programs.

Section 40 repeals s. 395.605, F.S., relating to licensing emergency care hospitals which is now an obsolete program.

Hospital Annual Assessments

Sections 41 and 64 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.[13]

Nursing Homes

Section 43 amends s. 400.0625, F.S., to strike language allowing nursing homes 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 44 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.

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.[14]

Section 45 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 bill eliminates a 10-day grace period for the cessation of unlicensed activity after receiving notification of such

[12] 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).
[13] Supra note 3.
[14] 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).

from the AHCA and ties penalties for unlicensed activity to s. 408.812, F.S.[15] The bill 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 46 amends s. 400.471, F.S., to require application for a change of ownership or for the addition of skilled services. Applicants for license renewal no longer need to provide volume data. Under the bill, evidence of contingency funding refers to the general licensing provisions in part II of ch. 408, F.S., to eliminate an inconsistency between the two chapters. Under current law, a home health agency that is not Medicare or Medicaid certified and does not provide skilled care is exempt from providing proof of accreditation. This bill provides the exemption only if the home health agency does not provide skilled care. The bill further clarifies that the accrediting organization must be recognized by the agency, the survey must demonstrate compliance with Florida laws pertaining to home health agencies, and must be continuously maintained.

Sections 46 and 47 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 48 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 49 amends s. 400.484, F.S., renaming deficiencies as violations with respect to providing care by home health agencies and tying these violations to the general licensing provisions for health care facilities in part II of ch. 408, F.S.

Nurse Registries

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

[15] 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.

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. 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 who 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. Current 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 they are 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.[16]

Section 51 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.[17] In addition, the bill removes the prohibitions on a nurse registry providing remuneration to a case manager, discharge planner, facility based staff member, third party vendor, physician, member of the physician's office staff, or an immediate family member of a physician for referrals. Current law 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."[18]

Hospices

Section 52 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.[19]

Home Medical Equipment Providers

Section 53 amends s. 400.925, F.S., to make technical clarifying changes to the definition of home medical equipment.

[16] Supra note 3
[17] Supra note 3
[18] Supra note 3
[19] Supra note 3

Section 54 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 56 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 58 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 will improve the integrity of the exemption process.[20]

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.[21]

Adult cardiovascular services (ACS), including percutaneous coronary intervention (PCI), were previously regulated through the CON program.[22] 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.[23] 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.[24] 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.[25] 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

[20] Supra note 3
[21] Section 408.032(3), F.S.
[22] *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.
[23] Chapter 2004-383, s. 7, Laws of Fla.
[24] 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.
[25] *See* s. 408.0361(3), F.S.

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[26] and Level II ACS.[27] 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;[28]
- 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.[29] Table 15 in that report provides criteria for the performance of primary PCI at hospitals without onsite cardiac surgery. It states:

> 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.[30] 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.

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[26] Rule 59A-3.2085(16), F.A.C.
[27] Rule 59A-3.2085(17), F.A.C.
[28] 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.
[29] 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%3D636412885499943000&usg=AFQjCNF0t0334L9yMm_XLA5rl0pXoCvPDw (last visited Nov. 29, 2017).
[30] Gregory J. Dehmer, et.al, *available at* http://circ.ahajournals.org/content/129/24/2610.full.pdf+html (last visited Nov. 29, 2017).

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

Section 61 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 would allow Lower Keys Medical Center to become a Level I provider.[32]

The bill 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 bill 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
- 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),[33] 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 significate decrease in the number of cases being reviewed by the panel.[34]

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[31] *See* The AHCA FloridaHealthFinder.gov *available at* http://www.floridahealthfinder.gov/facilitylocator/FacilitySearch.aspx, (last visited Nov. 29, 2017).
[32] Id.
[33] Pub. Law No. 111-148 (Mar. 23, 2010) amended by Pub. Law. No. 111-152 (Mar. 30, 2010).
[34] According to the agency, between FY 2011-2012 and FY 2012-2013, when the majority of plans opted to use the federal external review program, the number of cases received by the SAP dropped from 415 to 213. The number of cases heard by the SAP dropped from 74 to 17. There has been an uptick in both number of cases received by the subscriber assistance program and the number of cases heard by the panel for FY 2014-2015 and FY 2015-2016 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.

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[35] 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.[36]

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.[37]

Section 65 of the bill repeals s. 408.7056, F.S., relating to the subscriber assistance program.

General Licensing Provisions

Section 67 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).

Section 68 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 69 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 bill also requires background screening for contractors with a licensee who work for 20 hours or more per week and have access to client funds, personal property, or living areas.

Section 70 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,

[35] 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).
[36] Supra note 3.
[37] *Id.*

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.[38]

The bill also requires that the licensee must ensure that no person holds any ownership interest who has a disqualifying offense[39] or who holds any ownership interest in a provider that had a license revoke or application denied. This provision does not apply to shareholders in a publicly traded corporation.

Section 71 amends s. 408.812, F.S., relating to unlicensed activity to pronounce that unlicensed activity constitutes abuse and neglect, as defined in s. 415.102, F.S.[40] The bill 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.

Background Screening

Sections 74 and 87 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.[41] The bill also provides more specificity as to which offenses are disqualifying.

