Health Care Appropriations Subcommittee

Tuesday, January 23, 2018
8:00 a.m. - 11:00 a.m.
Sumner Hall (404 HOB)

MEETING PACKET

Richard Corcoran
Speaker

Jason Brodeur
Chair

The Florida House of Representatives
Appropriations Committee
Health Care Appropriations Subcommittee

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Agenda
Tuesday, January 23, 2018
8:00 a.m. – 11:00 a.m.
Sumner Hall (404 HOB)

I. **Call to Order/Roll Call**

II. **Opening Remarks**

III. **Consideration of the following bill(s):**

- HB 597 Health Care Facility Regulation by Yarborough
- HB 673 Reporting Of Adverse Incidents In Planned Out-Of-Hospital Births by Magar
- CS/HB 1099 Advanced Birth Centers by Health Quality Subcommittee, Magar
- HB 6057 Office of Public and Professional Guardians Direct-Support Organization by Fischer

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(850) 717-4810 Fax: (850) 488-9633

IV. Chair's Budget Proposal for FY 2018-19

V. Closing Remarks/Adjournment

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HOUSE OF REPRESENTATIVES STAFF ANALYSIS

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

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

SUMMARY ANALYSIS

HB 597 amends various authorizing and licensing statutes for entities regulated by the Agency for Health Care Administration (AHCA). The bill clarifies existing licensure and enforcement requirements, amends certain provisions to eliminate conflict between part I of ch. 395, F.S., ch. 400, F.S., and part II of ch. 408, F.S., increases administrative efficiency at AHCA, and repeals redundant or obsolete statutes. Specifically, the bill:

- Repeals part I of ch. 483, F.S. regulating clinical laboratories. Clinical laboratories that perform testing on specimens derived from within Florida will no longer be required to obtain state licensure. Clinical laboratories will continue to be certified by the federal Clinical Laboratory Improvement Amendments program.
- Repeals the health care risk manager licensure requirements and the Health Care Risk Manager Advisory Council.
- Addresses unlicensed assisted living facilities (ALFs) by strengthening the enforcement capabilities of AHCA.
- Defines the assistance an ALF must provide a resident under the Resident Bill of Rights.
- Repeals the Subscriber Assistance Program, which resolves disputes between health maintenance organizations and subscribers. Subscribers have several other options in state and federal law to resolve such disputes.
- Eliminates the mobile surgical facility license. To date, no license has been issued for a mobile surgical facility.
- Repeals obsolete special designations of rural hospitals.
- Eliminates conflict between part II of ch. 408, F.S., and home health agency licensure statutes.
- Protects vulnerable adults receiving health or custodial care by deeming unlicensed activity as abuse and neglect for purpose of triggering adult protective services under ch. 415, F.S.
- Repeals the Statewide Managed Care Ombudsman Committee. The last activity on record was in 2010, and there are currently no active committees.
- Eliminates the special procedures for investigating emergency access complaints against hospitals, allowing AHCA to use the existing hospital complaint investigation procedures used for all other types of complaints.
- Repeals an exemption to licensure for any facility that was providing obstetrical and gynecological surgical services and was owned and operated by a board-certified obstetrician on June 15, 1984. There are currently no providers who meet the definition.
- Removes language that prevents nurse registries from marketing their services.
- Excludes individuals from employment with licensees if they have a pending domestic violence offense and excludes providers from participation in the Medicaid program for criminal offenses including offenses related to the provision of health care services, fraud, and controlled substances.
- Extends the date for which an individual must be re-screened if required to undergo a level 2 background screening.
- Establishes the authority of a county with a public health trust over the trust's facility.
- Makes necessary conforming changes throughout the statutes to reflect the changes proposed in the bill.

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

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Agency for Health Care Administration – Division of Health Quality Assurance

The Division of Health Quality Assurance (HQA), housed within the Agency for Health Care Administration (AHCA), licenses, certifies, and regulates 40 different types of health care providers. In total, HQA regulates more than 49,500 individual providers.[1] Regulated providers include:

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

Health Care Facility Licensing

Background

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

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

authorizing statute which includes unique provisions for licensure beyond the uniform criteria. In the case of conflict between the Act and an individual authorizing statute, the Act prevails.[4]

Relatives

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

Unlicensed Activity

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

Ownership

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

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

Hospice Licensure

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

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

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

Background Investigations

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

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

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

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

Effect of the Bill – Health Care Facility Licensing

Relatives

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

Additionally, the bill grants AHCA rule-making authority to govern the circumstances under which a controlling interest of a licensed facility, an administrator, an employee, a contractor, or a representative thereof, who is not a relative of the patient or client, can act as the patient's or client's legal representative, agent, health care surrogate, power of attorney, or guardian. The bill requires the rules to include disclosure requirements, bonding, restrictions, and patient or client protections.

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

Unlicensed Activity

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

Ownership

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

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

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

Hospice Licensure

The bill removes the requirement for an existing licensed health care provider to provide a copy of the most recent profit-loss statement and licensure inspection report with his or her application for hospice licensure. Profit-loss statements and proof of financial ability are already required to be collected pursuant to the Act and licensure inspection reports for all health care providers are readily available via the internet.

Expiration Dates

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

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

Background Investigations

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

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

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

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

The bill authorizes FDLE to retain the fingerprints of individuals screened until January 1, 2021, unless a national fingerprint retention program becomes available before that date. AHCA may extend the screening renewal period of a person who passed a background screening after December 31, 2012, until January 1, 2020, F.S., unless a national fingerprint retention program becomes available before that date.

Clinical Laboratories

Background

A clinical laboratory is the physical location in which services are performed to provide information or materials for use in the diagnosis, prevention, or treatment of a disease or the identification or assessment of a medical or physical condition.[21] Services performed in clinical labs include:

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

Clinical laboratories are regulated under part I of ch. 483, F.S. In keeping with federal law and regulations, clinical laboratories must meet appropriate standards.[25] Such standards include overall standards of performance that comply with the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA), and the federal rules adopted thereunder, for a comprehensive quality assurance program[26] and standards of performance in the examination of specimens for clinical laboratory proficiency testing programs using external quality control procedures.[27] AHCA may impose an administrative fine of up to $1,000 per violation of any statute or rule.[28] In determining the penalty to be imposed for a violation, AHCA must consider the following factors:

- The severity of the violation.
- Actions taken by the licensee to correct the violation or to remedy the complaint.
- Any previous violation by the licensee.
- The financial benefit to the licensee of committing or continuing the violation.[29]

In 1993, Florida enacted legislation requiring all facilities, including doctor's offices, performing clinical laboratory testing to be licensed.[30] AHCA previously issued two types of clinical laboratory licenses: one for laboratories that only performed waived testing and one for laboratories that performed non-waived testing.[31] Waived tests are simple laboratory examinations and procedures that have an

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[21] S. 483.041, F.S.
[22] S. 483.041(2)(a), F.S.
[23] S. 483.041(2)(b), F.S.
[24] S. 483.041(2)(c), F.S.
[25] S. 483.021, F.S.
[26] S. 483.051(2)(a), F.S.
[27] S. 483.051(2)(b), F.S.
[28] S. 483.221(1), F.S.
[29] S. 483.221(2)(a)-(d), F.S.
[30] Id.
[31] Agency for Health Care Administration, *Clinical Laboratory Regulation in Florida*, pg. 2, available at http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Laboratory_Licensure/docs/clin_lab/OverviewBrochure_lab.pdf (last visited November 20, 2017).

insignificant risk of erroneous result; any other tests are considered non-waived.[32] In 2009, the requirement for laboratories that performed waived testing to obtain a state license was repealed. However, facilities performing any non-waived clinical laboratory testing or testing using microscopes must obtain a clinical laboratory license before the laboratory is authorized to perform testing.[33] Currently, all clinical laboratories performing non-waived testing in Florida must hold both a valid state license and federal CLIA certificate.[34]

Clinical Laboratory Improvement Amendments of 1988

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

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

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

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[32] Examples of waived tests include urine dipstick, blood glucose, etc. A full list of waived tests can be found at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm (last visited November 20, 2017).
[33] Agency for Health Care Administration, *Clinical Laboratories*, 2017, available at http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Laboratory_Licensure/non-waived_apps.shtml (last visited November 20, 2017).
[34] Id. In an effort to streamline the licensing process, Florida enacted comprehensive basic licensure requirements under part II of ch. 408, F.S. that impacted all facilities licensed by AHCA, including clinical laboratories. Health care facility licensing procedures can also be found in Chapter 59A-35, F.A.C.
[35] Centers for Medicare & Medicaid Services, *Clinical Laboratory Improvement Amendments (CLIA)*, available at https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/CLIA/10_Categorization_of_Tests.asp (last visited November 20, 2017).
[36] Department of Health and Human Services, Office of the Inspector General, *Enrollment and Certification Processes in the Clinical Laboratory Improvement Amendments Program*, (Aug. 2001), available at https://oig.hhs.gov/oei/reports/oei-05-00-00251.pdf (last visited November 20, 2017)
[37] Id.
[38] Supra, FN 31.
[39] Supra, FN 27.
[40] Center for Surveillance, Epidemiology, and Laboratory Services, *Provider-Performed Microscopy Procedures: A Focus on Quality Practices*, February 2016, available at https://wwwn.cdc.gov/clia/Resources/PPMP/pdf/15_258020-A_Stang_PPMP_Booklet_FINAL.pdf (last visited November 20, 2017). PPMPs are a select group of moderately complex microscopy tests commonly performed by health care providers during patient office visits. Tests included in PPMP do not meet the criteria for waiver because they are not simple procedures, but rather require training and specific skills to conduct such tests.
[41] Centers for Medicare and Medicaid Services, *Clinical Laboratory Improvement Amendments (CLIA): How to Obtain a CLIA Certificate*, (March 2006), available https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/HowObtainCLIACertificate.pdf (last visited November 20, 2017). All certificates are effective for two years.

Alternate Site Laboratory Testing

Generally, a hospital's main or central laboratory or satellite laboratories that are licensed clinical laboratories established on the same or adjoining grounds of a hospital licensed under ch. 395, F.S., may perform clinical laboratory testing.[42] Testing at satellite labs must be done by licensed clinical laboratory personnel. Section 483.051(9), F.S., allows for alternate-site testing, which is any laboratory testing done under the administrative control of a hospital, but performed out of the physical or administrative confines of the hospital's central laboratory. This allows tests to be performed bedside, at a nurse station, in an operating room or the emergency room, or anywhere else under the administrative control of a hospital. AHCA has rulemaking authority, in consultation with the Board of Clinical Laboratory Personnel, to adopt criteria for alternate-site testing to be performed under the supervision of a clinical laboratory director.

Effect of the Bill – Clinical Laboratories

The bill repeals part I of ch. 483, F.S., which regulates clinical laboratories. Clinical laboratories that perform testing on specimens from within the state will no longer be required to obtain state licensure. Clinical laboratories will continue to be certified by the CLIA program under federal law.[43] Such certification is required for a clinical laboratory to provide testing services in Florida.

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

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

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

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

Health Care Risk Managers

Background

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

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[42] Rule 59A-7.034, F.A.C.

[43] Agency for Health Care Administration, *2018 Agency Legislative Bill Analysis*, November 14, 2017 (on file with the Health and Human Services Committee).

[44] Healthcare Administration Degree Programs, *What is a Health Care Risk Manager?*, available at http://www.healthcare-administration-degree.net/faq/what-is-a-health-care-risk-manager/ (last viewed November 20, 2017).

[45] Id.

[46] American Society for Healthcare Risk Management, *Overview of the Healthcare Risk Management Profession*, available at http://www.ashrm.org/about/HRM_overview.dhtml (last visited November 20, 2017).

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

- A process to investigate and analyze the frequency and causes of adverse incidents to patients;
- Appropriate measures to minimize the risk of adverse incidents to patients;
- The analysis of patient grievances that relate to patient care and the quality of medical services;
- A system for informing a patient or an individual that she or he was the subject of an adverse incident; and
- An incident reporting system which allows for the reporting of adverse incidents to the risk manager within 3 business days after their occurrence.[49]

Licensure of Health Care Risk Managers

Florida is the only state to require the licensure of health care risk managers.[50] Health care risk managers are licensed by AHCA. To qualify for licensure, an applicant must demonstrate competence, by education or experience, in:

- Applicable standards of health care risk management;
- Applicable federal, state, and local health and safety laws and rules;
- General risk management administration;
- Patient care;
- Medical care;
- Personal and social care;
- Accident prevention;
- Departmental organization and management;
- Community interrelationships; and
- Medical terminology.[51]

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

- 18 years of age or over; and
- A high school graduate or equivalent; and
    - Has fulfilled the requirements of a 1-year program or its equivalent in health care risk management training which may be developed or approved by AHCA;
    - Has completed 2 years of college-level studies which would prepare the applicant for health care risk management, to be further defined by rule; or
    - Has obtained 1 year of practical experience in health care risk management.[52]

AHCA currently licenses 2,458 health care risk managers and 602, or 24.5 percent, report working in a licensed capacity for at least one hospital or ASC.[53] On average, for the past five years, approximately 174 initial applications for licensure are received and 181 licensees fail to renew each year.[54]

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[47] S. 395.0197(1)-(2), F.S.
[48] S. 395.10971, F.S.
[49] S. 395.0197(1)(a)-(d), F.S.
[50] American Society for Healthcare Risk Management, *A Brief History of ASHRM 1980-2010... 30 Years and Counting!*, 2010, pg. 7., available at http://www.ashrm.org/about/files/A_Brief_History_of_ASHRM.pdf (last visited November 20, 2017).
[51] S. 395.10974(1), F.S.
[52] S. 395.10974(2). F.S.
[53] Supra, FN 39.
[54] Id.

Denial, Suspension, or Revocation of a License

AHCA may deny, suspend, revoke, or refuse to renew or continue the license of an applicant or health care risk manager for various grounds, including submitting false information in a license application, unlicensed practice, various criminal disqualifications, and the following:

- Repeatedly acting in a manner inconsistent with the health and safety of the patients of the licensed facility in which the licensee is the health care risk manager;
- Being unable to practice health care risk management with reasonable skill and safety to patients by reason of illness; drunkenness; or use of drugs, narcotics, chemicals, or any other material or substance or as a result of any mental or physical condition;
- Willfully permitting unauthorized disclosure of information relating to a patient or a patient's records; or
- Discriminating against patients, employees, or staff on account of race, religion, color, sex, or national origin.[55]

When a health care risk manager fails to complete his or her tasks, the licensed facility is cited for any applicable violations, not the health care risk manager. Health care risk managers are exempt from monetary liability for any act or proceeding performed within the scope of the internal risk management program if the risk manager acts without intent to defraud.[56] In the last 5 years, AHCA received three complaints against health care risk managers. The complaints involved allegations for which AHCA does not have regulatory and disciplinary authority such as practicing law without a license and activities of the individuals as claims adjusters for an insurance company not as the risk manager of a licensed facility.[57]

Health Care Risk Manager Advisory Council

Current law authorizes AHCA to establish a seven-member Health Care Risk Manager Advisory Council (Council) to advise AHCA on health care risk manager issues.[58] If the Council is established, it must consist of:

- Two active health care risk managers, including one risk manager who is recommended by and a member of the Florida Society of Healthcare Risk Management.
- One active hospital administrator.
- One employee of an insurer or self-insurer of medical malpractice coverage.
- One public representative.
- Two licensed health care practitioners, one of whom must be a physician licensed under ch. 458 or ch. 459.[59]

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

Effect of the Bill – Health Care Risk Managers

The bill repeals health care risk manager licensure requirements and the Council. Licensed facilities must maintain an internal risk management program, but may hire any risk manager to run the program who meets criteria established by each facility. Repeal of the Council is appropriate if the health care risk manager licensure requirements are repealed.

