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 Appropriations Subcommittee on Health and Human Services

BILL:	SB 1760
INTRODUCER:	Senators Grimsley and Campbell
SUBJECT:	Health Care Facility Regulation
DATE:	April 17, 2017
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Stovall	HP	**Favorable**
2.	Forbes	Williams	AHS	**Pre-meeting**
3.			AP	
4.			RC	

I. Summary:

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

- Abolishes the licensure of clinical laboratories and health care risk managers. The requirement for clinical laboratories to be certified under federal requirements remains in effect. Health care risk managers remain an integral part of a comprehensive risk management program, but will no longer require licensure.
- Removes mobile surgical facilities from health care facility regulation.
- Authorizes hospitals to use alternate-site testing for certain laboratory services.
- Requires the agency to adopt rules for minimum licensure requirements relating to pediatric cardiac catheterization, pediatric open-heart surgery, organ transplantation, neonatal intensive care services, psychiatric services, and comprehensive medical rehabilitation.
- Requires each home health agency to identify the home health services it provides and indicate whether each service is considered skilled care. Additional regulatory requirements will apply to home health agencies providing skilled services.
- Establishes a voluntary process to apply for a certificate of exemption from licensure for a person providing home health services that are exempt from licensure.
- Enhances and clarifies the provisions affecting unlicensed activity for nurse registries and assisted living facilities.
- Clarifies responsibilities of nurse registries to reinforce the status of persons they refer to be independent contractors rather than employees.
- Removes prohibitions on a nurse registry providing remuneration to certain individuals who may provide referrals.

- Deletes certain provisions within specific facility licensing chapters to eliminate inconsistencies with the general facility licensing chapter, or to reduce regulatory burdens.
- Authorizes a licensee to request the alignment of the expiration date for multiple licenses held by the licensee.
- Repeals the subscriber assistance program and the statewide managed care ombudsman committee.

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

The act is effective July 1, 2017, except as otherwise expressly provided in the act.

II. Present Situation:

The AHCA is created in s. 20.42, F.S. It is the chief health policy and planning entity for the state and is responsible for, among other things, health facility licensure, inspection, and regulatory enforcement. It licenses or certifies and regulates 40 different types of health care providers, including hospitals, nursing homes, assisted living facilities, and home health agencies. In total, the agency licenses, certifies, regulates or provides exemptions for more than 42,000 providers.[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 within the bill, pertinent background is provided within the effect of proposed changes for the reader's convenience.

III. Effect of Proposed Changes:

Clinical Laboratories and Clinical Laboratory Personnel

Clinical Laboratories

The federal Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA).[3] 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.[4]

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[1] *See* the Agency for Health Care Administration, Division of Health Quality Assurance web page available at: http://ahca.myflorida.com/MCHQ/index.shtml (last visited March 22, 2017).
[2] *See* s. 408.802, F.S., for the health care provider types and applicable licensure statutes.
[3] https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/CLIA (last visited Mar. 17, 2017).
[4] 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

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.[5]

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

Section 72 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.

Conforming amendments:

- Sections 5, 7, 10, and 16 amend ss. 381.0031, 381.004, 384.31, and 395.009, F.S., respectively, to remove references to a laboratory licensed under ch. 483, F.S., and to instead refer to a laboratory certified by the CMS under the CLIA.
- Section 6 amends s. 381.0034, F.S., to conform a cross-reference to the repeal of part I of ch. 483, F.S.
- Section 8 amends s. 383.313, F.S., to conform the performance of laboratory services by a birth center with the repeal of clinical laboratory licensure and the changes in the licensure of clinical laboratory personnel.
- Section 33 amends s. 395.7015, F.S., to remove licensed clinical laboratories from the annual assessment imposed on health care entities.
- Section 34 amends s. 400.0625, F.S., to require all clinical laboratory tests performed for a nursing home to be performed by a licensed clinical laboratory, with certain exceptions. (See comment under technical deficiencies.) The bill also deletes the requirement that clinical laboratory tests performed prior to admission in the nursing home by qualified labs shall be accepted in lieu of additional laboratory tests that might be required as a part of the routine examinations for admission.

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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 Mar. 17, 2017).