Section 87 also amends s. 4 35.04, 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;

[38] Supra note 1.
[39] Pursuant to s. 408.809, F.S.
[40] 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.
[41] Supra n. 3

- 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 78 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,[42] intermediate care facilities, or transitional living facilities. Additionally, the bill assigns the burden of providing documentation substantiating an exemption to the person or entity asserting an exemption in response to an agency investigation of unlicensed activity.

A current exemption includes any person who provides housing, meals, or one or more personal services on a 24-hour basis in the person's own home to not more than two adults who do not receive optional state supplementation. The bill specifies that in addition to owning or renting the home, the person who provides these services must have established the home as the person's permanent residence. If the person holds a homestead exemption at a different address, a presumption exists that the person has not established permanent residence as required by this section. Furthermore, the bill provides that the exemption does not apply to a person or entity who previously held 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 79 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 80 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.

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

Section 82 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 83 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 bill 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.[43]

Sections 83 and 85 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 84 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.[44]

Section 86 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).[45] 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.[46]

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,

[43] 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.
[44] See s. 400.145, F.S.
[45] 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).
[46] 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).

optometrists, or dentists, exclusively in connection with the diagnosis and treatment of their own patients.[47]

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.[48]

Section 90 amends s. 456.054, F.S., to move anti-kickback language for clinical labs from s. 483.245, F.S., which is being repealed into the general provisions for healthcare practitioners.

Section 96 of the bill repeals part I of ch. 483, F.S., relating to the licensure and regulation of clinical laboratories by the agency. Part I includes ss. 483.011 - 483.26, F.S. Laboratories will continue to be certified by, or receive a certificate of waiver from the CMS under the CLIA. Included within the repeal is a requirement that lab results must be reported directly to the licensed practitioner or other authorized person who requested it, and the authorization for a laboratory to disclose the results without a patient's consent to other health care practitioners and providers involved in the care or treatment of the patient as specified in s. 456.057(7)(a), F.S.

Section 98 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.[49] The statewide committee is created within the agency as a consumer protection and advocacy organization on behalf of managed care subscribers. The statewide committee has administrative authority over the district committees and consists of the chairpersons of the district committees.

A district committee is created in s. 641.65, F.S., in each district of the agency that has staff assigned for the regulation of managed care programs. Each district committee must have no fewer than nine members or more than 16 members, including at least four physicians, one licensed under chs. 458, 459, 460, and 461; one psychologist; one registered nurse; one clinical social worker; one attorney; and one consumer.[50]

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

[47] Section 483.035(1), F.S.
[48] Supra note 3.
[49] Chapter 96-391, Laws of Fla.
[50] Section 641.65(2), F.S.

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.[51]

Sections 117-122 repeal ss. 641.60, 641.65, 641.67, 641.68, 641.70, and 641.75, F.S., to eliminate the state wide and district Managed Care Ombudsman Committees.

Miscellaneous Provisions

Section 62 amends s. 408.061, F.S., relating to data collection by the agency from health care facilities, to conform cross-references and to exclude hospitals operated by state agencies from the requirement to submit certain financial reports.

Section 88 amends s. 435.12, F.S., to allow a person who passed a level 2 screening after December 31, 2012, to extend the date for screening renewal until January 1, 2020, (rather than for 5 years as required in current law) unless the Florida Department of Law Enforcement (FDLE) begins participation in the nation retained print arrest notification program before that date. The bill also extends the retention of fingerprints by the FDLE until January 1, 2021, or the date the FDLE begins participation in the program.

Technical and Conforming Sections

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

Section 55 amends s. 400.933, F.S., to make a technical change specifying that it is the Department of Business and Professional Regulation that issues medical oxygen retail establishment permits and not the DOH.

Section 77 amends s. 492.02, F.S., to make technical grammatical changes to the section.

Sections 1, 3-15, 17, 19, 20-22, 25, 42,50, 57, 59, 63, 66, 72, 73, 75-76, 81, 89, 91-95, 97, 99-116, and 123-127.

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 128 establishes an effective date of July 1, 2018.

[51] Supra note 3

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.[52]

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 between $400 - $3,919 biennially, depending upon the annual volume of non-waived tests performed.[53]

C. Government Sector Impact:

Revenue of risk manager application fees will decrease by approximately $64,866 per year and revenue from laboratory licensure application fees will decrease by $1,540,000 per year.[54]

VI. Technical Deficiencies:

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

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[52] *See* the Application checklist available at: http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/risk_manager.shtml (last visited Nov. 29, 2017).
[53] *See* AHCA Clinical laboratory fees, available at: http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Laboratory_Licensure/fees.shtml (last visited Nov. 29, 2017).
[54] Supra n. 3

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.

The bill amends s. 491.003, F.S., to make technical grammatical changes to the bill. Line 2941 eliminates parentheses around the phrase "mental dysfunctions or disorders (whether cognitive, affective, or behavioral)." This phrase is part of a list and as such, the list should also be amended to use semicolons rather than commas in order to adequately distinguish the individual parts of the list from the phrase within the deleted parentheses. Additionally, the parenthetical phrase is used on lines 2838-2839, 2847-2848, 2882, 2893-2894, and 2951-2952 and these instances have not been amended. The bill should be amended to be consistent in its usage throughout the section.

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, 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, 408.061, 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, 435.12, 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 Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.