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

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

Assisted Living Facilities

Background

Licensure

An assisted living facility (ALF) is a residential establishment, or part of a residential establishment, that provides housing, meals, and one or more personal services for a period exceeding 24 hours to one or more adults who are not relatives of the owner or administrator.[61] A personal service is direct physical assistance with, or supervision of, the activities of daily living and the self-administration of medication.[62] Activities of daily living include ambulation, bathing, dressing, eating, grooming, toileting, and other similar tasks.[63]

ALFs are licensed and regulated by AHCA under part I of ch. 429, F.S., and part II of ch. 408, F.S.[64] In addition to a standard license, an ALF may have one or more specialty licenses that allow the ALF to provide additional care. These specialty licenses include limited nursing services,[65] limited mental health services,[66] and extended congregate care services.[67] The Department of Elder Affairs (DOEA) is responsible for establishing training requirements for ALF administrators and staff.[68]

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

An ALF administrator is responsible for the operation and maintenance of an ALF.[70] Administrators must meet minimum training and education requirements established by DOEA. The training and education requirements allow administrators to assist ALFs to appropriately respond to the needs of residents, to maintain resident care and facility standards, and to meet licensure requirements.[71] The required training and education must cover, at least, the following topics:

- State law and rules applicable to ALFs;
- Resident rights and identifying and reporting abuse, neglect, and exploitation;

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

- Special needs of elderly persons, persons with mental illness, and persons with developmental disabilities, and how to meet those needs;
- Nutrition and food service, including acceptable sanitation practices for preparing, storing, and serving food;
- Medication management, recordkeeping, and proper techniques for assisting residents with self-administered medication;
- Fire safety requirements, including fire evacuation drill procedures and other emergency procedures; and
- Care of persons with Alzheimer's disease and related disorders.[72]

All ALF administrators and managers must successfully complete ALF core training course and pass a competency test within 3 months from the date of becoming an ALF administrator.[73] Administrators must complete at least 12 contact hours of continuing education every 2 years.[74] Effective October 1, 2015, each new ALF administrator or manager, who has not previously completed core training, must attend a preservice orientation provided by the ALF before interacting with residents. The preservice orientation must be at least 2 hours in duration and cover topics that help the employee provide responsible care and respond to the needs of ALF residents.[75]

An ALF must provide appropriate care and services to meet the needs of the residents admitted to the facility.[76] The owner or facility administrator determines whether an individual is appropriate for admission to the facility based on certain criteria.[77] If a resident no longer meets the criteria for continued residency, or the facility is unable to meet the resident's needs, as determined by the facility administrator or a health care provider, the resident must be discharged in accordance with the Resident Bill of Rights.[78]

Unlicensed Assisted Living Facilities

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

- A facility, institution, or other place operated by the federal government;
- A facility licensed under ch. 393, F.S.,[79] or ch. 394, F.S.;[80]
- A facility licensed as an adult family-care home;
- Any person who provides housing, meals, and one or more personal services[81] on a 24-hour basis in the person's own for to not more than two adults who do not receive optional state supplementation.[82] The person providing the housing, meals, and personal services must own or rent the home and reside therein;
- Certain homes or facilities approved by the U.S. Department of Veterans Affairs;
- Certain facilities that have been incorporated in this state for 50 years or more on or before July 1, 1983;

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

- Any facility licensed under ch. 651, F.S., as a continuing care retirement community, or a retirement community that provide certain services to its residents who live in single-family homes, duplexes, quadraplexes, or apartments on its campus under certain conditions; and
- A residential unit for independent living located within a facility certified under ch. 651, F.S., or co-located with a licensed nursing home.[83]

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

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

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

Inspections, Surveys and Monitoring Visits

Current law authorizes AHCA to inspect each licensed ALF at least once every 24 months to determine compliance with statutes and rules. Section 408.813, F.S. categorizes violations into four classes according to the nature and gravity of its probable effect on residents. If an ALF is cited for a class I violation or three or more class II violations arising from separate surveys within a 60-day period or due to unrelated circumstances during the same survey, AHCA must conduct an additional licensure inspection within six months.[94] Similarly, the Resident Bill of Rights requires AHCA to perform a biennial survey to determine whether a facility is adequately protecting residents' rights.[95]

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

Facilities with limited nursing services (LNS) or extended congregate care (ECC) licenses are subject to monitoring visits by AHCA to inspect the facility for compliance with the requirements of the specialty license type. An LNS licensee is subject to monitoring inspections at least twice a year. At least one

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[83] S. 429.04, F.S.
[84] S. 429.08(1)(b), F.S.
[85] S. 429.08(1)(c), F.S.
[86] S. 429.08(2)(a), F.S.
[87] S. 429.08(2)(b), F.S.
[88] The Medicaid Fraud Control Unit investigates and prosecutes Medicaid provider fraud, as well as allegations of patient, abuse, neglect, and exploitation in facilities receiving payments under the Medicaid program, such as nursing homes and assisted living facilities. Office of the Attorney General, *Medicaid Fraud Control Unit,* available at http://www.myfloridalegal.com/pages.nsf/Main/EBC480598BBF32D885256CC6005B54D1 (last visited November 20, 2017).
[89] Supra, FN 39.
[90] S. 429.08, F.S.
[91] Id. A felony in the third degree is punishable by a term of imprisonment of up to 5 years (s. 775.082, F.S.), and a fine of up to $5,000 (s. 775.083, F.S.)
[92] Supra, FN 86.
[93] Supra, FN 53.
[94] S. 429.34(2), F.S.
[95] S. 429.28(3), F.S.
[96] Id.

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

Penalties

Under s. 408.813, F.S., ALFs are subject to administrative fines imposed by AHCA for certain types of violations. In addition, AHCA can take other actions against a facility. AHCA may deny, revoke, or suspend any license for any of the actions listed in s. 429.14(1)(a)-(k), F.S., such as an intentional or negligent act seriously affecting the health, safety, or welfare of a resident of the facility or a determination by AHCA that the owner lacks the financial responsibility to provide continuing adequate care to residents. AHCA must deny or revoke the license of an ALF with two or more class I violations that are similar to violations identified during a survey, inspection, monitoring visit, or complaint investigation occurring within the previous 2 years.[97] AHCA may also impose an immediate moratorium or emergency suspension on any provider if it determines that any condition presents a threat to the health, safety, or welfare of a client.[98] AHCA is required to publicly post notification of a license suspension or revocation, or denial of a license renewal, at the facility.[99] Finally, ch. 825, F.S., provides criminal penalties for the abuse, neglect, and exploitation of elderly persons[100] and disabled adults.[101]

Resident Contracts

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

Assistance to Residents

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

- Taking a medication from where it is stored and bring it to the resident;
- In the presence of the resident, reading the label, opening the container, removing the prescribed amount from the container, and closing the container;
- Placing the dosage in the resident's hand or in another container and lifting the container to the resident's mouth;
- Returning medication to proper storage; and

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[97] S. 429.14(4), F.S.
[98] S. 408.814(1), F.S.
[99] S. 429.14(7), F.S.
[100] "Elderly person" means a person 60 years of age or older who is suffering from the infirmities of aging as manifested by advanced age or organic brain damage, or other physical, mental, or emotional dysfunction, to the extent that the ability of the person to provide adequately for the person's own care or protection is impaired. S. 825.101(5), F.S. It does not constitute a defense to a prosecution for any violation of ch. 825, F.S., that the accused did not know the age of the victim. S. 825.104, F.S.
[101] "Disabled adult" means a person 18 years of age or older who suffers from a condition of physical or mental incapacitation due to a developmental disability, organic brain damage, or mental illness, or who has one or more physical or mental limitations that restrict the person's ability to perform the normal activities of daily living. S. 825.101(4), F.S.
[102] S. 429.24, F.S.
[103] S. 429.256(2), F.S.

- Maintaining a record of when a resident receives assistance with self-administration.[104]

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

Effect of the Bill – Assisted Living Facilities.

ALF Licensure Compliance

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

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

ALF Unlicensed Activity

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

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

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

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

The bill modifies the definition of "personal services" to close loopholes taken advantage of by unlicensed providers. Because s. 429.02(17), F.S., defines personal services as "direct physical assistance with supervision of the activities of daily living, *and* the self-administration of medicine, *and* other similar services which the department may define by rule," the statute could be interpreted to require all of the criteria be met in order to meet the definition of personal services. As an example, an

[104] S. 429.256(3)(a), F.S. A resident may also receive assistance with applying topical medications, using a nebulizer, using a glucometer to perform blood-glucose level checks, putting on and taking off anti-embolism stockings, applying and removing an oxygen cannula, the use of a continuous airway pressure device, measuring vital signs, and colostomy bags.
[105] S. 429.04(1)(d), F.S.

unlicensed provider giving multiple patients assistance with medication would not meet the definition because the unlicensed provider was also not giving direct physical assistance with the activities of daily living. The bill changes the definition of "personal services" to direct physical assistance with supervision of the activities of daily living, *or* the self-administration of medicine, *or* other similar services which the department may define by rule." The change allows AHCA to prosecute unlicensed providers who meet any of the criteria in the definition rather than only providers that meet all of the criteria.

ALF Inspections and Surveys

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

ALF Resident Contracts

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

ALF Assistance to Residents

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

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

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

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

[106] S. 400.145, F.S.

Mobile Surgical Facilities

Background

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

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

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

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

AHCA licenses and regulates mobile surgical facilities.[107] The initial application for licensure must include:

- Proof of fictitious name registration, if applicable;
- Articles of Incorporation or a similarly titled document registered by the applicant with the Florida Department of State; and
- The center's zoning certificate or proof of compliance with zoning requirements.[108]

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

- The governing board bylaws, rules and regulations, or other written organizational plan;
- A roster of medical staff members;
- A roster of registered nurses and licensed practical nurses with current license numbers; and
- The Comprehensive Emergency Management Plan, pursuant to Rule 59A-5.018, F.A.C.[109]

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

A license fee of $1,679.82 must accompany an application for an initial, renewal, or change of ownership license for a mobile surgical facility.[110] Upon receipt of the required information, AHCA will conduct a licensure inspection to determine compliance with the applicable statutes and rules.[111] Once the mobile surgical facility is in compliance and has received all approvals, AHCA will issue a license, which identifies the licensee and the name and location of the center.[112] AHCA may revoke or deny a license if it there has been substantial failure to comply with the applicable statutes and rules.[113]

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

Since the enactment of the mobile surgical facility license in statute, no such license has been issued and no applications for the license are anticipated.[114]

Effect of the Bill – Mobile Surgical Facilities

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

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

Hospital Regulation

Background

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

State-Operated Hospitals

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

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[110] Rule 59A-5.003(7), F.A.C.
[111] Rule 59A-5.003(12), F.A.C.
[112] Rule 59A-5.003(13), F.A.C.
[113] Rule 59A-5.003(15), F.A.C. A "substantial failure to comply" means that there has been a major, or significant, breach of a requirement in law or rule. If a licensee fails to pay its renewal fee after receiving notice, AHCA may find that there is a substantial failure to comply and may suspend or revoke the license.
[114] Supra, FN 39.
[115] S. 409.918, F.S.
[116] S. 395.701, F.S.
[117] Id.

DCF operates seven hospitals and treatment centers statewide:

- Florida State Hospital in Chattahoochee;
- Northeast Florida State Hospital in Macclenny;
- South Florida State Hospital in Pembroke Pines;
- North Florida Evaluation and Treatment Center in Gainesville;
- South Florida Evaluation and Treatment Center in Florida City;
- Treasure Coast Forensic Treatment Center in Indiantown; and
- West Florida Community Care Center in Milton.[118]

The Department of Corrections (DOC) operates the Reception and Medical Center in Lake Butler, where newly committed male inmates are processed into the corrections system and medical care is provided to inmates.[119]

Complaint Investigation Procedures

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

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

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

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

Emergency Services

The federal Emergency Medical Treatment and Labor Act (EMTALA)[122] passed in 1986 after "patient dumping," the practice of refusing to treat uninsured patients in need of emergency care, came to the

[118] Department of Children and Families, *State Mental Health Treatment Facilities*, available at http://www.myflfamilies.com/service-programs/mental-health/state-mental-health-treatment-facilities (last visited November 20, 2017).
[119] Department of Corrections, *Reception and Medical Center (RMC)*, 2014, available at http://www.dc.state.fl.us/facilities/region2/209.html (last visited November 20, 2017).
[120] S. 408.811, F.S.
[121] S. 408.813, F.S.
[122] 42 U.S.C. §1395

attention of the U.S. Congress.[123] In 1987, Florida enacted the first statute requiring some degree of emergency services to be provided to a patient regardless of the patient's ability to pay.[124]

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

- A person requests emergency services and care; or
- Emergency services and care are requested on behalf of a person by:
  - An emergency medical services provider who is rendering care to or transporting the person; or
  - Another hospital, when such hospital is seeking a medically necessary transfer.[125]

If a medically necessary transfer is made, it must be made to the geographically closest hospital with the service capability, unless another prior arrangement is in place or the geographically closest hospital is at service capacity.[126] Each hospital must retain records of each transfer made or received for a period of five years.[127] Decisions about services and care provided to an individual cannot be based upon the individual's:

- Race;
- Ethnicity;
- Religion;
- National origin;
- Citizenship;
- Age;
- Sex;
- Preexisting medical condition;
- Physical or mental handicap;
- Insurance status;
- Economic status; or
- Ability to pay for medical services.[128]

AHCA may deny, revoke, or suspend a hospital's license or impose an administrative fine, not to exceed $10,000 per violation, for any violation of access to emergency service and care laws.[129]

Section 395.1046, F.S., provides the procedures for complaints against hospitals regarding emergency access issues, such as a person being denied emergency services and care.[130] AHCA must investigate any complaint against a hospital for any violation which AHCA reasonably believes to be legally sufficient. A complaint is legally sufficient if it contains facts showing that a violation of ch. 395, F.S., or any rule adopted under ch. 395, F.S., has occurred.[131] AHCA may investigate emergency access complaints even if the complaint is withdrawn.[132] When the investigation is complete, AHCA prepares a report making a probable cause determination.[133]

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[123] Richard E. Mills, *Access to Emergency Services and Care in Florida*, The Florida Bar Journal, January 1998, available at https://www.floridabar.org/news/tfb-journal/?durl=/DIVCOM/JN/jnjournal01.nsf/cb53c80c8fabd49d85256b5900678f6c/1C3429F6216E4EA985256ADB005D6190!opendocument (last viewed November 20, 2017).
[124] Id.
[125] S. 395.1041(3)(a), F.S.
[126] S. 395.1041(3)(e), F.S.
[127] S. 395.1041(4)(a)1., F.S.
[128] S. 395.1041(3)(f), F.S.
[129] S. 395.1041(5)(a), F.S.
[130] S. 395.1041(1), F.S.
[131] S. 395.1046(1), F.S.
[132] Id.
[133] S. 395.1046(2), F.S.

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

Adult Cardiovascular Services

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

Level I ACS Programs

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

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

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

Level I ACS programs must meet the following staffing requirements:

- Each cardiologist shall be an experienced physician who has performed a minimum of 75 interventional cardiology procedures, exclusive of fellowship training, within the previous 12 months from the date of the Level I ACS application or renewal application.

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

- Physicians with less than 12 months experience shall fulfill applicable training requirements prior to being allowed to perform emergency PCI in a hospital that is not licensed for a Level II ACS program.
- Nursing and technical catheterization laboratory staff must:
  - Be experienced in handling acutely ill patients requiring intervention or balloon pump;
  - Have at least 500 hours of previous experience in dedicated cardiac interventional laboratories at a hospital with a Level II adult cardiovascular services program;
  - Be skilled in all aspects of interventional cardiology equipment; and
  - Participate in a 24-hour-per-day, 365 day-per-year call schedule.
- A member of the cardiac care nursing staff who is adept in hemodynamic monitoring and Intra-aortic Balloon Pump management shall be in the hospital at all times.[142]

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

Level II ACS Programs

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

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

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

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

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

Background Screening - Distinct Part Nursing Units

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

Standards for Tertiary Services

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

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

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

Effect of the Bill – Hospital Regulation

Emergency Access Complaints

The bill eliminates redundant procedures for investigating hospital emergency access complaints and allows AHCA to employ existing hospital complaint investigation procedures used for all other types of complaints. Section 395.1046, F.S., duplicates the complaint investigation procedure found in s. 408.811, F.S. Section 408.811, F.S., authorizes AHCA to inspect or investigate a licensed facility to ensure compliance with licensing requirements.

State-Operated Hospitals

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

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[151] A distinct part nursing unit is a unit of a hospital certified for participation in the Medicare and Medicaid nursing facility program (s. 395.1055(3), F.S. A distinct part must be physically distinguishable from the larger institution and fiscally separate for cost reporting purposes. *Medicare Provider Reimbursement Manual (2000)* available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R418PR1.pdf (last visited December 14, 2017).

[152] S. 408.032, F.S.

[153] Id.

Adult Cardiovascular Services

The bill provides an exception to the qualifications for a Level I ASC program, which will allow the Lower Keys Medical Center to become a Level I ACS provider. The facility would have to meet the physician qualification requirements for Level I ACS providers currently in rule, and meet lower annual volume requirements. Currently, Level I ACS providers must provide a minimum of 300 adult inpatient and outpatient diagnostic cardiac catheterizations. The facility must provide a minimum of 100 adult inpatient and outpatient diagnostic cardiac catheterizations. The facility will not have to meet the transfer time requirements to a Level II hospital.

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

Background Screening - Distinct Part Nursing Units

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

Standards for Tertiary Services

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

Rural Hospitals

Background

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

- The sole provider within a county with a population density of up to 100 persons per square mile;[155]
- An acute care hospital in a county with a population density of up to 100 persons per square mile, which is at least 30 minutes of travel time, on normally traveled roads under normal traffic conditions, from any other acute care hospital within the same county;[156]
- A hospital supported by a tax district or subdistrict whose boundaries encompass a population of up to 100 persons per square mile;[157]
- A hospital classified as a sole community hospital under 42 C.F.R. § 412.92 which has up to 175 licensed beds;[158]

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

- A hospital with a service area that has a population of up to 100 persons per square mile;[159] or
- A hospital designated as a critical access hospital, as defined in s. 408.07.[160]

Special Designations for Rural Hospitals

AHCA licenses four classes of hospital.[161] Class I licenses include rural hospitals.[162] All licensed hospitals must have:

- Inpatient beds;
- A governing authority legally responsible for the conduct of the hospital;
- A chief executive officer or others similarly titled official to who the governing authority delegates the full-time authority for the operation of the hospital in accordance with the established policy of the governing authority;
- An organized medical staff to which the governing authority delegates responsibility for maintaining proper standards for medical and other health care;
- A current and complete medical record for each patient admitted to the hospital;
- A policy requiring that all patients be admitted on the authority of and under the care of a member of the organized medical staff;
- Facilities and professional staff available to provide food to patients to meet their nutritional needs;
- A procedure for providing care in emergency cases;
- A method and policy for infection control; and
- An on-going organized program to enhance the quality of patient care and review the appropriateness of utilization of services.[163]

In addition, Class I hospitals must have:

- One licensed registered nurse on duty at all times on each floor or similarly titled part of the hospital for rendering patient care services;
- A pharmacy supervised by a licensed pharmacist either in the facility or by contract sufficient to meet patient needs;
- Diagnostic imaging services either in the facility or by contract sufficient to meet patient needs;
- Clinical laboratory services either in the facility or by contract sufficient to meet patient needs;
- Operating room services; and
- Anesthesia service.[164]

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

An emergency care hospital is a medical facility which provides:

- Emergency medical treatment; and
- Inpatient care to ill or injured person prior to their transportation to another hospital; or
- Inpatient medical care to persons needing such care up to 96 hours.[165]

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[159] S. 395.602(2)(e)5., F.S. As used in this subparagraph, the term "service area" means the fewest number of zip codes that account for 75 percent of the hospital's discharges for the most recent 5-year period, based on information available from the hospital inpatient discharge database at the Florida Center for Health Information and Transparency.
[160] S. 395.602(2)(e)6., F.S.
[161] Rule 59A-3.252(1), F.A.C.
[162] Rule 59A-3.252(1)(a)3., F.A.C.
[163] Rule 59A-3.252(2), F.A.C.
[164] Rule 59A-3.252(3), F.A.C.
[165] S. 395.602(2)(a), F.S.