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

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

- Section 47 amends s. 400.9905, F.S., relating to health care clinics, to remove cross-reference to licensure under part I of ch. 483.
- Section 48 amends s. 408.033, F.S., relating to local and state health planning, to remove the assessment imposed on clinical laboratories as a funding source of local health councils.
- Section 51 amends s. 408.07, F.S., relating to the Florida Center for Health Information and Transparency and related reporting by licensed health care facilities to remove the definition of clinical laboratories.
- Section 54 amends s. 408.802, F.S., to delete clinical laboratories from regulation under part II of ch. 408, F.S.
- Section 59 amends s. 408.820, F.S., to delete specified exemptions applicable to the regulation of clinical laboratories.
- Section 60 amends s. 409.905, F.S., to delete reference to licensure under ch. 483 and adds the requirement for certification by the CMS under CLIA for laboratory services that are paid for by Medicaid.
- Sections 62 and 71 amend ss. 409.975 and 458.345, F.S., respectively, to conform a cross-reference to the renumbered definitions in s. 408.07, F.S., in section 51.
- Sections 68 and 69 amend ss. 456.001 and 456.057 F.S., respectively, to conform cross-references that have changed due to the repeal of part I of ch. 483, F.S.
- Section 75 amends s. 483.803, F.S., to conform definitions to the repeal of part I of ch. 483, F.S.
- Sections 76 and 77 amend ss. 483.813 and 491.003, F.S., to remove references to provisions in part I of ch. 483, F.S.
- Section 78 amends s. 627.351, F.S., relating to medical malpractice risk apportionment to remove clinical laboratories from the definition of health care provider.
- Section 94 amends s. 945.36, F.S., to affirmatively authorize certain law enforcement personnel to administer a urine screen drug test on inmates and releases, rather than exempting the law enforcement personnel from part I of ch. 483, F.S.

Clinical Laboratory Personnel

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

Section 1 amends s. 20.43. F.S., to repeal the Board of Clinical Laboratory Personnel under the Division of Medical Quality Assurance in the Department of Health.

Section 74 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

[7] Sections 483.801 and 483.813, F.S.

laboratory work is performed for patients referred by a health care provider who is not a member of the same group.

Hospital and Health Care Facility Licensure

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

Conforming amendments:

- Sections 11, 12, 61, 62, and 80 amend ss. 385.211, 394.4787, 409.9116, 409.975, and 627.64194, F.S., respectively, to conform a cross-reference to the renumbered definitions in s. 395.002, F.S.
- Sections 13, 14, 15, 18, 19, 92, and 93 amend ss. 395.001, 395.002, 395.003, 395.0161, 395.0163, 766.118, and 766.202, F.S., respectively, to remove reference to a mobile surgical facility in the section.
- Section 33 amends s. 395.7015, F.S., to remove mobile surgical facilities from the annual assessment imposed on health care entities.
- Section 49 amends s. 408.036, F.S., to remove mobile surgical facilities as a project subject to an exemption for certificates of need (CON).
- Section 54 amends s. 408.802, F.S., to delete mobile surgical facilities from regulation under part II of ch. 408, F.S.
- Section 59 amends s. 408.820, F.S., to delete specified exemptions applicable to the regulation of mobile surgical facilities.

Section 17 creates s. 395.0091, F.S., relating to alternate-site testing, to enable hospitals to use a laboratory testing site in which the testing is done under the administrative control of a hospital but performed out of the physical or administrative confines of the central laboratory. This section directs the agency, in consultation with the Board of Clinical Laboratory Personnel, to adopt by rule the criteria for alternate-site testing to be performed under the supervision of a clinical laboratory director. The rule must address, at a minimum, a hospital internal needs assessment, a protocol of implementation, criteria to be used in selecting the method of testing, minimum training and education requirements of professionals in the laboratory, an internal and external quality control protocol, tracking mechanisms between the alternate-site and the central laboratory, and recordkeeping. An alternate-site testing location must be registered when the hospital renews its license.

Section 26 repeals s. 395.10974, F.S., which establishes the licensure requirements for health care risk managers. Section 20 amends s. 395.0197, F.S., to require an internal risk manager of a health care facility to demonstrate to the hiring facility or its governing board, competence, by

[8] *Supra* note 6, p. 3.

education or experience in the same areas[9] as required to be demonstrated to the agency for licensure as a health care risk manager. This section also removes references to licensure under s. 395.10974, F.S., as a risk manager.