An essential access community hospital is a facility which:

- Has at least 100 beds;
- Is located more than 35 miles from any other essential access community hospital, rural referral center, or urban hospital meeting the criteria for classification as a regional referral center;[166]
- Is part of a network that includes rural primary care hospitals;
- Provides emergency and medical backup services to rural primary care hospitals in its rural health network;
- Extends staff privileges to rural primary care hospital physicians in its network; and
- Accepts patients transferred from rural primary care hospitals in its network.[167]

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

- Provides twenty-four-hour emergency medical care;
- Provides temporary inpatient care for 72 hours or less to patients requiring stabilization before discharge or transfer to another hospital; and
- Has no more than six licensed acute care inpatient beds.[168]

The essential access community hospital and rural primary care hospital designations were established under federal programs that were implemented in 1993 and subsequently replaced in 1997 by the Critical Access Hospital program.[169] The designations of "emergency care hospital," "essential access community hospital," and "rural primary care hospital are redundant or obsolete since the implementation of the Critical Access Hospital program.[170]

Effect of the Bill – Rural Hospitals

The bill repeals the emergency care hospital, essential access community hospital, and rural primary care hospital designations. There are no rural hospitals with those designations, and the federal Critical Access Hospital program has replaced the essential access community hospital and rural primary care hospital designations. A hospital currently meeting the definition of rural hospital will continue to be classified as a rural hospital.

An inactive rural hospital bed is a licensed acute care hospital bed, as defined in s. 395.002(13), that cannot be occupied by an acute care inpatient.[171] There is no longer a need for hospitals to track inactive beds because AHCA no longer maintains a list of facilities with inactive beds for the purpose of publishing the need for additional acute care beds under the Certificate of Need (CON) program.[172]

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

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

Home Health Agencies

Background

Home health agencies (HHAs) are organizations licensed by AHCA to provide home health and staffing services.[173] Home health services are health and medical services and medical supplies furnished to an individual in the individual's home or place of residence. These services include:

- Nursing care;
- Physical, occupational, respiratory, or speech therapy;
- Home health aide services (assistance with daily living such as bathing, dressing, eating, personal hygiene, and ambulation);
- Dietetics and nutrition practice and nutrition counseling; and
- Medical supplies, restricted to drugs and biologicals prescribed by a physician.[174]

Staffing services are provided to health care facilities, schools, or other business entities on a temporary or school-year basis by licensed health care personnel and by certified nursing assistants and home health aides who are employed by, or work under the umbrella of, a licensed HHA.[175]

A HHA may also provide homemaker[176] and companion[177] services without additional licensing or registration. These services do not involve hands-on personal care to a client and typically include housekeeping, meal planning and preparation, shopping assistance, routine household activities, and accompanying the client on outings. Personnel providing homemaker or companion services are employed by or under contract with a HHA.[178]

Licensure and Exceptions

Since 1975, HHAs operating in Florida have been required to obtain a state license.[179] HHAs must meet the general health care licensing provisions[180] and specific HHA licensure provisions and standards.[181] A HHA license is valid for 2 years, unless revoked.[182] If a HHA operates related offices, each related office outside the health service planning district where the main office is located must be separately licensed.[183] As of November 20, 2017, there are 1,917 licensed HHAs in Florida.[184]

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

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

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

- A HHA operated by the federal government;
- A home health aide or certified nursing assistant who is acting in his or her individual capacity, within the definitions and standards of his or her occupation, and who provides hands-on care to patients in their homes;
- The delivery of nursing home services for which the nursing home is licensed under part II of ch. 400, F.S., to serve its residents; and
- A not-for-profit, community-based agency that provides early intervention services to infants and toddlers.[188]

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

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

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

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

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

A director of nursing may be the director for a maximum of five licensed HHAs if the HHAs have identical controlling interests, are located within one geographic service area or within an immediately contiguous county, and each HHA has a registered nurse who meets the qualifications of a director of nursing and has been delegated by the director of nursing to serve in the stead of the director. An employee of a retirement community that provides multiple levels of care may serve as the director of

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

nursing of a HHA and of up to four entities licensed under ch. 400, F.S., or ch. 429, F.S., if they are owned, operated, or managed by the same corporate entity.[196]

Effect of the Bill – Home Health Agencies

The bill requires that any HHA license issued on or after July 1, 2018, must specify the home health services the HHA is authorized to perform and whether such services are considered "skilled care." Currently, an initial licensure applicant must be fully accredited to obtain a license to provide skilled nursing services, however, accreditation is not required if, after initial licensure, a home health agency requests to begin providing skilled nursing services. The bill closes the loophole by which a home health agency could forgo full accreditation after initial licensure by requiring proof of accreditation when seeking approval to begin providing skilled nursing services.

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

The bill removes the exemption for HHAs that are not Medicaid or Medicare certified and do not provide skilled care, or provide only physical, occupational, or speech therapy to have a director of nursing. The provision ensures that skilled nursing care services are overseen by a registered nurse, and ensures recipients of such services are receiving appropriate care.

The bill removes the definitions of Class I, II, III, and IV violations from s. 400.484(2), F.S., and instead references the definitions of the violations found in s. 408.813, F.S. This eliminates redundancy and resolves differences between the two sections of law. The bill retains the specified administrative fines that may be charged for each class of violations.

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

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

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

Birth Centers

Background

A birth center is any facility, institution, or place, which is not an ambulatory surgical center, a hospital or in a hospital, in which births are planned to occur away from the mother's usual residence following a normal, uncomplicated, low-risk pregnancy.[198] A birth center must include:

- Birthing rooms;

[196] S. 400.476(2), F.S.
[197] Supra, FN 39.
[198] S. 383.302(2), F.S.

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

A birth center must be equipped with those items needed to provide low-risk maternity care and readily available equipment to initiate emergency procedures in life-threatening events to a mother and baby.[200]
Current law provides an exemption to birth center licensure for any facility that was providing obstetrical and gynecological surgical services and was owned and operated by a board-certified obstetrician on June 15, 1984.[201] According to AHCA, there are currently no providers who meet these criteria.[202]

Effect of the Bill – Birth Centers

The bill repeals the exemption to birth center licensure for any facility that was providing obstetrical and gynecological surgical services and was owned and operated by a board-certified obstetrician on June 15, 1984.

Nurse Registries

Background

A nurse registry refers to any person that procures, offers, promises, or attempts to secure healthcare-related contracts for registered nurses, licensed practical nurses, certified nursing assistants, home health aides, companions, or homemakers, who are compensated by fees as independent contractors, including, but not limited to, contracts for the provision of services to patients and contracts to provide private duty or staffing services to hospitals, nursing homes, hospices, ALFs, and other business entities.[203] A nurse registry is exempt from the licensing requirements of a HHA, but must be licensed as a nurse registry.[204]

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

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

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

Agency to impose a $500.00 fine for each day of continued non-compliance. However, s. 408.812, F.S., authorizes the Agency to impose a $1000.00 per day fine for each day of continued operation after Agency notification.

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

Effect of the Bill – Nurse Registries

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

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

Home Medical Equipment

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

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

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

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[208] Id.
[209] S. 400.925(6), F.S., defines home medical equipment as any product as defined by the Federal Drug Administration, any products reimbursed under the Medicare Part B Durable Medical Equipment benefits or the Florida Medicaid durable medical equipment program. Such equipment includes oxygen and related respiratory equipment, wheelchairs and related seating and positioning, but does not include motorized scooters, personal transfer systems, specialty beds, prosthetics, orthotics, or custom-fabricated splints, braces, or aids.
[210] S. 400.925(9), F.S., defined home medical equipment services as equipment management and consumer instruction, including selection, delivery, setup, and maintenance of equipment, and other related services for the use of home medical equipment in the consumer's place of residence.
[211] See generally s. 400.931, F.S.
[212] The United States Pharmacopoeia (USP) is a list of drugs licensed for use in the U.S. with standards necessary to determine purity suitable for persons.
[213] S. 499.82(10), F.S.
[214] Ch. 499, F.S.
[215] Supra, FN 39.

Health Care Service Pools

A health care services pool is any person, firm, corporation, partnership, or association which provides temporary employment in health care facilities, residential facilities, and agencies for licensed, certified, or trained health care personnel, including nursing assistants, nurses' aides, and orderlies.[216] Registration or a license issued by AHCA is required for the operation of a health care services pool.[217] Currently, if a health care services pool must change information contained its original registration application, it must notify AHCA 14 days prior to the change.[218]

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

Health Care Clinics

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

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

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

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[216] S. 400.980(1), F.S.
[217] S. 400.980(2), F.S.
[218] Id.
[219] The Health Care Clinic Act was enacted in 2003 to reduce fraud and abuse in the personal injury protection insurance system. A health care clinic is an entity where health care services are provided to individuals and which tenders charges for reimbursement of such services (s. 400.9905(4), F.S.)
[220] Section 400.9905(4), F.S.
[221] S. 400.9905(4), F.S.
[222] Rule 59A-33.006, F.A.C.
[223] Supra, FN 39.

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

Nursing Home Guide

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

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

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

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

Public Health Trusts

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

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

- Sanatoriums;
- Clinics;
- Ambulatory care centers;
- Primary care centers;
- Hospitals;
- Rehabilitation centers;
- Health training facilities;

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

- Nursing homes;
- Nurses' residence buildings;
- Infirmaries;
- Outpatient clinics;
- Mental health facilities;
- Residences for the aged;
- Rest homes;
- Health care administration buildings; and
- Parking facilities and areas serving health care facilities.

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

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

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

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

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

Subscriber Assistance Program

Background

Managed Health Care

Managed care refers to a variety of methods of financing and organizing the delivery of comprehensive health care in an effort to control costs and improve quality by controlling the provision of services.

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

Managed care, in varying degrees, integrates the financing and delivery of medical care through contracts with selected physicians, hospitals, and other health care providers that provide comprehensive health care services to enrolled members for a predetermined monthly premium. The term "managed care organization" or "entity" includes health maintenance organizations, exclusive provider organizations, prepaid health clinics and Medicaid prepaid health plans. In addition, a health insurer that sells a preferred provider contract may be considered to be a "managed care" plan.[236] Since 1973, under federal law,[237] HMOs have been required to establish and provide meaningful procedures for hearing and resolving grievances between the HMO and members of the organization. Medical groups and other health care delivery entities providing health care services for the organization must also be afforded grievance procedures under the federal law. Grievance procedures provide a mechanism to ensure that subscribers have a means of receiving further consideration of a HMO's decisions that deny care, treatment, or services. Under state law, such mechanisms are extended to adverse decisions of other types of managed care entities.[238]

Health insurance regulators have also had a substantial role in helping to resolve disputes arising between consumers and their health insurance carriers and health plans.[239] The types of disputes that regulators consider relate to decisions to deny or limit coverage and judgments about medical necessity or appropriateness of care.[240]

External Review Process

Section 641.47(1), F.S., defines the term "adverse determination" to mean a coverage determination by a HMO or prepaid health clinic that an admission, availability of care, continued stay, or other health care service has been reviewed and, based upon the information provided, does not meet the organization's requirements for medical necessity, appropriateness, health care setting, level of care or effectiveness, and coverage for the requested service is therefore denied, reduced, or terminated. An adverse determination may be the basis for a grievance. A subscriber who chooses to challenge an adverse determination or file another type of grievance is required to first go through the managed care entity's internal grievance procedure. Once a final decision is rendered through this process, if the decision is unsatisfactory to the subscriber, then the subscriber may appeal through a binding arbitration process provided by the managed care entity or to the Subscriber Assistance Program (SAP).[241]

Subscriber Assistance Program

In 1985, Florida became the second state, following Michigan, to provide a mechanism for consumers to resolve managed care disputes through a state-administered external review process. The Florida program was moved from the Department of Health and Rehabilitative Services (HRS) to AHCA in 1993, and renamed the Statewide Provider and Subscriber Assistance Program (SAP).[242]

Section 408.7056, F.S., requires AHCA to implement the SAP to assist consumers of managed care entities with grievances that have not been satisfactorily resolved through the managed care entity's internal grievance process. The program can hear grievances of subscribers of HMOs, prepaid health clinics and exclusive provider organizations.[243]

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[236] The Florida Senate, *Review of the Implementation of the Statewide Provider and Subscriber Assistance Program*, September 2001, pg. 1-2, available at http://archive.flsenate.gov/data/Publications/2002/Senate/reports/interim_reports/pdf/2002-138hc.pdf (last visited November 27, 2017).
[237] Health Maintenance Organization Act of 1973, Title 42, Sec. 300e, et seq.
[238] Id.
[239] Pollitz, K., Dallek, G., et al., *External Review of Health Plan Decisions: An Overview of Key Program Features in the States and Medicare*, (prepared for Kaiser Family Foundation) Institute for Health Care Research and Policy, November 1998.
[240] Supra, FN 233.
[241] Id.
[242] Id.
[243] Id.

The panel must consist of:

- Members employed by AHCA and members employed by the Office of Insurance Regulation (OIR), chosen by their respective agencies;
- A consumer appointed by the Governor;
- A physician appointed by the Governor, as a standing member; and
- Physicians who have expertise relevant to the case to be heard, on a rotating basis.[244]

The agency may contract with a medical director and a primary care physician who may provide additional expertise. The medical director must be selected from a Florida licensed HMO.[245]

SAP hearings are public, unless a closed hearing is requested by the subscriber. A portion of a hearing may be closed by the panel when deliberating information of a sensitive personal nature, such as medical records.[246] In addition to hearings, the panel must meet as often as necessary to timely review, consider, and hear grievances about disputes between a subscriber, or a provider on behalf of a subscriber, and a managed care entity. Following its review, the panel must make a recommendation to AHCA or DOI. The recommendation may include specific actions the managed care entity must take to comply with state laws or rules. AHCA or DOI may adopt all or some of the panel's recommendations and may impose administrative sanctions on the managed care entity.[247] The following chart shows the number of cases received by the SAP, the number of cases heard by the panel, and the outcome of each case heard since FY 2009-2010.

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

SAP Cases	FY 2009-2010	FY 2010-2011	FY 2011-2012	FY 2012-2013	FY 2013-2014	FY 2014-2015	FY 2015-2016	FY 2016-2017
Total Number of Cases Received by SAP (MCD - # Medicaid cases)	498 (70 MCD)	506 (75 MCD)	415 (50 MCD)	213 (57 MCD)	160 (50 MCD)	238 (114 MCD)	350 (204 MCD)	253 (101 MCD)
Total Number of Cases Heard by The Panel (MCD - # Medicaid cases)	124 (7 MCD)	96 (9 MCD)	74 (3 MCD)	17 (2 MCD)	19 (8 MCD)	29 (12 MCD)	53 (37 MCD)	28 (12 MCD)
Outcomes of Cases								
Determined Non-jurisdictional	246	260	224	145	115	166	221	165
Incomplete Application	39	37	40	24	11	27	31	24
Request Withdrawn	27	21	20	9	6	11	26	10
Resolved Prior to Panel Hearing	68	82	55	18	9	7	19	26
Panel Found in Favor of Subscriber	23	23	19	5	7	7	27	6
Panel Found in Favor of Plan	95	83	57	12	12	17	25	22

The Patient Protection and Affordable Care Act (PPACA) governs how insurance companies handle initial appeals and how consumers can request reconsideration of a payment denial.[249] If an insurance company upholds its decision to deny payment, the law provides consumers with the right to appeal the decision to an outside, independent decision-maker. Insurance companies may choose to participate in a process administered by the federal Department of Health and Human Services (HHS) or contract with independent review organizations in states where the federal government oversees the process.[250] Managed care plans that elected to participate in the federal program established by PPACA are no

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

longer required to participate in the SAP.[251] Following enactment of PPACA, the majority of the health plans elected to use the federal program and, as a result, the SAP is no longer an external appeal option for the majority of their members.[252]

Effect of the Bill – Subscriber Assistance Program

The bill repeals s. 408.7056, F.S. that established the SAP. Consumers will no longer be able to use the SAP as an alternative appeal option after exhausting the managed care entity's grievance process. However, consumers have access to the grievance resolution program provided by PPACA, through either the federally administered process or independent contractor review. Further, the number of cases received by the SAP and the number of cases heard by the panel have steadily decreased over the past eight years. There will be an insignificant adverse effect to consumers as a result of repeal of the SAP because of the small percentage of people currently taking advantage of the program.

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

Medicaid Provider Background Investigations

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

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

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

Effect of the bill – Medicaid Provider Background Investigations

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

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

Managed Care Ombudsman Committees

Background

The Statewide Managed Care Ombudsman Committee (Committee) is established by s. 641.60, F.S., and was created to serve as a consumer protection and advocacy organization on behalf of health care consumers receiving services through managed care organizations.[254] In addition to the statewide Committee, district committees are established to protect consumers receiving managed care services at a more local level. The districts are established by each health service planning district, composed of the following counties:

- District 1—Escambia, Santa Rosa, Okaloosa, and Walton Counties.
- District 2—Holmes, Washington, Bay, Jackson, Franklin, Gulf, Gadsden, Liberty, Calhoun, Leon, Wakulla, Jefferson, Madison, and Taylor Counties.
- District 3—Hamilton, Suwannee, Lafayette, Dixie, Columbia, Gilchrist, Levy, Union, Bradford, Putnam, Alachua, Marion, Citrus, Hernando, Sumter, and Lake Counties.
- District 4—Baker, Nassau, Duval, Clay, St. Johns, Flagler, and Volusia Counties.
- District 5—Pasco and Pinellas Counties.
- District 6—Hillsborough, Manatee, Polk, Hardee, and Highlands Counties.
- District 7—Seminole, Orange, Osceola, and Brevard Counties.
- District 8—Sarasota, DeSoto, Charlotte, Lee, Glades, Hendry, and Collier Counties.
- District 9—Indian River, Okeechobee, St. Lucie, Martin, and Palm Beach Counties.
- District 10—Broward County.
- District 11—Miami-Dade and Monroe Counties.[255]

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

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

Each district committee or member of the committee:

- Must serve to protect the health, safety, and rights of all enrollees participating in managed care programs in this state.
- Must receive complaints regarding quality of care from the agency, and may assist the agency with the resolution of complaints.
- May conduct site visits with the agency, as the agency determines is appropriate.