Conforming amendments:

- Section 23 repeals s. 395.10971, F.S., which provides legislative findings and intent with respect to the health care risk manager program.
- Section 24 repeals s. 395.10972, F.S., which establishes a health care risk manager advisory council within the agency. There are no current council members, and there have been no council meetings for at least 10 years. In addition, the statute contains no defined role or responsibilities for the council.[10]
- Section 25 amends s. 395.10973, F.S., to eliminate the agency's rulemaking authority for licensure standards, determination of qualification, and licensure of a health care risk manager.
- Section 27 repeals s. 395.10975, F.S., relating to grounds for denial, suspension, or revocation of a health care risk manager's license.
- Section 54 amends s. 408.802, F.S., to delete health care risk managers from regulation under part II of ch. 408, F.S.
- Section 59 amends s. 408.820, F.S., to delete specified exemptions applicable to the regulation of health care risk managers.
- Sections 70 and 88 amend ss. 458.307 and 641.55, F.S., respectively, to remove reference to the licensure requirement for a health care risk manager.

Section 21 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.[11] The agency enforces the emergency access to care requirements through the uniform complaint investigation procedure used for all license types and these complaints are given top priority. Section 395.1046, F.S., duplicates the complaint investigation procedures found in the general licensing provisions in part II of ch. 408, F.S. Also, s. 395.1046, F.S., provides confidentiality protections and a public records exemption for the results in the investigation report, that the agency proposes is an unnecessary level of confidentiality.[12]

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

[10] *Supra* n. 6, p .4.

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

[12] *Supra* n. 6, p. 3.

Section 22 amends s. 395.1055, F.S., to requires the agency to adopt rules to ensure that all hospitals providing pediatric cardiac catheterization, pediatric open-heart surgery, organ transplantation, neonatal intensive care services, psychiatric services, or comprehensive medical rehabilitation meet the minimum licensure requirements adopted by the agency. The licensure requirement shall include quality of care, nurse staffing, physician staffing, physical plant, equipment, emergency transportation, and data reporting standards. The agency indicates that adopted rules for all these procedures may take some time due to the interaction of various stakeholders.[13] The CON process includes standards; however, these conditions are not required to be met for continued licensure.[14]

Section 28 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.[15]

Conforming amendments:

- Section 29 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 30 repeals s. 395.604, F.S., relating to licensing hospitals for these obsolete programs.
- Section 31 repeals s. 395.605, F.S., relating to licensing emergency care hospitals which is now an obsolete program.
- Section 95 amends s. 1009.65, F.S., to conform a cross-reference to the renumbered definitions in s. 395.602, F.S.

Section 32 amends s, 395.701, F.S., relating to hospital assessments on inpatient and outpatient services. Current law excludes hospitals operated by the agency or the DOC. This section amends the current exclusion to any hospital operated by a state agency, to specifically exclude hospitals operated by the Department of Children and Families.[16]

Home Health Agencies

Section 35 amends s. 400.464, F.S., to require any license issued after June 30, 2017, to specify the home health services that the organization is authorized to perform and indicate whether each service is considered skilled care. In addition, providing or advertising services that require licensure and which are not specified on the face of the license issued after June 30, 2017, constitutes prohibited unlicensed activity.

[13] *Supra* note 6, p. 4.
[14] *Id.*
[15] *Id.*
[16] *Id.*

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

Conforming amendment:
Section 40 amends s. 400.497, F.S., relating to agency rulemaking to include applications for certificates of exemption from licensure.

Section 36 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.

Section 36 and 37 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 38 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 39 amends s. 400.484, F.S., renaming deficiencies as violations with respect to providing care by home health agencies and tying these violations to the general licensing provisions for health care facilities in part II of ch. 408, F.S.