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

- Must submit an annual report to the statewide committee concerning activities, recommendations, and complaints reviewed or developed by the district committee during the year.
- Must conduct meetings as required at the call of its chairperson, the call of the agency director, the call of the statewide committee, or by written request of a majority of the district committee members.[259]

Effect of the Bill - Managed Care Ombudsman Committees

The bill repeals the Statewide Managed Care Ombudsman Committee and district managed care ombudsman committees. Due to the very stringent committee requirements, the Committee could not meet the requirements in the majority of the districts and the program was never fully implemented. The last activity on record was in 2010, and there are currently no active committees.[260]

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

B. SECTION DIRECTORY:

Section 1: Amends s. 20.43, F.S., relating to Department of Health.
Section 2: Creates s. 154.13, F.S.; relating to designated facilities; jurisdiction.
Section 3: Amends s. 220.1845, F.S., relating to contaminated site rehabilitation tax credit.
Section 4: Amends s. 376.30781, F.S., relating to tax credits for rehabilitation of drycleaning-solvent-contaminated sites and brownfield sites in in designated brownfield areas; application process; rulemaking authority; revocation authority.
Section 5: Amends s. 376.86, F.S., relating to Brownfield Areas Loan Guarantee Program.
Section 6: Amends s. 381.0031, F.S., relating to epidemiological research; report of diseases of public health significance to department.
Section 7: Amends s. 381.0034, F.S., relating to requirement for instruction on HIV and AIDS.
Section 8: Amends s. 381.004, F.S., relating to HIV testing.
Section 9: Amends s. 381.0405, F.S., relating to Office of Rural Health.
Section 10: Amends s. 381.14, F.S. relating to screening for metabolic disorders, other hereditary and congenital disorders, and environmental risk factors.
Section 11: Amends s. 383.30, F.S., relating to Birth Center Licensure Act; short title.
Section 12: Amends s. 383.301, F.S., relating to licensure and regulation of birth centers.
Section 13: Amends s. 383.302, F.S., relating to definitions of terms used in ss. 383.30-383.335.
Section 14: Amends s. 383.305, F.S., relating to licensure; fees.
Section 15: Amends s. 383.309, F.S., relating to minimum standards for birth centers; rules and enforcement.
Section 16: Amends s. 383.313, F.S., relating to performance of laboratory and surgical services; use of anesthetic and chemical agents.
Section 17: Amends s. 383.33, F.S., relating to administrative penalties; moratorium on admissions.
Section 18: Repeals s. 383.335, F.S., relating to partial exemptions.
Section 19: Amends s. 384.31, F.S., relating to testing of pregnant women; duty of the attendant.
Section 20: Amends s. 385.211, F.S., relating to refractory and intractable epilepsy treatment and research at recognized medical centers.
Section 21: Amends s. 394.4787, F.S., relating to definitions; ss. 394-4786, 394.4787, 394.4788, and 394.4789.
Section 22: Amends s. 395.001, F.S., relating to legislative intent.
Section 23: Amends s. 395.002, F.S., relating to definitions
Section 24: Amends s. 395.003, F.S., relating to licensure; denial, suspension, and revocation.
Section 25: Amends s. 395.009, F.S., relating to minimum standards for clinical laboratory test results and diagnostic X-ray results; prerequisite for issuance or renewal of license.
Section 26: Creates s. 395.0091, F.S., relating to alternate-site testing.

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

Section 27: Amends s. 395.0161, F.S., relating to licensure inspection.
Section 28: Amends s. 395.0163, F.S., relating to construction inspections; plan submission and approval; fees.
Section 29: Amends s. 395.0197, F.S., relating to internal risk management program.
Section 30: Repeals s. 395.1046, F.S., relating to complaint investigation procedures.
Section 31: Amends s. 395.1055, F.S., relating to rules and enforcement.
Section 32: Repeals s. 395.10971, F.S., relating to purpose.
Section 33: Repeals s. 395.10972, F.S., relating to Health Care Risk Manager Advisory Council.
Section 34: Amends s. 395.10973, F.S., relating to powers and duties of the agency.
Section 35: Repeals s. 395.10974, F.S., relating to health care risk managers; qualifications, licensure, fees.
Section 36: Repeals s. 395.10975, F.S., relating to grounds for denial, suspension, or revocation of a health care risk manager's license; administrative fine.
Section 37: Amends s. 395.602, F.S., relating to rural hospitals.
Section 38: Amends s. 395.603, F.S., relating to deactivation of general hospital beds; rural hospital impact statement.
Section 39: Repeals s. 395.604, F.S., relating to other rural hospital programs.
Section 40: Repeals s. 395.605, F.S., relating to emergency care hospitals.
Section 41: Amends s. 395.701, F.S., relating to annual assessments on net operating revenues for inpatient and outpatient services to fund public medical assistance; administrative fines for failure to pay assessments when due; exemption.
Section 42: Amends s. 395.7015, F.S., relating to annual assessment on health care entities.
Section 43: Amends s. 400.0625, F.S. relating to minimum standards for clinical laboratory test results and diagnostic X-ray results.
Section 44: Amends s. 400.191, F.S., relating to availability, distribution, and posting of reports and records.
Section 45: Amends s. 400.464, F.S., relating to home health agencies to be licensed; expiration of license; exemptions; unlawful acts; penalties.
Section 46: Amends s. 400.471, F.S., relating to application for license; fee.
Section 47: Amends s. 400.474, F.S., relating to administrative penalties.
Section 48: Amends s. 400.476, F.S., relating to staffing requirements; notifications; limitations on staffing services.
Section 49: Amends s. 400.484, F.S., relating to right of inspection; deficiencies; fines.
Section 50: Amends s. 400.497, F.S., relating to rules establishing minimum standards.
Section 51: Amends s. 400.506, F.S., relating to licensure of nurse registries; requirements; penalties.
Section 52: Amends s. 400.606, F.S., relating to license; application; renewal; conditional license or permit; certificate of need.
Section 53: Amends s. 400.925, F.S. relating to definitions.
Section 54: Amends s. 400.931, F.S., relating to application for license; fee.
Section 55: Amends s. 400.933, F.S., relating to licensure inspections and investigations.
Section 56: Amends s. 400.980, F.S., relating to health care services pools.
Section 57: Amends s. 400.9905, F.S., relating to definitions.
Section 58: Amends s. 400.9935, F.S., relating to clinic responsibilities.
Section 59: Amends s. 408.033, F.S., relating to local and state health planning.
Section 60: Amends s. 408.036, F.S., relating to projects subject to review; exemptions.
Section 61: Amends s. 408.0361, F.S., relating to cardiovascular services and burn unit licensure.
Section 62: Amends s. 408.061, F.S., relating to data collection; uniform systems of financial reporting; information relating to physician charges; confidential information; immunity.
Section 63: Amends s. 408.07, F.S., relating to definitions.
Section 64: Amends s. 408.20, F.S., relating to assessments; Health Care Trust Fund.
Section 65: Repeals s. 408.7056, F.S., relating to Subscriber Assistance Program.
Section 66: Amends s. 408.802, F.S., relating to applicability.
Section 67: Creates s. 408.803, F.S., relating to definitions.
Section 68: Amends s. 408.806, F.S., relating to license application process.
Section 69: Amends s. 408.809, F.S., relating to background screening; prohibited offenses.

Section 70: Amends s. 408.810, F.S., relating to minimum licensure requirements.
Section 71: Amends s. 408.812, F.S., relating to unlicensed activity.
Section 72: Amends s. 408.820, F.S., relating to exemptions.
Section 73: Amends s. 409.905, F.S., relating to mandatory Medicaid services.
Section 74: Amends s. 409.907, F.S., relating to Medicaid provider agreements.
Section 75: Amends s. 409.9116, F.S., relating to disproportionate share/financial assistance program for rural hospitals.
Section 76: Amends s. 409.975, F.S., relating to managed care plan accountability.
Section 77: Amends s. 429.02, F.S., relating to definitions.
Section 78: Amends s. 429.04, F.S. relating to facilities to be licensed; exemptions.
Section 79: Amends s. 429.08, F.S., relating to unlicensed facilities; referral of person for residency to unlicensed facility; penalties.
Section 80: Amends s. 429.176, F.S., relating to notice of change of administrator.
Section 81: Amends s. 429.19, F.S., relating to violations; imposition of administrative fines; grounds.
Section 82: Amends s. 429.24, F.S., relating to contracts.
Section 83: Amends s. 429.28, F.S., relating to Resident Bill of Rights.
Section 84: Amends s. 429.294, F.S., relating to availability of facility records for investigation of resident's rights violations and defenses; penalty.
Section 85: Amends s. 429.34, F.S., relating to right of entry and inspection.
Section 86: Amends s. 429.52, F.S., relating to staff training and educational programs; core educational requirements.
Section 87: Amends s. 435.04, F.S., relating to level 2 screening standards.
Section 88: Amends s. 435.12, F.s., relating to Care Provider Background Screening Clearinghouse.
Section 89: Amends s. 456.001, F.S., relating to definitions.
Section 90: Amends s. 456.054, F.S., relating to kickbacks prohibited.
Section 91: Amends s. 456.057, F.S., relating to ownership and control of patient records; report or copies of records to be furnished; disclosure of information.
Section 92: Amends s. 456.076, F.S., relating to impaired practitioner programs.
Section 93: Amends s. 458.307, F.S., relating to Board of Medicine.
Section 94: Amends s. 458.345, F.S., relating to registration of resident physicians, interns, and fellows; list of hospital employees; prescribing of medicinal drugs; penalty.
Section 95: Amends s. 459.021, F.S., relating to registration of resident physicians, interns, and fellows; list of hospital employees; penalty.
Section 96: Repeals part I of ch. 483, F.S., relating to clinical laboratories.
Section 97: Amends s. 483.294, F.S., relating to inspection of centers.
Section 98: Amends s. 483.801, F.S., relating to exemptions.
Section 99: Amends s. 483.803, F.S., relating to definitions.
Section 100: Amends s. 483.813, F.S., relating to clinical laboratory personnel license.
Section 101: Amends s. 483.823, F.S., relating to qualifications of clinical laboratory personnel.
Section 102: Amends s. 491.003, F.S., relating to definitions.
Section 103: Amends s. 627.351, F.S., relating to insurance risk apportionment plans.
Section 104: Amends s. 627.602, F.S., relating to scope, format of policy.
Section 105: Amends s. 627.6406, F.S., relating to maternity care.
Section 106: Amends s. 627.64194, F.S., relating to coverage requirements for services provided by nonparticipating providers; payment collection limitations.
Section 107: Amends s. 627.6513, F.S., relating to scope.
Section 108: Amends s. 627.6574, F.S., relating to maternity care.
Section 109: Amends s. 641.185, F.S., relating to health maintenance organization subscriber protections.
Section 110: Amends s. 641.31, F.S., relating to health maintenance contracts.
Section 111: Amends s. 641.312, F.S., relating to scope.
Section 112: Amends s. 641.3154, F.S., relating to organization liability; provider billing prohibited.
Section 113: Amends s. 641.51, F.S., relating to quality assurance program; second medical opinion requirement.

Section 114: Amends s. 641.511, F.S., relating to subscriber grievance reporting and resolution requirements.
Section 115: Amends s. 641.515, F.S., relating to investigation by the agency.
Section 116: Amends s. 641.55, F.S., relating to internal risk management program.
Section 117: Repeals s. 641.60, F.S., relating to Statewide Managed Care Ombudsman Committee.
Section 118: Repeals s. 641.65, F.S., relating to district managed care ombudsman committees.
Section 119: Repeals s. 641.67, F.S., relating to district managed care ombudsman committees; exemption from public records requirements; exceptions.
Section 120: Repeals s. 641.68, F.S., relating to district managed care ombudsman committees; exemption from public meeting requirements.
Section 121: Repeals s. 641.70, F.S., relating to agency duties relating to the Statewide Managed Care Ombudsman Committee and the district managed care ombudsman committees.
Section 122: Repeals s. 641.75, F.S., relating to immunity from liability; limitation on testimony.
Section 123: Amends s. 766.118, F.S., relating to determination of noneconomic damages.
Section 124: Amends s. 766.202, F.S., relating to definitions; ss. 766.201-766.212.
Section 125: Amends s. 945.36, F.S., relating to exemption from health testing regulations for law enforcement personnel conducting drug tests on inmates and releasees.
Section 126: Amends s. 1009.65, F.S., relating to Medical Education Reimbursement and Loan Repayment Program.
Section 127: Amends s. 1011.52, F.S., relating to appropriation to first accredited medical school.
Section 128: Provides an effective date of July 1, 2018.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

AHCA will realize an annual decrease in revenue of approximately $64,866 from the repeal of the risk manager application licensure and licensure fees. There will be an annual decrease in revenue of approximately $1,540,000 from the repeal of AHCA's clinical laboratory licensure requirement and subsequent licensure application fees.[261]

FDLE will experience an indeterminate negative fiscal impact due to the extension for fingerprint retention. Applicants who submitted fingerprints between January 1, 2013 and December 31, 2014 would be required to submit retention payment between the effective date of the bill and January 1, 2020. This would be a one- to two-year payment in advance, as opposed to the current standard five-year advance payment. These changes will affect cash flow into the agency's Operating Trust Fund, potentially generating dramatic highs and lows in revenues over the next three to five years.[262]

2. Expenditures:

AHCA will no longer expend funds to administer the SAP, health care risk manager licensure, and clinical laboratory licensure programs. AHCA will see an increased workload due to the new background screening requirements for distinct part nursing units and enforcement, issuance of certificates of exemption for health care clinics and home health agencies, and enforcement of rules regarding NICU, transplant, psychiatric and CMR services. However, AHCA will be able to absorb these costs and employees from the eliminated SAP, health care risk manager licensure, and clinical laboratory licensure programs will be reassigned to handle the increased workload.[263] The chart below shows the decreased need in FTEs, as well as the decrease in the number of licensure application reviews that will take place due to the elimination of the programs. Conversely, the chart

[261] Supra, FN 39.
[262] FDLE, *2018 Agency Legislative Bill Analysis*, December 1, 2017 (on file with the Health and Human Services Committee).
[263] E-mail correspondence with AHCA staff (on file with the Health and Human Services Committee).

also shows the new need for FTEs and the increased licensure application reviews due to the new programs that will be added.

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

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

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

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

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

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

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

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to health care facility regulation; creating s. 154.13, F.S.; providing that a 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; amending ss. 381.0031, 381.004, 384.31, 395.009, 400.0625, and 409.905, F.S.; eliminating state licensure requirements for clinical laboratories; requiring clinical laboratories to be federally certified; amending s. 383.313, F.S.; requiring a birth center to be federally certified and meet specified requirements to perform certain laboratory tests; repealing s. 383.335, F.S., relating to partial exemptions from licensure requirements for certain facilities that provide obstetrical and gynecological surgical services; amending s. 395.002, F.S.; revising and deleting definitions to remove the term "mobile surgical facility"; conforming a cross-reference; creating s. 395.0091, F.S.; requiring the Agency for Health Care Administration, in consultation with the Board of Clinical Laboratory Personnel, to adopt rules establishing criteria for alternate-site laboratory testing; requiring specifications to be included in

the criteria; defining the term "alternate-site testing"; amending ss. 395.0161 and 395.0163, F.S.; deleting licensure and inspection requirements for mobile surgical facilities to conform to changes made by the act; amending s. 395.0197, F.S.; requiring the manager of a hospital or ambulatory surgical center internal risk management program to demonstrate competence in specified administrative and health care service areas; conforming provisions to changes made by the act; repealing s. 395.1046, F.S., relating to hospital complaint investigation procedures; amending s. 395.1055, F.S.; requiring hospitals that provide specified services to meet agency licensure requirements; providing standards to be included in licensure requirements; conforming a provision to changes made by the act; requiring a level 2 background screening for personnel of distinct part nursing units; repealing ss. 395.10971 and 395.10972, F.S., relating to the purpose and the establishment of the Health Care Risk Manager Advisory Council, respectively; amending s. 395.10973, F.S.; removing requirements relating to agency standards for health care risk managers to conform provisions to changes made by the act; repealing s. 395.10974, F.S., relating to licensure of health care risk managers,

qualifications, licensure, and fees; repealing s. 395.10975, F.S., relating to grounds for denial, suspension, or revocation of a health care risk manager's license and an administrative fine; amending s. 395.602, F.S.; deleting definitions for the terms "emergency care hospital", "essential access community hospital," "inactive rural hospital bed", and "rural primary care hospital"; amending s. 395.603, F.S.; deleting provisions relating to deactivation of general hospital beds by certain rural and emergency care hospitals; repealing s. 395.604, F.S., relating to other rural hospital programs; repealing s. 395.605, F.S., relating to emergency care hospitals; amending s. 395.701, F.S.; revising the definition of the term "hospital" to exclude hospitals operated by a state agency; amending s. 400.191, F.S.; removing the 30-month reporting timeframe for the Nursing Home Guide; amending s. 400.464, F.S.; requiring that a license issued to a home health agency on or after a specified date specify the services the organization is authorized to perform and whether the services constitute skilled care; providing that the provision or advertising of certain services constitutes unlicensed activity under certain circumstances; authorizing certain persons, entities or organizations

providing home health services to voluntarily apply for a certificate of exemption from licensure by providing certain information to the agency; providing that the certificate is valid for a specified time and is nontransferable; authorizing the agency to charge a fee for the certificate; amending s. 400.471, F.S.; revising home health agency licensure requirements; providing requirements for proof of accreditation for home health agencies applying for change of ownership or the addition of skilled care services; removing a provision prohibiting the agency from issuing a license to a home health agency that fails to satisfy the requirements of a Medicare certification survey from the agency; amending s. 400.474, F.S.; revising conditions for the imposition of a fine against a home health agency; amending s. 400.476, F.S.; requiring a home health agency providing skilled nursing care to have a director of nursing; amending s. 400.484, F.S.; imposing administrative fines on home health agencies for specified classes of violations; amending s. 400.497, F.S.; requiring the agency to adopt, publish, and enforce rules establishing standards for certificates of exemption; amending s. 400.506, F.S.; specifying a criminal penalty for any person who owns, operates, or maintains an unlicensed nurse registry