Nurse Registries

Section 41 amends s. 400.506, F.S., to remove a grace period of 10-working days after notification from the agency that licensure is required, for an unlicensed nurse registry to cease operating to avoid committing a misdemeanor of the second degree. Under the bill, the unlicensed nurse registry must cease operations immediately. The agency is authorized to impose a fine of $1,000 per day in accordance with s. 408.812, F.S., in the general licensing provisions pertaining to unlicensed activity, rather than the $500 fine specified in this statute specifically relating to nurse registries.

This section clarifies the status of persons referred by the nurse registry as independent contractors rather than employees. Current law provides that is in not the obligation of a nurse registry to monitor, supervise, manage, or train a referred caregiver. The bill strengthens this concept by providing that a nurse registry is not permitted to do any of those activities. Similarly,

although a nurse registry is required to act as a repository of records, the bill provides that the nurse registry is not permitted to review or act upon such records, except for providing patients with information and notifying applicable licensing boards if a referred caregiver has credentialing deficiencies.

In addition, this section of the bill removes the prohibitions on a nurse registry providing remuneration to a case manager, discharge planner, facility based staff member, third party vendor, physician, member of the physician's office staff, or an immediate family member of a physician for referrals. Current law already exempts nurse registries from this prohibition if they do not bill Medicare or Medicaid or share a controlling interest with any entity that bills Medicare or Medicaid.

Assisted Living Facilities (ALF)

Section 63 amends s. 429.02, F.S., to revise the definition of personal services to prohibit an ALF from providing personal services to individuals who are not residents of the facility unless the ALF is providing authorized adult day care services within the licensed ALF. Section 67 amends s. 429.41, F.S., to require rulemaking for reasonable and fair minimum standards on this prohibition.

Section 64 amends s. 429.04, F.S., relating to exemptions from licensure to clarify and expand the exemptions to include a licensed hospital, nursing home, inpatient hospice, home for special services,[17] intermediate care facility, or transitional living facility. Additionally, this 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 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 65 amends s. 429.08, F.S., relating to unlicensed facilities to clarify and create a felony of the third degree penalty for renting or otherwise maintaining a building or property that operates or maintains an unlicensed ALF. Similarly, this section now provides that any person who owns, operates, or maintains an unlicensed ALF after receiving notice from the agency that licensure is required and to cease such operation commits a felony of the third degree. Current law provides a six-month window after a statutory or rule change takes place if the change

[17] 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.

placed the person in the position of violating this provision before the violation occurs. This six-month timeframe is repealed in the bill.

Section 66 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.

Multiphasic Health Testing Centers

Section 73 amends s. 483.294, F.S., to remove the requirement that a multiphasic health testing center must be inspected at least annually. Inspections are to be done in accordance with s. 408.811, F.S., which provides that inspections for relicensure shall occur biennially; however, an inspection may be performed at any time as needed. The general licensing provisions in part II of ch. 408, F.S., allow for accreditation inspections to be accepted in lieu of a full licensure inspection.

Amendments referencing General Licensing Provisions and Technical Amendments

Hospices

Section 42 amends s. 400.606, F.S., to remove the required submission of certain financial information at licensure renewal. This requirement conflicts with submission requirements in the general licensure requirements in part II of ch. 408, F.S.

Home Medical Equipment Providers

Section 43 is a technical amendment to s. 400.925, F.S., to move wheelchairs and related seating and positioning devices to a separate paragraph within the definition of home medical equipment.

Section 44 amends s. 400.931, F.S., to require a licensed home medical equipment provider to notify the agency of a change in the general manager within the timeframes established in part II of ch. 408, F.S., which is 21 days, rather than the 45-day timeframe provided in this section of law.

Section 45 is a technical amendment to s. 400.933, F.S., correcting the name of the state agency that issues medical oxygen retail establishment permits. It is now the Department of Business and Professional Regulation.

Health Care Service Pools

Section 46 amends s. 400.980, F.S., to require changes of information contained on the original registration application to be submitted to the agency within the timeframes established in part II of ch. 408, F.S., rather than 14 days prior to the change as required in this section of law.

General Licensing Provisions

Section 55 amends s. 408.803, F.S., to add a definition of “relative.”