that fails to cease operation immediately and apply for a license after notification from the agency; revising provisions authorizing the agency to impose a fine on a nurse registry that fails to cease operation after agency notification; revising circumstances under which the agency is authorized to deny, suspend, or revoke a license or impose a fine on a nurse registry; amending s. 400.606, F.S.; removing a requirement that an existing licensed health care provider's hospice licensure application be accompanied by a copy of the most recent profit-loss statement and licensure inspection report; amending s. 400.925, F.S.; revising the definition of the term "home medical equipment"; amending s. 400.931, F.S.; requiring a home medical equipment provider to notify the agency of certain personnel changes within a specified timeframe; amending s. 400.933, F.S.; requiring the agency to accept the submission of a valid medical oxygen retail establishment permit issued by the Department of Business and Professional Regulation in lieu of an agency inspection for licensure; amending s. 400.980, F.S.; revising the timeframe within which a health care services pool registrant must provide the agency with certain changes of information; amending s. 400.9935, F.S.;

specifying that a voluntary certificate of exemption may be valid for up to 2 years; amending s. 408.0361, F.S.; providing an exception for a hospital to become a Level I Adult Cardiovascular provider if certain requirements are met; amending s. 408.061, F.S.; excluding hospitals operated by state agencies from certain financial reporting requirements; conforming a cross-reference; amending s. 408.07, F.S.; deleting the definition for the term "clinical laboratory"; amending s. 408.20, F.S.; exempting hospitals operated by any state agency from assessments against the Health Care Trust Fund to fund certain agency activities; repealing s. 408.7056, F.S., relating to the Subscriber Assistance Program; amending s. 408.803, F.S.; defining the term "relative" for purposes of the Health Care Licensing Procedures Act; amending s. 408.806, F.S.; authorizing licensees who hold licenses for multiple providers to request that the agency align related license expiration dates; authorizing the agency to issue licenses for an abbreviated licensure period and to charge a prorated licensure fee; amending s. 408.809, F.S.; expanding the scope of persons subject to a level 2 background screening to include any employee of a licensee who is a controlling interest and certain part-time

contractors; amending s. 408.810, F.S.; providing that an applicant for change of ownership licensure is exempt from furnishing proof of financial ability to operate if certain conditions are met; authorizing the agency to adopt rules governing circumstances under which a controlling interest may act in certain legal capacities on behalf of a patient or client; requiring a licensee to ensure that certain persons do not hold an ownership interest if the licensee is not organized as or owned by a publicly traded corporation; defining the term "publicly traded corporation"; amending s. 408.812, F.S.; providing that certain unlicensed activity by a provider constitutes abuse and neglect; clarifying that the agency may impose a fine or penalty, as prescribed in an authorizing statute, if an unlicensed provider who has received notification fails to cease operation; authorizing the agency to revoke all licenses and impose a fine or penalties upon a controlling interest or licensee who has an interest in more than one provider and who fails to license a provider rendering services that require licensure in certain circumstances; amending s. 408.820, F.S.; deleting certain exemptions from part II of ch. 408, F.S., for specified providers to conform provisions to changes made by the act;

amending s. 409.907, F.S.; removing the agency's authority to consider certain factors in determining whether to enter into, and in maintaining, a Medicaid provider agreement; amending s. 429.02, F.S.; revising definitions of the terms "assisted living facility" and "personal services"; amending s. 429.04, F.S.; providing additional exemptions from licensure as an assisted living facility; requiring a person or entity asserting the exemption to provide documentation that substantiates the claim upon agency investigation of unlicensed activity; amending s. 429.08, F.S.; providing criminal penalties and fines for a person who rents or otherwise maintains a building or property used as an unlicensed assisted living facility; providing criminal penalties and fines for a person who owns, operates, or maintains an unlicensed assisted living facility after receiving notice from the agency; amending s. 429.176, F.S.; prohibiting an assisted living facility from operating for more than a specified time without an administrator who has completed certain educational requirements; amending s. 429.24, F.S.; providing that 30-day written notice of rate increase for residency in an assisted living facility is not required in certain situations; amending s. 429.28, F.S.; revising the assisted living

facility resident bill of rights to include assistance with obtaining access to adequate and appropriate health care; defining the term "adequate and appropriate health care"; deleting a requirement that the agency conduct at least one monitoring visit under certain circumstances; deleting provisions authorizing the agency to conduct periodic followup inspections and complaint investigations under certain circumstances; amending s. 429.294, F.S.; deleting the specified timeframe within which an assisted living facility must provide complete copies of a resident's records in an investigation of resident's rights; amending s. 429.34, F.S.; authorizing the agency to inspect and investigate assisted living facilities as necessary to determine compliance with certain laws; removing a provision requiring the agency to inspect each licensed assisted living facility at least biennially; authorizing the agency to conduct monitoring visits of each facility cited for prior violations under certain circumstances; amending s. 429.52, F.S.; requiring an assisted living facility administrator to complete required training and education within a specified timeframe; amending s. 435.04, F.S.; providing that security background investigations must ensure that a person has not been

arrested for, and is not awaiting final disposition of, certain offenses; requiring that security background investigations for purposes of participation in the Medicaid program screen for violations of federal or state law, rule, or regulation governing any state Medicaid program, the Medicare program, or any other publicly funded federal or state health care or health insurance program; specifying offenses under federal law or any state law that the security background investigations must screen for; amending s. 435.12, F.S.; revising fingerprinting requirements for purposes of a person's inclusion in the care provider background screening clearinghouse; amending s. 456.054, F.S.; prohibiting any person or entity from paying or receiving a kickback for referring patients to a clinical laboratory; prohibiting a clinical laboratory from providing personnel to perform certain functions or duties in a health care practitioner's office or dialysis facility; providing an exception; prohibiting a clinical laboratory from leasing space in any part of a health care practitioner's office or dialysis facility; repealing part I of ch. 483, F.S., relating to clinical laboratories; amending s. 483.294, F.S.; removing a requirement that the agency inspect

multiphasic health testing centers at least once annually; amending s. 483.801, F.S.; providing an exemption from regulation for certain persons employed by certain laboratories; amending s. 483.803, F.S.; revising definitions of the terms "clinical laboratory", and "clinical laboratory examination"; removing a cross-reference; amending s. 641.511, F.S.; revising health maintenance organization subscriber grievance reporting requirements; repealing s. 641.60, F.S., relating to the Statewide Managed Care Ombudsman Committee; repealing s. 641.65, F.S., relating to district managed care ombudsman committees; repealing s. 641.67, F.S., relating to a district managed care ombudsman committee, exemption from public records requirements, and exceptions; repealing s. 641.68, F.S., relating to a district managed care ombudsman committee and exemption from public meeting requirements; repealing s. 641.70, F.S., relating to agency duties relating to the Statewide Managed Care Ombudsman Committee and the district managed care ombudsman committees; repealing s. 641.75, F.S., relating to immunity from liability and limitation on testimony; amending s. 945.36, F.S.; authorizing law enforcement personnel to conduct drug tests on certain inmates and releasees; amending ss. 20.43, 220.1845,

376.30781, 376.86, 381.0034, 381.0405, 383.14, 383.30, 383.301, 383.302, 383.305, 383.309, 383.33, 385.211, 394.4787, 395.001, 395.003, 395.7015, 400.9905, 408.033, 408.036, 408.802, 409.9116, 409.975, 429.19, 456.001, 456.057, 456.076, 458.307, 458.345, 459.021, 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, 641.515, 641.55, 766.118, 766.202, 1009.65, and 1011.52, F.S.; conforming provisions to changes made by the act; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Paragraph (g) of subsection (3) of section 20.43, Florida Statutes, is amended to read:

20.43 Department of Health.—There is created a Department of Health.

(3) The following divisions of the Department of Health are established:

(g) Division of Medical Quality Assurance, which is responsible for the following boards and professions established within the division:

1. The Board of Acupuncture, created under chapter 457.

2. The Board of Medicine, created under chapter 458.

3. The Board of Osteopathic Medicine, created under chapter 459.

4. The Board of Chiropractic Medicine, created under chapter 460.

5. The Board of Podiatric Medicine, created under chapter 461.

6. Naturopathy, as provided under chapter 462.

7. The Board of Optometry, created under chapter 463.

8. The Board of Nursing, created under part I of chapter 464.

9. Nursing assistants, as provided under part II of chapter 464.

10. The Board of Pharmacy, created under chapter 465.

11. The Board of Dentistry, created under chapter 466.

12. Midwifery, as provided under chapter 467.

13. The Board of Speech-Language Pathology and Audiology, created under part I of chapter 468.

14. The Board of Nursing Home Administrators, created under part II of chapter 468.

15. The Board of Occupational Therapy, created under part III of chapter 468.

16. Respiratory therapy, as provided under part V of chapter 468.

17. Dietetics and nutrition practice, as provided under part X of chapter 468.

18. The Board of Athletic Training, created under part XIII of chapter 468.

19. The Board of Orthotists and Prosthetists, created under part XIV of chapter 468.

20. Electrolysis, as provided under chapter 478.

21. The Board of Massage Therapy, created under chapter 480.

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

23. Medical physicists, as provided under part IV of chapter 483.

24. The Board of Opticianry, created under part I of chapter 484.

25. The Board of Hearing Aid Specialists, created under part II of chapter 484.

26. The Board of Physical Therapy Practice, created under chapter 486.

27. The Board of Psychology, created under chapter 490.

28. School psychologists, as provided under chapter 490.

29. The Board of Clinical Social Work, Marriage and Family Therapy, and Mental Health Counseling, created under chapter 491.

30. Emergency medical technicians and paramedics, as provided under part III of chapter 401.

Section 2. Section 154.13, Florida Statutes, is created to

read:

154.13 Designated facilities; jurisdiction.—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 is not within the jurisdiction of the municipality.

Section 3. Paragraph (k) of subsection (2) of section 220.1845, Florida Statutes, is amended to read:

220.1845 Contaminated site rehabilitation tax credit.—

(2) AUTHORIZATION FOR TAX CREDIT; LIMITATIONS.—

(k) In order to encourage the construction and operation of a new health care facility as defined in s. 408.032 or s. 408.07, or a health care provider as defined in s. 408.07 ~~or s. 408.7056~~, on a brownfield site, an applicant for a tax credit may claim an additional 25 percent of the total site rehabilitation costs, not to exceed $500,000, if the applicant meets the requirements of this paragraph. In order to receive this additional tax credit, the applicant must provide documentation indicating that the construction of the health care facility or health care provider by the applicant on the brownfield site has received a certificate of occupancy or a license or certificate has been issued for the operation of the health care facility or health care provider.

Section 4. Paragraph (f) of subsection (3) of section 376.30781, Florida Statutes, is amended to read:

376.30781 Tax credits for rehabilitation of drycleaning-solvent-contaminated sites and brownfield sites in designated brownfield areas; application process; rulemaking authority; revocation authority.—

(3)(f) In order to encourage the construction and operation of a new health care facility or a health care provider, as defined in s. 408.032 or~~,~~ s. 408.07, ~~or s. 408.7056,~~ on a brownfield site, an applicant for a tax credit may claim an additional 25 percent of the total site rehabilitation costs, not to exceed $500,000, if the applicant meets the requirements of this paragraph. In order to receive this additional tax credit, the applicant must provide documentation indicating that the construction of the health care facility or health care provider by the applicant on the brownfield site has received a certificate of occupancy or a license or certificate has been issued for the operation of the health care facility or health care provider.

Section 5. Subsection (1) of section 376.86, Florida Statutes, is amended to read:

376.86 Brownfield Areas Loan Guarantee Program.—

(1) The Brownfield Areas Loan Guarantee Council is created to review and approve or deny, by a majority vote of its membership, the situations and circumstances for participation in partnerships by agreements with local governments, financial institutions, and others associated with the redevelopment of

brownfield areas pursuant to the Brownfields Redevelopment Act for a limited state guaranty of up to 5 years of loan guarantees or loan loss reserves issued pursuant to law. The limited state loan guaranty applies only to 50 percent of the primary lenders loans for redevelopment projects in brownfield areas. If the redevelopment project is for affordable housing, as defined in s. 420.0004, in a brownfield area, the limited state loan guaranty applies to 75 percent of the primary lender's loan. If the redevelopment project includes the construction and operation of a new health care facility or a health care provider, as defined in s. 408.032 or~~,~~ s. 408.07, ~~or s. 408.7056,~~ on a brownfield site and the applicant has obtained documentation in accordance with s. 376.30781 indicating that the construction of the health care facility or health care provider by the applicant on the brownfield site has received a certificate of occupancy or a license or certificate has been issued for the operation of the health care facility or health care provider, the limited state loan guaranty applies to 75 percent of the primary lender's loan. A limited state guaranty of private loans or a loan loss reserve is authorized for lenders licensed to operate in the state upon a determination by the council that such an arrangement would be in the public interest and the likelihood of the success of the loan is great.

Section 6. Subsection (2) of section 381.0031, Florida Statutes, is amended to read:

381.0031 Epidemiological research; report of diseases of public health significance to department.—

(2) Any practitioner licensed in this state to practice medicine, osteopathic medicine, chiropractic medicine, naturopathy, or veterinary medicine; any hospital licensed under part I of chapter 395; or any laboratory appropriately certified by the Centers for Medicare and Medicaid Services under the federal Clinical Laboratory Improvement Amendments and the federal rules adopted thereunder which ~~licensed under chapter 483 that~~ diagnoses or suspects the existence of a disease of public health significance shall immediately report the fact to the Department of Health.

Section 7. Subsection (3) of section 381.0034, Florida Statutes, is amended to read:

381.0034 Requirement for instruction on HIV and AIDS.—

(3) The department shall require, as a condition of granting a license under chapter 467 or part II ~~III~~ of chapter 483, that an applicant making initial application for licensure complete an educational course acceptable to the department on human immunodeficiency virus and acquired immune deficiency syndrome. Upon submission of an affidavit showing good cause, an applicant who has not taken a course at the time of licensure shall be allowed 6 months to complete this requirement.

Section 8. Paragraph (c) of subsection (4) of section 381.004, Florida Statutes, is amended to read:

381.004 HIV testing.—

(4) HUMAN IMMUNODEFICIENCY VIRUS TESTING REQUIREMENTS; REGISTRATION WITH THE DEPARTMENT OF HEALTH; EXEMPTIONS FROM REGISTRATION.—No county health department and no other person in this state shall conduct or hold themselves out to the public as conducting a testing program for acquired immune deficiency syndrome or human immunodeficiency virus status without first registering with the Department of Health, reregistering each year, complying with all other applicable provisions of state law, and meeting the following requirements:

(c) The program shall have all laboratory procedures performed in a laboratory <u>appropriately certified by the Centers for Medicare and Medicaid Services under the federal Clinical Laboratory Improvement Amendments and the federal rules adopted thereunder</u> ~~licensed under the provisions of chapter 483~~.

Section 9. Paragraph (f) of subsection (4) of section 381.0405, Florida Statutes, is amended to read:

381.0405 Office of Rural Health.—

(4) COORDINATION.—The office shall:

(f) Assume responsibility for state coordination of the Rural Hospital Transition Grant Program~~, the Essential Access Community Hospital Program,~~ and other federal rural health care programs.

Section 10. Paragraph (a) of subsection (2) of section 383.14, Florida Statutes, is amended to read:

383.14 Screening for metabolic disorders, other hereditary and congenital disorders, and environmental risk factors.—

(2) RULES.—

(a) After consultation with the Genetics and Newborn Screening Advisory Council, the department shall adopt and enforce rules requiring that every newborn in this state shall:

1. Before becoming 1 week of age, be subjected to a test for phenylketonuria;

2. Be tested for any condition included on the federal Recommended Uniform Screening Panel which the council advises the department should be included under the state's screening program. After the council recommends that a condition be included, the department shall submit a legislative budget request to seek an appropriation to add testing of the condition to the newborn screening program. The department shall expand statewide screening of newborns to include screening for such conditions within 18 months after the council renders such advice, if a test approved by the United States Food and Drug Administration or a test offered by an alternative vendor ~~which is compatible with the clinical standards established under part I of chapter 483~~ is available. If such a test is not available within 18 months after the council makes its recommendation, the department shall implement such screening as soon as a test offered by the United States Food and Drug Administration or by an alternative vendor is available; and

3. At the appropriate age, be tested for such other metabolic diseases and hereditary or congenital disorders as the department may deem necessary from time to time.

Section 11. Section 383.30, Florida Statutes, is amended to read:

383.30 Birth Center Licensure Act; short title.—Sections 383.30-383.332 ~~383.30-383.335~~ shall be known and may be cited as the "Birth Center Licensure Act."

Section 12. Section 383.301, Florida Statutes, is amended to read:

383.301 Licensure and regulation of birth centers; legislative intent.—It is the intent of the Legislature to provide for the protection of public health and safety in the establishment, maintenance, and operation of birth centers by providing for licensure of birth centers and for the development, establishment, and enforcement of minimum standards with respect to birth centers. The requirements of part II of chapter 408 shall apply to the provision of services that require licensure pursuant to ss. 383.30-383.332 ~~383.30-383.335~~ and part II of chapter 408 and to entities licensed by or applying for such licensure from the Agency for Health Care Administration pursuant to ss. 383.30-383.332 ~~383.30-383.335~~. A license issued by the agency is required in order to operate a birth center in this state.

Section 13. Section 383.302, Florida Statutes, is amended

to read:

383.302 Definitions of terms used in ss. 383.30-383.332 ~~383.30-383.335~~.—As used in ss. 383.30-383.332 ~~383.30-383.335~~, the term:

(1) "Agency" means the Agency for Health Care Administration.

(2) "Birth center" means any facility, institution, or place, which is not an ambulatory surgical center or a hospital or in a hospital, in which births are planned to occur away from the mother's usual residence following a normal, uncomplicated, low-risk pregnancy.

(3) "Clinical staff" means individuals employed full time or part time by a birth center who are licensed or certified to provide care at childbirth.

(4) "Consultant" means a physician licensed pursuant to chapter 458 or chapter 459 who agrees to provide advice and services to a birth center and who either:

(a) Is certified or eligible for certification by the American Board of Obstetrics and Gynecology, or

(b) Has hospital obstetrical privileges.

(5) "Governing body" means any individual, group, corporation, or institution which is responsible for the overall operation and maintenance of a birth center.

(6) "Governmental unit" means the state or any county, municipality, or other political subdivision or any department,

division, board, or other agency of any of the foregoing.

(7) "Licensed facility" means a facility licensed in accordance with s. 383.305.