Section 56 amends s. 408.806, F.S., relating to the license application process, to require the licensee to ensure that no person has any ownership interest in a licensee, directly or indirectly, who is ineligible pursuant to s. 408.809(4), F.S., which lists additional disqualifying offenses, most of which are fraud-related activity. Additionally, the licensee is required to ensure that no person holds or has held any ownership interest in a provider that has had a license or change of ownership application denied, revoked, or excluded pursuant to s. 408.815, F.S., which includes false representation; intentional or negligent acts affecting a client; demonstrated pattern of deficient performance; or being excluded, suspended, or terminated from participation in any state's Medicaid program or Medicare.

This section also authorizes 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 57 amends s. 408.810, F.S., to exempt an applicant for a change of ownership from submitting proof of financial ability to operate if the provider has been licensed for at least five years and the change is the result of a corporate reorganization under which the controlling interest is unchanged or solely due to the death of a controlling interest, and the surviving controlling 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.[18]

Section 58 amends s. 408.812, F.S., relating to unlicensed activity, to provide that unlicensed activity constitutes abuse and neglect, as defined in s. 415.102, F.S.[19] This section eliminates 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.

Subscriber Assistance Program

Section 53 of the bill repeals s. 408.7056, F.S., relating to the subscriber assistance program, effective January 1, 2018.

[18] *Supra* note 6, pp. 6-7.

[19] 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.

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),[20] 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.[21]

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[22] 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.[23]

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.[24]

Conforming amendments:

- Sections 2, 3, 4, 85, and 87 amend ss. 220.1845, 376.30781, 376.86, 641.51, and 641.515, F.S., respectively, to strike a cross-reference to s. 408.7056, F.S., to conform those provisions to repeal of the subscriber assistance program.
- Sections 79, 81, and 83 amend ss. 627.602, 627.6531, and 641.312, F.S., respectively, to delete an exemption for a health insurance policy, group health insurance policy, and health maintenance organization (HMO) contract that is subject to the subscriber assistance program.
- Section 82 amends s. 641.185, F.S., to remove a principle concerning regulatory oversight by various state entities relating to an HMO's expedited review of unresolved grievances pursuant to the subscriber assistance program.

[20] Pub. Law No. 111-148 (Mar. 23, 2010) amended by Pub. Law. No. 111-152 (Mar. 30, 2010).
[21] According to the agency, between FY 2011-2012 and FY 2012-2013, when the majority of plans opted to use the federal external review program, the number of cases received by the SAP dropped from 415 to 213. The number of cases heard by the SAP dropped from 74 to 17. There has been an uptick in both number of cases received by the subscriber assistance program and the number of cases heard by the panel for FY 2014-2015 and FY 2015-2016, with the latest full year of data showing 350 cases received and 53 cases heard. The predominant outcome of the cases in FY 2015-2016 was a determination of non-jurisdiction (#221), followed by submission of an incomplete application (#31) and found in favor of the subscriber (#27). *See* the chart prepared by the agency for activity since FY 2009-2010 at *supra* note 4, p. 7.
[22] A grandfathered health plan is a plan that existed on March 23, 2010, the date that the PPACA was enacted, and that at least one person had been continuously covered for 1 year. Plans or policies may lose their "grandfathered" status if they make certain significant changes that reduce benefits or increase costs to consumers. *See* Healthcare.gov, *Grandfathered Health Plans*, https://www.healthcare.gov/glossary/grandfathered-health-plan/ (last visited Mar. 23, 2017).
[23] *Supra* note 6, p. 7.
[24] *Id.*

- Section 84 amends s. 641.3154, F.S., to remove reference to an action after a recommendation is made by the SAP.
- Section 86 amends s. 641.511, F.S., relating to HMOs, to remove notice requirements to subscribers regarding the subscriber assistance program and authorizations for a subscriber to submit a grievance to the subscriber assistance program. This section also repeals a requirement for the HMO to maintain records of all grievances and report annually to the agency the total number of grievances handled, a categorization of the cases underlying the grievance, and the final disposition of the grievances.

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.[25] 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.[26]

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.[27]

Section 89 repeals s. 641.60, F.S., which authorizes the Statewide Managed Care Ombudsman Council.

Conforming amendments:
- Section 90 amends s. 641.70, F.S., relating to district managed care ombudsman committees, to remove all references to the statewide Managed Care Ombudsman Council.
- Section 91 amends s. 641.75, F.S., to conform cross-references to the repeal of s. 641.60, F.S.