(8) "Low-risk pregnancy" means a pregnancy which is expected to result in an uncomplicated birth, as determined through risk criteria developed by rule of the department, and which is accompanied by adequate prenatal care.

(9) "Person" means any individual, firm, partnership, corporation, company, association, institution, or joint stock association and means any legal successor of any of the foregoing.

(10) "Premises" means those buildings, beds, and facilities located at the main address of the licensee and all other buildings, beds, and facilities for the provision of maternity care located in such reasonable proximity to the main address of the licensee as to appear to the public to be under the dominion and control of the licensee.

Section 14. Subsection (1) of section 383.305, Florida Statutes, is amended to read:

383.305 Licensure; fees.—

(1) In accordance with s. 408.805, an applicant or a licensee shall pay a fee for each license application submitted under ss. 383.30-383.332 ~~383.30-383.335~~ and part II of chapter 408. The amount of the fee shall be established by rule.

Section 15. Subsection (1) of section 383.309, Florida

Statutes, is amended to read:

383.309 Minimum standards for birth centers; rules and enforcement.—

(1) The agency shall adopt and enforce rules to administer ss. 383.30-383.332 ~~383.30-383.335~~ and part II of chapter 408, which rules shall include, but are not limited to, reasonable and fair minimum standards for ensuring that:

(a) Sufficient numbers and qualified types of personnel and occupational disciplines are available at all times to provide necessary and adequate patient care and safety.

(b) Infection control, housekeeping, sanitary conditions, disaster plan, and medical record procedures that will adequately protect patient care and provide safety are established and implemented.

(c) Licensed facilities are established, organized, and operated consistent with established programmatic standards.

Section 16. Subsection (1) of section 383.313, Florida Statutes, is amended to read:

383.313 Performance of laboratory and surgical services; use of anesthetic and chemical agents.—

(1) LABORATORY SERVICES.—A birth center may collect specimens for those tests that are requested under protocol. A birth center must obtain and continuously maintain certification by the Centers for Medicare and Medicaid Services under the federal Clinical Laboratory Improvement Amendments and the

federal rules adopted thereunder in order to ~~may~~ perform ~~simple~~ laboratory tests specified~~, as defined~~ by rule of the agency, and which are appropriate to meet the needs of the patient ~~is exempt from the requirements of chapter 483, provided no more than five physicians are employed by the birth center and testing is conducted exclusively in connection with the diagnosis and treatment of clients of the birth center~~.

Section 17. Subsection (1) and paragraph (a) of subsection (2) of section 383.33, Florida Statutes, are amended to read:

383.33 Administrative penalties; moratorium on admissions.—

(1) In addition to the requirements of part II of chapter 408, the agency may impose an administrative fine not to exceed $500 per violation per day for the violation of any provision of ss. 383.30-383.332 ~~383.30-383.335~~, part II of chapter 408, or applicable rules.

(2) In determining the amount of the fine to be levied for a violation, as provided in this section, the following factors shall be considered:

(a) The severity of the violation, including the probability that death or serious harm to the health or safety of any person will result or has resulted; the severity of the actual or potential harm; and the extent to which ~~the provisions of~~ ss. 383.30-383.332 ~~383.30-383.335~~, part II of chapter 408, or applicable rules were violated.

Section 18. Section 383.335, Florida Statutes, is repealed.

Section 19. Section 384.31, Florida Statutes, is amended to read:

384.31 Testing of pregnant women; duty of the attendant.—Every person, including every physician licensed under chapter 458 or chapter 459 or midwife licensed under part I of chapter 464 or chapter 467, attending a pregnant woman for conditions relating to pregnancy during the period of gestation and delivery shall cause the woman to be tested for sexually transmissible diseases, including HIV, as specified by department rule. Testing shall be performed by a laboratory appropriately certified by the Centers for Medicare and Medicaid Services under the federal Clinical Laboratory Improvement Amendments and the federal rules adopted thereunder ~~approved~~ for such purposes ~~under part I of chapter 483~~. The woman shall be informed of the tests that will be conducted and of her right to refuse testing. If a woman objects to testing, a written statement of objection, signed by the woman, shall be placed in the woman's medical record and no testing shall occur.

Section 20. Subsection (2) of section 385.211, Florida Statutes, is amended to read:

385.211 Refractory and intractable epilepsy treatment and research at recognized medical centers.—

(2) Notwithstanding chapter 893, medical centers

recognized pursuant to s. 381.925, or an academic medical research institution legally affiliated with a licensed children's specialty hospital as defined in s. 395.002(27) ~~s. 395.002(28)~~ that contracts with the Department of Health, may conduct research on cannabidiol and low-THC cannabis. This research may include, but is not limited to, the agricultural development, production, clinical research, and use of liquid medical derivatives of cannabidiol and low-THC cannabis for the treatment for refractory or intractable epilepsy. The authority for recognized medical centers to conduct this research is derived from 21 C.F.R. parts 312 and 316. Current state or privately obtained research funds may be used to support the activities described in this section.

Section 21. Subsection (7) of section 394.4787, Florida Statutes, is amended to read:

394.4787 Definitions; ss. 394.4786, 394.4787, 394.4788, and 394.4789.—As used in this section and ss. 394.4786, 394.4788, and 394.4789:

(7) "Specialty psychiatric hospital" means a hospital licensed by the agency pursuant to s. 395.002(27) ~~s. 395.002(28)~~ and part II of chapter 408 as a specialty psychiatric hospital.

Section 22. Section 395.001, Florida Statutes, is amended to read:

395.001 Legislative intent.—It is the intent of the Legislature to provide for the protection of public health and

safety in the establishment, construction, maintenance, and operation of hospitals and~~,~~ ambulatory surgical centers~~, and mobile surgical facilities~~ by providing for licensure of same and for the development, establishment, and enforcement of minimum standards with respect thereto.

Section 23. Present subsections (22) through (33) of section 395.002, Florida Statutes, are redesignated as subsections (21) through (32), respectively, and subsections (3) and (16) of that section and present subsections (21) and (23) of that section are amended, to read:

395.002 Definitions.—As used in this chapter:

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

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

(16) "Licensed facility" means a hospital or~~,~~ ambulatory surgical center~~, or mobile surgical facility~~ licensed in accordance with this chapter.

~~(21) "Mobile surgical facility" is a mobile facility in which licensed health care professionals provide elective surgical care under contract with the Department of Corrections or a private correctional facility operating pursuant to chapter 957 and in which inmate patients are admitted to and discharged from said facility within the same working day and are not permitted to stay overnight. However, mobile surgical facilities may only provide health care services to the inmate patients of the Department of Corrections, or inmate patients of a private correctional facility operating pursuant to chapter 957, and not to the general public.~~

(22)~~(23)~~ "Premises" means those buildings, beds, and equipment located at the address of the licensed facility and all other buildings, beds, and equipment for the provision of hospital or~~,~~ ambulatory surgical~~, or mobile surgical~~ care located in such reasonable proximity to the address of the licensed facility as to appear to the public to be under the dominion and control of the licensee. For any licensee that is a

teaching hospital as defined in s. 408.07 ~~s. 408.07(45)~~, reasonable proximity includes any buildings, beds, services, programs, and equipment under the dominion and control of the licensee that are located at a site with a main address that is within 1 mile of the main address of the licensed facility; and all such buildings, beds, and equipment may, at the request of a licensee or applicant, be included on the facility license as a single premises.

Section 24. Paragraphs (a) and (b) of subsection (1) and paragraph (b) of subsection (2) of section 395.003, Florida Statutes, are amended to read:

395.003 Licensure; denial, suspension, and revocation.—

(1)(a) The requirements of part II of chapter 408 apply to the provision of services that require licensure pursuant to ss. 395.001-395.1065 and part II of chapter 408 and to entities licensed by or applying for such licensure from the Agency for Health Care Administration pursuant to ss. 395.001-395.1065. A license issued by the agency is required in order to operate a hospital or~~,~~ ambulatory surgical center~~, or mobile surgical facility~~ in this state.

(b)1. It is unlawful for a person to use or advertise to the public, in any way or by any medium whatsoever, any facility as a "hospital~~,~~" or "ambulatory surgical center~~,~~" ~~or "mobile surgical facility"~~ unless such facility has first secured a license under ~~the provisions of~~ this part.

2. This part does not apply to veterinary hospitals or to commercial business establishments using the word "hospital~~,~~" or "ambulatory surgical center~~,~~" ~~or "mobile surgical facility"~~ as a part of a trade name if no treatment of human beings is performed on the premises of such establishments.

(2)(b) The agency shall, at the request of a licensee that is a teaching hospital as defined in s. 408.07 ~~s. 408.07(45)~~, issue a single license to a licensee for facilities that have been previously licensed as separate premises, provided such separately licensed facilities, taken together, constitute the same premises as defined in s. 395.002 ~~s. 395.002(23)~~. Such license for the single premises shall include all of the beds, services, and programs that were previously included on the licenses for the separate premises. The granting of a single license under this paragraph may ~~shall~~ not in any manner reduce the number of beds, services, or programs operated by the licensee.

Section 25. Subsection (1) of section 395.009, Florida Statutes, is amended to read:

395.009 Minimum standards for clinical laboratory test results and diagnostic X-ray results; prerequisite for issuance or renewal of license.—

(1) As a requirement for issuance or renewal of its license, each licensed facility shall require that all clinical laboratory tests performed by or for the licensed facility be

performed by a clinical laboratory appropriately certified by the Centers for Medicare and Medicaid Services under the federal Clinical Laboratory Improvement Amendments and the federal rules adopted thereunder ~~licensed under the provisions of chapter 483~~.

Section 26. Section 395.0091, Florida Statutes, is created to read:

395.0091 Alternate-site testing.—The agency, in consultation with the Board of Clinical Laboratory Personnel, shall adopt by rule the criteria for alternate-site testing to be performed under the supervision of a clinical laboratory director. At a minimum, the criteria must address hospital internal needs assessment; a protocol for implementation, including the identification of tests to be performed and who will perform them; selection of the method of testing to be used for alternate-site testing; minimum training and education requirements for those who will perform alternate-site testing, such as documented training, licensure, certification, or other medical professional background not limited to laboratory professionals; documented inservice training and initial and ongoing competency validation; an appropriate internal and external quality control protocol; an internal mechanism for the central laboratory to identify and track alternate-site testing; and recordkeeping requirements. Alternate-site testing locations must register when the hospital applies to renew its license. For purposes of this section, the term "alternate-site testing"

includes any laboratory testing done under the administrative control of a hospital, but performed out of the physical or administrative confines of the central laboratory.

Section 27. Paragraph (f) of subsection (1) of section 395.0161, Florida Statutes, is amended to read:

395.0161 Licensure inspection.—

(1) In addition to the requirement of s. 408.811, the agency shall make or cause to be made such inspections and investigations as it deems necessary, including:

~~(f) Inspections of mobile surgical facilities at each time a facility establishes a new location, prior to the admission of patients. However, such inspections shall not be required when a mobile surgical facility is moved temporarily to a location where medical treatment will not be provided.~~

Section 28. Subsection (3) of section 395.0163, Florida Statutes, is amended to read:

395.0163 Construction inspections; plan submission and approval; fees.—

~~(3) In addition to the requirements of s. 408.811, the agency shall inspect a mobile surgical facility at initial licensure and at each time the facility establishes a new location, prior to admission of patients. However, such inspections shall not be required when a mobile surgical facility is moved temporarily to a location where medical treatment will not be provided.~~

Section 29. Subsection (2), paragraph (c) of subsection (6), and subsections (16) and (17) of section 395.0197, Florida Statutes, are amended to read:

395.0197 Internal risk management program.—

(2) The internal risk management program is the responsibility of the governing board of the health care facility. Each licensed facility shall hire a risk manager~~,~~ ~~licensed under s. 395.10974,~~ who is responsible for implementation and oversight of the ~~such~~ facility's internal risk management program and who demonstrates competence, through education or experience, in all of the following areas:

(a) Applicable standards of health care risk management.

(b) Applicable federal, state, and local health and safety laws and rules.

(c) General risk management administration.

(d) Patient care.

(e) Medical care.

(f) Personal and social care.

(g) Accident prevention.

(h) Departmental organization and management.

(i) Community interrelationships.

(j) Medical terminology ~~as required by this section. A risk manager must not be made responsible for more than four internal risk management programs in separate licensed facilities, unless the facilities are under one corporate~~

~~ownership or the risk management programs are in rural hospitals~~.

(6)(c) The report submitted to the agency must ~~shall~~ also contain the name ~~and license number~~ of the risk manager of the licensed facility, a copy of its policy and procedures which govern the measures taken by the facility and its risk manager to reduce the risk of injuries and adverse incidents, and the results of such measures. The annual report is confidential and is not available to the public pursuant to s. 119.07(1) or any other law providing access to public records. The annual report is not discoverable or admissible in any civil or administrative action, except in disciplinary proceedings by the agency or the appropriate regulatory board. The annual report is not available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the agency or the appropriate regulatory board. However, the agency or the appropriate regulatory board shall make available, upon written request by a health care professional against whom probable cause has been found, any such records which form the basis of the determination of probable cause.

(16) There shall be no monetary liability on the part of, and no cause of action for damages shall arise against, any risk manager~~, licensed under s. 395.10974,~~ for the implementation and oversight of the internal risk management program in a facility

licensed under this chapter or chapter 390 as required by this section, for any act or proceeding undertaken or performed within the scope of the functions of such internal risk management program if the risk manager acts without intentional fraud.

(17) A privilege against civil liability is hereby granted to any ~~licensed~~ risk manager or licensed facility with regard to information furnished pursuant to this chapter, unless the ~~licensed~~ risk manager or facility acted in bad faith or with malice in providing such information.

Section 30. Section 395.1046, Florida Statutes, is repealed.

Section 31. Subsections (2) and (3) of section 395.1055, Florida Statutes, are amended, and paragraph (i) is added to subsection (1), to read:

395.1055 Rules and enforcement.—

(1) The agency shall adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this part, which shall include reasonable and fair minimum standards for ensuring that:

(i) 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. Such licensure requirements must include

quality of care, nurse staffing, physician staffing, physical plant, equipment, emergency transportation, and data reporting standards.

(2) Separate standards may be provided for general and specialty hospitals, ambulatory surgical centers, ~~mobile surgical facilities,~~ and statutory rural hospitals as defined in s. 395.602.

(3) The agency shall adopt rules with respect to the care and treatment of patients residing in distinct part nursing units of hospitals which are certified for participation in Title XVIII (Medicare) and Title XIX (Medicaid) of the Social Security Act skilled nursing facility program. Such rules shall take into account the types of patients treated in hospital skilled nursing units, including typical patient acuity levels and the average length of stay in such units, and shall be limited to the appropriate portions of the Omnibus Budget Reconciliation Act of 1987 (Pub. L. No. 100-203) (December 22, 1987), Title IV (Medicare, Medicaid, and Other Health-Related Programs), Subtitle C (Nursing Home Reform), as amended. The agency shall require level 2 background screening as specified in s. 408.809(1)(e) pursuant to s. 408.809 and chapter 435 for personnel of distinct part nursing units.

Section 32. Section 395.10971, Florida Statutes, is repealed.

Section 33. Section 395.10972, Florida Statutes, is

repealed.

Section 34. Section 395.10973, Florida Statutes, is amended to read:

395.10973 Powers and duties of the agency.—It is the function of the agency to:

(1) Adopt rules pursuant to ss. 120.536(1) and 120.54 to implement ~~the provisions of~~ this part and part II of chapter 408 conferring duties upon it.

~~(2) Develop, impose, and enforce specific standards within the scope of the general qualifications established by this part which must be met by individuals in order to receive licenses as health care risk managers. These standards shall be designed to ensure that health care risk managers are individuals of good character and otherwise suitable and, by training or experience in the field of health care risk management, qualified in accordance with the provisions of this part to serve as health care risk managers, within statutory requirements.~~

~~(3) Develop a method for determining whether an individual meets the standards set forth in s. 395.10974.~~

~~(4) Issue licenses to qualified individuals meeting the standards set forth in s. 395.10974.~~

~~(5) Receive, investigate, and take appropriate action with respect to any charge or complaint filed with the agency to the effect that a certified health care risk manager has failed to comply with the requirements or standards adopted by rule by the~~

~~agency or to comply with the provisions of this part.~~

~~(6) Establish procedures for providing periodic reports on persons certified or disciplined by the agency under this part.~~

(2)~~(7)~~ Develop a model risk management program for health care facilities which will satisfy the requirements of s. 395.0197.

(3)~~(8)~~ Enforce the special-occupancy provisions of the Florida Building Code which apply to hospitals, intermediate residential treatment facilities, and ambulatory surgical centers in conducting any inspection authorized by this chapter and part II of chapter 408.

Section 35. Section 395.10974, Florida Statutes, is repealed.

Section 36. Section 395.10975, Florida Statutes, is repealed.

Section 37. Subsection (2) of section 395.602, Florida Statutes, is amended to read:

395.602 Rural hospitals.—

(2) DEFINITIONS.—As used in this part, the term:

~~(a) "Emergency care hospital" means a medical facility which provides:~~

~~1. Emergency medical treatment; and~~

~~2. Inpatient care to ill or injured persons prior to their transportation to another hospital or provides inpatient medical care to persons needing care for a period of up to 96 hours. The~~

~~96-hour limitation on inpatient care does not apply to respite, skilled nursing, hospice, or other nonacute care patients.~~

~~(b) "Essential access community hospital" means any facility which:~~

~~1. Has at least 100 beds;~~

~~2. Is located more than 35 miles from any other essential access community hospital, rural referral center, or urban hospital meeting criteria for classification as a regional referral center;~~

~~3. Is part of a network that includes rural primary care hospitals;~~

~~4. Provides emergency and medical backup services to rural primary care hospitals in its rural health network;~~

~~5. Extends staff privileges to rural primary care hospital physicians in its network; and~~

~~6. Accepts patients transferred from rural primary care hospitals in its network.~~

~~(c) "Inactive rural hospital bed" means a licensed acute care hospital bed, as defined in s. 395.002(13), that is inactive in that it cannot be occupied by acute care inpatients.~~

(a) ~~(d)~~ "Rural area health education center" means an area health education center (AHEC), as authorized by Pub. L. No. 94-484, which provides services in a county with a population density of up to ~~no greater than~~ 100 persons per square mile.