Obsolete and Miscellaneous Provisions

Section 9 repeals s. 383.335, F.S., to remove a birth center exemption to one aspect of licensure for providers in existence over 30 years ago. Currently, no providers meet this exemption.[28]

Conforming Amendment:

[25] Chapter 96-391, L.O.F.
[26] Section 641.65(2), F.S.
[27] *Supra* note 6, p. 8.
[28] *Supra* note 6, p. 10.

- Section 47 amends s. 400.9905, F.S., relating to health care clinics to correct the cross-reference to statutes affecting birth centers.

Section 50 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.

The effective date of the bill is July 1, 2017, except as otherwise expressly provided in the bill.

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.[29]

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.[30]

[29] *See* the Application checklist available at: http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/risk_manager.shtml (last visited Mar. 24, 2017).
[30] *See* AHCA Clinical laboratory fees, available at: http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Laboratory_Licensure/fees.shtml (last visited Mar. 24, 2017).

C. Government Sector Impact:

The AHCA expects a reduction in revenue related to risk manager application fees (approximately $64,866 per year), and for laboratory licensure application fees ($1,383,400 per year). The total revenue reduction is approximately $1,448,266 annually.

VI. Technical Deficiencies:

The bill repeals the Board of Clinical Laboratory Personnel within the DOH, authorized by s. 20.43(3)(g)22, F.S. However, section 17 creates a new section of law, s. 395.0091, relating to alternate-site testing, that requires the agency, acting in consultation with the Board of Clinical Laboratory Personnel, to adopt rules pertaining to alternate-site testing.

Section 34 amends s. 400.0625, F.S., to require all clinical laboratory tests performed for a nursing home to be performed by a licensed clinical laboratory with certain exceptions. Given the repeal of clinical laboratory licensure in section 72, and the corresponding substitution of CMS-issued certificates under CLIA, an amendment might be needed for clarity.

Section 56 amends s. 408.806, F.S., relating to the license application process. The new language in the bill for subsection (1) refers to a licensee. For an initial application, a license has not yet been issued. It may be appropriate to assign the responsibilities to the applicant.

Section 89 of the bill repeals the Statewide Managed Care Ombudsman Committee but fails to conform references to the statewide committee in ss. 641.65 and 641.75(1) and (2), F.S.

VII. Related Issues:

Section 86 amends s. 641.511, F.S., relating to HMOs. Among other things, it eliminates a requirement for the HMO to maintain records of all grievances and report annually to the agency the total number of grievances handled, a categorization of the cases underlying the grievance, and the final disposition of the grievances. Eliminating this provision may be overly broad, if a similar recordkeeping/reporting provision does not exist, because it is not apparent how regulators could monitor subscriber grievances.

The bill repeals the Statewide Managed Care Ombudsman Committee but does not eliminate the district managed care ombudsman committees. District committees have not been established in most of the districts and no committees have been active since 2010. Other resources exist for protecting the rights of subscribers in managed care plans. For example, the Office of the Insurance Consumer Advocate is established in s. 627.0613, F.S., to represent subscribers as appropriate.[31] Eliminating the district committees or revising their structure might also be considered.

[31] *See also* The Office of the Insurance Consumer Advocate *Overview* website: http://www.myfloridacfo.com/division/ICA/Overview.htm (last visited March 23, 2017).

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, 383.313, 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, 400.464, 400.471, 400.474, 400.476, 400.484, 400.497, 400.506, 400.606, 400.925, 400.931, 400.933, 400.980, 400.9905, 408.033, 408.036, 408.061, 408.07, 408.20, 408.802, 408.803, 408.806, 408.810, 408.812, 408.820, 409.905, 409.9116, 409.975, 429.02, 429.04, 429.08, 429.176, 429.41, 456.001, 456.057, 458.307, 458.345, 483.294, 483.801, 483.803, 483.813, 491.003, 627.351, 627.602, 627.64194, 627.6513, 641.185, 641.312, 641.3154, 641.51, 641.511, 641.515, 641.55, 641.70, 641.75, 766.118, 766.202, 945.36, and 1009.65.

This bill creates section 395.0091 of the Florida Statutes.

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

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.