(b) ~~(e)~~ "Rural hospital" means an acute care hospital

licensed under this chapter, having 100 or fewer licensed beds and an emergency room, which is:

1. The sole provider within a county with a population density of up to 100 persons per square mile;

2. An acute care hospital, in a county with a population density of up to 100 persons per square mile, which is at least 30 minutes of travel time, on normally traveled roads under normal traffic conditions, from any other acute care hospital within the same county;

3. A hospital supported by a tax district or subdistrict whose boundaries encompass a population of up to 100 persons per square mile;

4. A hospital classified as a sole community hospital under 42 C.F.R. s. 412.92 which has up to 175~~, regardless of the number of~~ licensed beds;

5. A hospital with a service area that has a population of up to 100 persons per square mile. As used in this subparagraph, the term "service area" means the fewest number of zip codes that account for 75 percent of the hospital's discharges for the most recent 5-year period, based on information available from the hospital inpatient discharge database in the Florida Center for Health Information and Transparency at the agency; or

6. A hospital designated as a critical access hospital, as defined in s. 408.07.

Population densities used in this paragraph must be based upon the most recently completed United States census. A hospital that received funds under s. 409.9116 for a quarter beginning no later than July 1, 2002, is deemed to have been and shall continue to be a rural hospital from that date through June 30, 2021, if the hospital continues to have up to 100 licensed beds and an emergency room. An acute care hospital that has not previously been designated as a rural hospital and that meets the criteria of this paragraph shall be granted such designation upon application, including supporting documentation, to the agency. A hospital that was licensed as a rural hospital during the 2010-2011 or 2011-2012 fiscal year shall continue to be a rural hospital from the date of designation through June 30, 2021, if the hospital continues to have up to 100 licensed beds and an emergency room.

~~(f) "Rural primary care hospital" means any facility meeting the criteria in paragraph (e) or s. 395.605 which provides:~~

~~1. Twenty-four-hour emergency medical care;~~

~~2. Temporary inpatient care for periods of 72 hours or less to patients requiring stabilization before discharge or transfer to another hospital. The 72-hour limitation does not apply to respite, skilled nursing, hospice, or other nonacute care patients; and~~

~~3. Has no more than six licensed acute care inpatient~~

~~beds.~~

(c) ~~(g)~~ "Swing-bed" means a bed which can be used interchangeably as either a hospital, skilled nursing facility (SNF), or intermediate care facility (ICF) bed pursuant to 42 C.F.R. parts 405, 435, 440, 442, and 447.

Section 38. Section 395.603, Florida Statutes, is amended to read:

395.603 ~~Deactivation of general hospital beds;~~ Rural hospital impact statement.—

~~(1) The agency shall establish, by rule, a process by which a rural hospital, as defined in s. 395.602, that seeks licensure as a rural primary care hospital or as an emergency care hospital, or becomes a certified rural health clinic as defined in Pub. L. No. 95-210, or becomes a primary care program such as a county health department, community health center, or other similar outpatient program that provides preventive and curative services, may deactivate general hospital beds. Rural primary care hospitals and emergency care hospitals shall maintain the number of actively licensed general hospital beds necessary for the facility to be certified for Medicare reimbursement. Hospitals that discontinue inpatient care to become rural health care clinics or primary care programs shall deactivate all licensed general hospital beds. All hospitals, clinics, and programs with inactive beds shall provide 24-hour emergency medical care by staffing an emergency room. Providers~~

~~with inactive beds shall be subject to the criteria in s. 395.1041. The agency shall specify in rule requirements for making 24-hour emergency care available. Inactive general hospital beds shall be included in the acute care bed inventory, maintained by the agency for certificate-of-need purposes, for 10 years from the date of deactivation of the beds. After 10 years have elapsed, inactive beds shall be excluded from the inventory. The agency shall, at the request of the licensee, reactivate the inactive general beds upon a showing by the licensee that licensure requirements for the inactive general beds are met.~~

~~(2)~~ In formulating and implementing policies and rules that may have significant impact on the ability of rural hospitals to continue to provide health care services in rural communities, the agency, the department, or the respective regulatory board adopting policies or rules regarding the licensure or certification of health care professionals shall provide a rural hospital impact statement. The rural hospital impact statement shall assess the proposed action in light of the following questions:

(1) ~~(a)~~ Do the health personnel affected by the proposed action currently practice in rural hospitals or are they likely to in the near future?

(2) ~~(b)~~ What are the current numbers of the affected health personnel in this state, their geographic distribution, and the

number practicing in rural hospitals?

(3)~~(c)~~ What are the functions presently performed by the affected health personnel, and are such functions presently performed in rural hospitals?

(4)~~(d)~~ What impact will the proposed action have on the ability of rural hospitals to recruit the affected personnel to practice in their facilities?

(5)~~(e)~~ What impact will the proposed action have on the limited financial resources of rural hospitals through increased salaries and benefits necessary to recruit or retain such health personnel?

(6)~~(f)~~ Is there a less stringent requirement which could apply to practice in rural hospitals?

(7)~~(g)~~ Will this action create staffing shortages, which could result in a loss to the public of health care services in rural hospitals or result in closure of any rural hospitals?

Section 39. Section 395.604, Florida Statutes, is repealed.

Section 40. Section 395.605, Florida Statutes, is repealed.

Section 41. Paragraph (c) of subsection (1) of section 395.701, Florida Statutes, is amended to read:

395.701 Annual assessments on net operating revenues for inpatient and outpatient services to fund public medical assistance; administrative fines for failure to pay assessments

when due; exemption.—

(1) For the purposes of this section, the term:

(c) "Hospital" means a health care institution as defined in s. 395.002(12), but does not include any hospital operated by a state ~~the~~ agency ~~or the Department of Corrections~~.

Section 42. Paragraph (b) of subsection (2) of section 395.7015, Florida Statutes, is amended to read:

395.7015 Annual assessment on health care entities.—

(2) There is imposed an annual assessment against certain health care entities as described in this section:

(b) For the purpose of this section, "health care entities" include the following:

1. Ambulatory surgical centers ~~and mobile surgical facilities licensed under s. 395.003. This subsection shall only apply to mobile surgical facilities operating under contracts entered into on or after July 1, 1998~~.

~~2. Clinical laboratories licensed under s. 483.091, excluding any hospital laboratory defined under s. 483.041(6), any clinical laboratory operated by the state or a political subdivision of the state, any clinical laboratory which qualifies as an exempt organization under s. 501(c)(3) of the Internal Revenue Code of 1986, as amended, and which receives 70 percent or more of its gross revenues from services to charity patients or Medicaid patients, and any blood, plasma, or tissue bank procuring, storing, or distributing blood, plasma, or~~

~~tissue either for future manufacture or research or distributed on a nonprofit basis, and further excluding any clinical laboratory which is wholly owned and operated by 6 or fewer physicians who are licensed pursuant to chapter 458 or chapter 459 and who practice in the same group practice, and at which no clinical laboratory work is performed for patients referred by any health care provider who is not a member of the same group.~~

2.~~3.~~ Diagnostic-imaging centers that are freestanding outpatient facilities that provide specialized services for the identification or determination of a disease through examination and also provide sophisticated radiological services, and in which services are rendered by a physician licensed by the Board of Medicine under s. 458.311, s. 458.313, or s. 458.317, or by an osteopathic physician licensed by the Board of Osteopathic Medicine under s. 459.0055 or s. 459.0075. For purposes of this paragraph, "sophisticated radiological services" means the following: magnetic resonance imaging; nuclear medicine; angiography; arteriography; computed tomography; positron emission tomography; digital vascular imaging; bronchography; lymphangiography; splenography; ultrasound, excluding ultrasound providers that are part of a private physician's office practice or when ultrasound is provided by two or more physicians licensed under chapter 458 or chapter 459 who are members of the same professional association and who practice in the same medical specialties; and such other sophisticated radiological

services, excluding mammography, as adopted in rule by the board.

Section 43. Subsection (1) of section 400.0625, Florida Statutes, is amended to read:

400.0625 Minimum standards for clinical laboratory test results and diagnostic X-ray results.—

(1) Each nursing home, as a requirement for issuance or renewal of its license, shall require that all clinical laboratory tests performed for the nursing home be performed by a ~~clinical~~ laboratory appropriately certified by the Centers for Medicare and Medicaid Services under the federal Clinical Laboratory Improvement Amendments and the federal rules adopted thereunder ~~licensed under the provisions of chapter 483~~, except for such self-testing procedures as are approved by the agency by rule. ~~Results of clinical laboratory tests performed prior to admission which meet the minimum standards provided in s. 483.181(3) shall be accepted in lieu of routine examinations required upon admission and clinical laboratory tests which may be ordered by a physician for residents of the nursing home.~~

Section 44. Paragraph (a) of subsection (2) of section 400.191, Florida Statutes, is amended to read:

400.191 Availability, distribution, and posting of reports and records.—

(2) The agency shall publish the Nursing Home Guide quarterly in electronic form to assist consumers and their

families in comparing and evaluating nursing home facilities.

(a) The agency shall provide an Internet site which shall include at least the following information either directly or indirectly through a link to another established site or sites of the agency's choosing:

1. A section entitled "Have you considered programs that provide alternatives to nursing home care?" which shall be the first section of the Nursing Home Guide and which shall prominently display information about available alternatives to nursing homes and how to obtain additional information regarding these alternatives. The Nursing Home Guide shall explain that this state offers alternative programs that permit qualified elderly persons to stay in their homes instead of being placed in nursing homes and shall encourage interested persons to call the Comprehensive Assessment Review and Evaluation for Long-Term Care Services (CARES) Program to inquire if they qualify. The Nursing Home Guide shall list available home and community-based programs which shall clearly state the services that are provided and indicate whether nursing home services are included if needed.

2. A list by name and address of all nursing home facilities in this state, including any prior name by which a facility was known during the previous 24-month period.

3. Whether such nursing home facilities are proprietary or nonproprietary.

4. The current owner of the facility's license and the year that that entity became the owner of the license.

5. The name of the owner or owners of each facility and whether the facility is affiliated with a company or other organization owning or managing more than one nursing facility in this state.

6. The total number of beds in each facility and the most recently available occupancy levels.

7. The number of private and semiprivate rooms in each facility.

8. The religious affiliation, if any, of each facility.

9. The languages spoken by the administrator and staff of each facility.

10. Whether or not each facility accepts Medicare or Medicaid recipients or insurance, health maintenance organization, Veterans Administration, CHAMPUS program, or workers' compensation coverage.

11. Recreational and other programs available at each facility.

12. Special care units or programs offered at each facility.

13. Whether the facility is a part of a retirement community that offers other services pursuant to part III of this chapter or part I or part III of chapter 429.

14. Survey and deficiency information, including all

federal and state recertification, licensure, revisit, and complaint survey information, for each facility ~~for the past 30 months~~. For noncertified nursing homes, state survey and deficiency information, including licensure, revisit, and complaint survey information ~~for the past 30 months~~ shall be provided.

Section 45. Subsection (1) and paragraphs (b), (e), and (f) of subsection (4) of section 400.464, Florida Statutes, are amended, and subsection (6) is added to that section, to read:

400.464 Home health agencies to be licensed; expiration of license; exemptions; unlawful acts; penalties.—

(1) The requirements of part II of chapter 408 apply to the provision of services that require licensure pursuant to this part and part II of chapter 408 and entities licensed or registered by or applying for such licensure or registration from the Agency for Health Care Administration pursuant to this part. A license issued by the agency is required in order to operate a home health agency in this state. A license issued on or after July 1, 2018, must specify the home health services the organization is authorized to perform and indicate whether such specified services are considered skilled care. The provision or advertising of services that require licensure pursuant to this part without such services being specified on the face of the license issued on or after July 1, 2018, constitutes unlicensed activity as prohibited under s. 408.812.

(4)(b) The operation or maintenance of an unlicensed home health agency or the performance of any home health services in violation of this part is declared a nuisance, inimical to the public health, welfare, and safety. The agency or any state attorney may, in addition to other remedies provided in this part, bring an action for an injunction to restrain such violation, or to enjoin the future operation or maintenance of the home health agency or the provision of home health services in violation of this part or part II of chapter 408, until compliance with this part or the rules adopted under this part has been demonstrated to the satisfaction of the agency.

(e) Any person who owns, operates, or maintains an unlicensed home health agency and who, ~~within 10 working days~~ after receiving notification from the agency, fails to cease operation and apply for a license under this part commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083. Each day of continued operation is a separate offense.

(f) Any home health agency that fails to cease operation after agency notification may be fined in accordance with s. 408.812 ~~$500 for each day of noncompliance~~.

(6) Any person, entity, or organization providing home health services which is exempt from licensure under subsection (5) may voluntarily apply for a certificate of exemption from licensure under its exempt status with the agency on a form that

specifies its name or names and addresses, a statement of the reasons why it is exempt from licensure as a home health agency, and other information deemed necessary by the agency. A certificate of exemption is valid for a period of not more than 2 years and is not transferable. The agency may charge an applicant $100 for a certificate of exemption or charge the actual cost of processing the certificate.

Section 46. Subsections (6) through (9) of section 400.471, Florida Statutes, are redesignated as subsections (5) through (8), respectively, and present subsections (2), (6), and (9) of that section are amended to read:

400.471 Application for license; fee.—

(2) In addition to the requirements of part II of chapter 408, the initial applicant, the applicant for a change of ownership, and the applicant for the addition of skilled care services must file with the application satisfactory proof that the home health agency is in compliance with this part and applicable rules, including:

(a) A listing of services to be provided, either directly by the applicant or through contractual arrangements with existing providers.

(b) The number and discipline of professional staff to be employed.

~~(c) Completion of questions concerning volume data on the renewal application as determined by rule.~~

(c) ~~(d)~~ A business plan, signed by the applicant, which details the home health agency's methods to obtain patients and its plan to recruit and maintain staff.

(d) ~~(e)~~ Evidence of contingency funding as required under s. 408.8065 ~~equal to 1 month's average operating expenses during the first year of operation~~.

(e) ~~(f)~~ A balance sheet, income and expense statement, and statement of cash flows for the first 2 years of operation which provide evidence of having sufficient assets, credit, and projected revenues to cover liabilities and expenses. The applicant has demonstrated financial ability to operate if the applicant's assets, credit, and projected revenues meet or exceed projected liabilities and expenses. An applicant may not project an operating margin of 15 percent or greater for any month in the first year of operation. All documents required under this paragraph must be prepared in accordance with generally accepted accounting principles and compiled and signed by a certified public accountant.

(f) ~~(g)~~ All other ownership interests in health care entities for each controlling interest, as defined in part II of chapter 408.

(g) ~~(h)~~ In the case of an application for initial licensure, an application for a change of ownership, or an application for the addition of skilled care services, documentation of accreditation, or an application for

accreditation, from an accrediting organization that is recognized by the agency as having standards comparable to those required by this part and part II of chapter 408. A home health agency that ~~is not Medicare or Medicaid certified and~~ does not provide skilled care is exempt from this paragraph. Notwithstanding s. 408.806, an initial applicant ~~that has applied for accreditation~~ must provide proof of accreditation that is not conditional or provisional and a survey demonstrating compliance with the requirements of this part, part II of chapter 408, and applicable rules from an accrediting organization that is recognized by the agency as having standards comparable to those required by this part and part II of chapter 408 within 120 days after the date of the agency's receipt of the application for licensure ~~or the application shall be withdrawn from further consideration~~. Such accreditation must be continuously maintained by the home health agency to maintain licensure. The agency shall accept, in lieu of its own periodic licensure survey, the submission of the survey of an accrediting organization that is recognized by the agency if the accreditation of the licensed home health agency is not provisional and if the licensed home health agency authorizes releases of, and the agency receives the report of, the accrediting organization.

~~(6) The agency may not issue a license designated as certified to a home health agency that fails to satisfy the~~

~~requirements of a Medicare certification survey from the agency.~~

(8)~~(9)~~ The agency may not issue a renewal license for a home health agency in any county having at least one licensed home health agency and that has more than one home health agency per 5,000 persons, as indicated by the most recent population estimates published by the Legislature's Office of Economic and Demographic Research, if the applicant or any controlling interest has been administratively sanctioned by the agency during the 2 years prior to the submission of the licensure renewal application for one or more of the following acts:

(a) An intentional or negligent act that materially affects the health or safety of a client of the provider;

(b) Knowingly providing home health services in an unlicensed assisted living facility or unlicensed adult family-care home, unless the home health agency or employee reports the unlicensed facility or home to the agency within 72 hours after providing the services;

(c) Preparing or maintaining fraudulent patient records, such as, but not limited to, charting ahead, recording vital signs or symptoms which were not personally obtained or observed by the home health agency's staff at the time indicated, borrowing patients or patient records from other home health agencies to pass a survey or inspection, or falsifying signatures;

(d) Failing to provide at least one service directly to a

patient for a period of 60 days;

(e) Demonstrating a pattern of falsifying documents relating to the training of home health aides or certified nursing assistants or demonstrating a pattern of falsifying health statements for staff who provide direct care to patients. A pattern may be demonstrated by a showing of at least three fraudulent entries or documents;

(f) Demonstrating a pattern of billing any payor for services not provided. A pattern may be demonstrated by a showing of at least three billings for services not provided within a 12-month period;

(g) Demonstrating a pattern of failing to provide a service specified in the home health agency's written agreement with a patient or the patient's legal representative, or the plan of care for that patient, except ~~unless a reduction in service is mandated by Medicare, Medicaid, or a state program or~~ as provided in s. 400.492(3). A pattern may be demonstrated by a showing of at least three incidents, regardless of the patient or service, in which the home health agency did not provide a service specified in a written agreement or plan of care during a 3-month period;

(h) Giving remuneration to a case manager, discharge planner, facility-based staff member, or third-party vendor who is involved in the discharge planning process of a facility licensed under chapter 395, chapter 429, or this chapter from

whom the home health agency receives referrals or gives remuneration as prohibited in s. 400.474(6)(a);

(i) Giving cash, or its equivalent, to a Medicare or Medicaid beneficiary;

(j) Demonstrating a pattern of billing the Medicaid program for services to Medicaid recipients which are medically unnecessary as determined by a final order. A pattern may be demonstrated by a showing of at least two such medically unnecessary services within one Medicaid program integrity audit period;

(k) Providing services to residents in an assisted living facility for which the home health agency does not receive fair market value remuneration; or

(l) Providing staffing to an assisted living facility for which the home health agency does not receive fair market value remuneration.

Section 47. Subsection (5) of section 400.474, Florida Statutes, is amended to read:

400.474 Administrative penalties.—

(5) The agency shall impose a fine of $5,000 against a home health agency that demonstrates a pattern of failing to provide a service specified in the home health agency's written agreement with a patient or the patient's legal representative, or the plan of care for that patient, except ~~unless a reduction in service is mandated by Medicare, Medicaid, or a state program~~

~~or~~ as provided in s. 400.492(3). A pattern may be demonstrated by a showing of at least three incidences, regardless of the patient or service, where the home health agency did not provide a service specified in a written agreement or plan of care during a 3-month period. The agency shall impose the fine for each occurrence. The agency may also impose additional administrative fines under s. 400.484 for the direct or indirect harm to a patient, or deny, revoke, or suspend the license of the home health agency for a pattern of failing to provide a service specified in the home health agency's written agreement with a patient or the plan of care for that patient.

Section 48. Paragraph (c) of subsection (2) of section 400.476, Florida Statutes, is amended to read:

400.476 Staffing requirements; notifications; limitations on staffing services.—

(2) DIRECTOR OF NURSING.—

(c) A home health agency that provides skilled nursing care must ~~is not Medicare or Medicaid certified and does not provide skilled care or provides only physical, occupational, or speech therapy is not required to~~ have a director of nursing ~~and is exempt from paragraph (b)~~.

Section 49. Section 400.484, Florida Statutes, is amended to read:

400.484 Right of inspection; violations ~~deficiencies~~; fines.—

(1) In addition to the requirements of s. 408.811, the agency may make such inspections and investigations as are necessary in order to determine the state of compliance with this part, part II of chapter 408, and applicable rules.

(2) The agency shall impose fines for various classes of violations ~~deficiencies~~ in accordance with the following schedule:

(a) Class I violations are as provided in s. 408.813 ~~A class I deficiency is any act, omission, or practice that results in a patient's death, disablement, or permanent injury, or places a patient at imminent risk of death, disablement, or permanent injury~~. Upon finding a class I violation ~~deficiency~~, the agency shall impose an administrative fine in the amount of $15,000 for each occurrence and each day that the violation ~~deficiency~~ exists.

(b) Class II violations are as provided in s. 408.813 ~~A class II deficiency is any act, omission, or practice that has a direct adverse effect on the health, safety, or security of a patient~~. Upon finding a class II violation ~~deficiency~~, the agency shall impose an administrative fine in the amount of $5,000 for each occurrence and each day that the violation ~~deficiency~~ exists.

(c) Class III violations are as provided in s. 408.813 ~~A class III deficiency is any act, omission, or practice that has an indirect, adverse effect on the health, safety, or security~~

~~of a patient~~. Upon finding an uncorrected or repeated class III violation ~~deficiency~~, the agency shall impose an administrative fine not to exceed $1,000 for each occurrence and each day that the uncorrected or repeated violation ~~deficiency~~ exists.

(d) Class IV violations are as provided in s. 408.813 ~~A class IV deficiency is any act, omission, or practice related to required reports, forms, or documents which does not have the potential of negatively affecting patients~~. These violations are of a type that the agency determines do not threaten the health, safety, or security of patients. Upon finding an uncorrected or repeated class IV violation ~~deficiency~~, the agency shall impose an administrative fine not to exceed $500 for each occurrence and each day that the uncorrected or repeated violation ~~deficiency~~ exists.

(3) In addition to any other penalties imposed pursuant to this section or part, the agency may assess costs related to an investigation that results in a successful prosecution, excluding costs associated with an attorney's time.

Section 50. Subsection (4) of section 400.497, Florida Statutes, is amended to read:

400.497 Rules establishing minimum standards.—The agency shall adopt, publish, and enforce rules to implement part II of chapter 408 and this part, including, as applicable, ss. 400.506 and 400.509, which must provide reasonable and fair minimum standards relating to:

(4) Licensure application and renewal and certificates of exemption.

Section 51. Subsection (5) and paragraph (a) of subsection (15) of section 400.506, Florida Statutes, are amended to read:

400.506 Licensure of nurse registries; requirements; penalties.—

(5)(a) In addition to the requirements of s. 408.812, any person who owns, operates, or maintains an unlicensed nurse registry and who, ~~within 10 working days~~ after receiving notification from the agency, fails to cease operation and apply for a license under this part commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083. Each day of continued operation is a separate offense.

(b) If a nurse registry fails to cease operation after agency notification, the agency may impose a fine pursuant to s. 408.812 ~~of $500 for each day of noncompliance~~.

(15)(a) The agency may deny, suspend, or revoke the license of a nurse registry and shall impose a fine of $5,000 against a nurse registry that:

1. Provides services to residents in an assisted living facility for which the nurse registry does not receive fair market value remuneration.

2. Provides staffing to an assisted living facility for which the nurse registry does not receive fair market value remuneration.

3. Fails to provide the agency, upon request, with copies of all contracts with assisted living facilities which were executed within the last 5 years.

~~4. Gives remuneration to a case manager, discharge planner, facility-based staff member, or third-party vendor who is involved in the discharge planning process of a facility licensed under chapter 395 or this chapter and from whom the nurse registry receives referrals. A nurse registry is exempt from this subparagraph if it does not bill the Florida Medicaid program or the Medicare program or share a controlling interest with any entity licensed, registered, or certified under part II of chapter 408 that bills the Florida Medicaid program or the Medicare program.~~

~~5. Gives remuneration to a physician, a member of the physician's office staff, or an immediate family member of the physician, and the nurse registry received a patient referral in the last 12 months from that physician or the physician's office staff. A nurse registry is exempt from this subparagraph if it does not bill the Florida Medicaid program or the Medicare program or share a controlling interest with any entity licensed, registered, or certified under part II of chapter 408 that bills the Florida Medicaid program or the Medicare program.~~

Section 52. Subsection (1) of section 400.606, Florida Statutes, is amended to read:

400.606 License; application; renewal; conditional license

or permit; certificate of need.—

(1) In addition to the requirements of part II of chapter 408, the initial application and change of ownership application must be accompanied by a plan for the delivery of home, residential, and homelike inpatient hospice services to terminally ill persons and their families. Such plan must contain, but need not be limited to:

(a) The estimated average number of terminally ill persons to be served monthly.

(b) The geographic area in which hospice services will be available.

(c) A listing of services which are or will be provided, either directly by the applicant or through contractual arrangements with existing providers.

(d) Provisions for the implementation of hospice home care within 3 months after licensure.

(e) Provisions for the implementation of hospice homelike inpatient care within 12 months after licensure.

(f) The number and disciplines of professional staff to be employed.

(g) The name and qualifications of any existing or potential contractee.

(h) A plan for attracting and training volunteers.

~~If the applicant is an existing licensed health care provider,~~

~~the application must be accompanied by a copy of the most recent profit-loss statement and, if applicable, the most recent licensure inspection report.~~

Section 53. Subsection (6) of section 400.925, Florida Statutes, is amended to read:

400.925 Definitions.—As used in this part, the term:

(6) "Home medical equipment" includes any product as defined by the Food and Drug Administration's Federal Food, Drug, and Cosmetic Act, any products reimbursed under the Medicare Part B Durable Medical Equipment benefits, or any products reimbursed under the Florida Medicaid durable medical equipment program. Home medical equipment includes:

(a) Oxygen and related respiratory equipment; ~~manual, motorized, or customized wheelchairs and related seating and positioning, but does not include prosthetics or orthotics or any splints, braces, or aids custom fabricated by a licensed health care practitioner;~~

(b) Motorized scooters;

(c) Personal transfer systems; ~~and~~

(d) Specialty beds, for use by a person with a medical need; and

(e) Manual, motorized, or customized wheelchairs and related seating and positioning, but does not include prosthetics or orthotics or any splints, braces, or aids custom fabricated by a licensed health care practitioner.

Section 54. Subsection (4) of section 400.931, Florida Statutes, is amended to read:

400.931 Application for license; fee.—

(4) When a change of the general manager of a home medical equipment provider occurs, the licensee must notify the agency of the change within the timeframes established in part II of chapter 408 and applicable rules ~~45 days~~.

Section 55. Subsection (2) of section 400.933, Florida Statutes, is amended to read:

400.933 Licensure inspections and investigations.—

(2) The agency shall accept, in lieu of its own periodic inspections for licensure, submission of the following:

(a) The survey or inspection of an accrediting organization, provided the accreditation of the licensed home medical equipment provider is not provisional and provided the licensed home medical equipment provider authorizes release of, and the agency receives the report of, the accrediting organization; or

(b) A copy of a valid medical oxygen retail establishment permit issued by the Department of Business and Professional Regulation ~~Health~~, pursuant to chapter 499.

Section 56. Subsection (2) of section 400.980, Florida Statutes, is amended to read:

400.980 Health care services pools.—

(2) The requirements of part II of chapter 408 apply to

the provision of services that require licensure or registration pursuant to this part and part II of chapter 408 and to entities registered by or applying for such registration from the agency pursuant to this part. Registration or a license issued by the agency is required for the operation of a health care services pool in this state. In accordance with s. 408.805, an applicant or licensee shall pay a fee for each license application submitted using this part, part II of chapter 408, and applicable rules. The agency shall adopt rules and provide forms required for such registration and shall impose a registration fee in an amount sufficient to cover the cost of administering this part and part II of chapter 408. In addition to the requirements in part II of chapter 408, the registrant must provide the agency with any change of information contained on the original registration application within the timeframes established in this part, part II of chapter 408, and applicable rules ~~14 days prior to the change~~.

Section 57. Paragraphs (a) through (d) of subsection (4) of section 400.9905, Florida Statutes, are amended to read:

400.9905 Definitions.—

(4) "Clinic" means an entity where health care services are provided to individuals and which tenders charges for reimbursement for such services, including a mobile clinic and a portable equipment provider. As used in this part, the term does not include and the licensure requirements of this part do not

apply to:

(a) Entities licensed or registered by the state under chapter 395; entities licensed or registered by the state and providing only health care services within the scope of services authorized under their respective licenses under ss. 383.30-383.332 ~~383.30-383.335~~, chapter 390, chapter 394, chapter 397, this chapter except part X, chapter 429, chapter 463, chapter 465, chapter 466, chapter 478, ~~part I of chapter 483,~~ chapter 484, or chapter 651; end-stage renal disease providers authorized under 42 C.F.R. part 405, subpart U; providers certified under 42 C.F.R. part 485, subpart B or subpart H; or any entity that provides neonatal or pediatric hospital-based health care services or other health care services by licensed practitioners solely within a hospital licensed under chapter 395.

(b) Entities that own, directly or indirectly, entities licensed or registered by the state pursuant to chapter 395; entities that own, directly or indirectly, entities licensed or registered by the state and providing only health care services within the scope of services authorized pursuant to their respective licenses under ss. 383.30-383.332 ~~383.30-383.335~~, chapter 390, chapter 394, chapter 397, this chapter except part X, chapter 429, chapter 463, chapter 465, chapter 466, chapter 478, ~~part I of chapter 483,~~ chapter 484, or chapter 651; end-stage renal disease providers authorized under 42 C.F.R. part

405, subpart U; providers certified under 42 C.F.R. part 485, subpart B or subpart H; or any entity that provides neonatal or pediatric hospital-based health care services by licensed practitioners solely within a hospital licensed under chapter 395.

(c) Entities that are owned, directly or indirectly, by an entity licensed or registered by the state pursuant to chapter 395; entities that are owned, directly or indirectly, by an entity licensed or registered by the state and providing only health care services within the scope of services authorized pursuant to their respective licenses under ss. 383.30-383.332 ~~383.30-383.335~~, chapter 390, chapter 394, chapter 397, this chapter except part X, chapter 429, chapter 463, chapter 465, chapter 466, chapter 478, ~~part I of chapter 483,~~ chapter 484, or chapter 651; end-stage renal disease providers authorized under 42 C.F.R. part 405, subpart U; providers certified under 42 C.F.R. part 485, subpart B or subpart H; or any entity that provides neonatal or pediatric hospital-based health care services by licensed practitioners solely within a hospital under chapter 395.

(d) Entities that are under common ownership, directly or indirectly, with an entity licensed or registered by the state pursuant to chapter 395; entities that are under common ownership, directly or indirectly, with an entity licensed or registered by the state and providing only health care services

within the scope of services authorized pursuant to their respective licenses under ss. 383.30-383.332 ~~383.30-383.335~~, chapter 390, chapter 394, chapter 397, this chapter except part X, chapter 429, chapter 463, chapter 465, chapter 466, chapter 478, ~~part I of chapter 483,~~ chapter 484, or chapter 651; end-stage renal disease providers authorized under 42 C.F.R. part 405, subpart U; providers certified under 42 C.F.R. part 485, subpart B or subpart H; or any entity that provides neonatal or pediatric hospital-based health care services by licensed practitioners solely within a hospital licensed under chapter 395.

Notwithstanding this subsection, an entity shall be deemed a clinic and must be licensed under this part in order to receive reimbursement under the Florida Motor Vehicle No-Fault Law, ss. 627.730-627.7405, unless exempted under s. 627.736(5)(h).

Section 58. Subsection (6) of section 400.9935, Florida Statutes, is amended to read:

400.9935 Clinic responsibilities.—

(6) Any person or entity providing health care services which is not a clinic, as defined under s. 400.9905, may voluntarily apply for a certificate of exemption from licensure under its exempt status with the agency on a form that sets forth its name or names and addresses, a statement of the reasons why it cannot be defined as a clinic, and other

information deemed necessary by the agency. An exemption may be valid for up to 2 years and is not transferable. The agency may charge an applicant for a certificate of exemption in an amount equal to $100 or the actual cost of processing the certificate, whichever is less. An entity seeking a certificate of exemption must publish and maintain a schedule of charges for the medical services offered to patients. The schedule must include the prices charged to an uninsured person paying for such services by cash, check, credit card, or debit card. The schedule must be posted in a conspicuous place in the reception area of the entity and must include, but is not limited to, the 50 services most frequently provided by the entity. The schedule may group services by three price levels, listing services in each price level. The posting must be at least 15 square feet in size. As a condition precedent to receiving a certificate of exemption, an applicant must provide to the agency documentation of compliance with these requirements.

Section 59. Paragraph (a) of subsection (2) of section 408.033, Florida Statutes, is amended to read:

408.033 Local and state health planning.—

(2) FUNDING.—

(a) The Legislature intends that the cost of local health councils be borne by assessments on selected health care facilities subject to facility licensure by the Agency for Health Care Administration, including abortion clinics, assisted

living facilities, ambulatory surgical centers, birth ~~birthing~~ centers, ~~clinical laboratories except community nonprofit blood banks and clinical laboratories operated by practitioners for exclusive use regulated under s. 483.035,~~ home health agencies, hospices, hospitals, intermediate care facilities for the developmentally disabled, nursing homes, health care clinics, and multiphasic testing centers and by assessments on organizations subject to certification by the agency pursuant to chapter 641, part III, including health maintenance organizations and prepaid health clinics. Fees assessed may be collected prospectively at the time of licensure renewal and prorated for the licensure period.

Section 60. Paragraphs (f) through (t) of subsection (3) of section 408.036, Florida Statutes, are redesignated as paragraphs (e) through (s), respectively, and present paragraphs (e) and (p) of that subsection are amended, to read:

408.036 Projects subject to review; exemptions.—

(3) EXEMPTIONS.—Upon request, the following projects are subject to exemption from the provisions of subsection (1):

~~(e) For mobile surgical facilities and related health care services provided under contract with the Department of Corrections or a private correctional facility operating pursuant to chapter 957.~~

(o) ~~(p)~~ For replacement of a licensed nursing home on the same site, or within 5 miles of the same site if within the same

subdistrict, if the number of licensed beds does not increase except as permitted under paragraph (e) ~~(f)~~.

Section 61. Paragraph (b) of subsection (3) of section 408.0361, Florida Statutes, is amended to read:

408.0361 Cardiovascular services and burn unit licensure.—

(3) In establishing rules for adult cardiovascular services, the agency shall include provisions that allow for:

(b)1. For a hospital seeking a Level I program, demonstration that, for the most recent 12-month period as reported to the agency, it has provided a minimum of 300 adult inpatient and outpatient diagnostic cardiac catheterizations or, for the most recent 12-month period, has discharged or transferred at least 300 patients ~~inpatients~~ with the principal diagnosis of ischemic heart disease and that it has a formalized, written transfer agreement with a hospital that has a Level II program, including written transport protocols to ensure safe and efficient transfer of a patient within 60 minutes.

2.a. A hospital located more than 100 road miles from the closest Level II adult cardiovascular services program does not need to meet the diagnostic cardiac catheterization volume and ischemic heart disease diagnosis volume requirements in subparagraph 1., 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.

b. ~~However,~~ A hospital located more than 100 road miles from the closest Level II adult cardiovascular services program does not need to meet the 60-minute transfer time protocol requirement in subparagraph 1., if the hospital demonstrates that it has a formalized, written transfer agreement with a hospital that has a Level II program. The agreement must include written transport protocols to ensure the safe and efficient transfer of a patient, taking into consideration the patient's clinical and physical characteristics, road and weather conditions, and viability of ground and air ambulance service to transfer the patient.

3. At a minimum, the rules for adult cardiovascular services must require nursing and technical staff to have demonstrated experience in handling acutely ill patients requiring intervention, based on the staff member's previous experience in dedicated cardiac interventional laboratories or surgical centers. If a staff member's previous experience is in a dedicated cardiac interventional laboratory at a hospital that does not have an approved adult open-heart-surgery program, the staff member's previous experience qualifies only if, at the time the staff member acquired his or her experience, the dedicated cardiac interventional laboratory:

a. Had an annual volume of 500 or more percutaneous cardiac intervention procedures;

b. Achieved a demonstrated success rate of 95 percent or greater for percutaneous cardiac intervention procedures;

c. Experienced a complication rate of less than 5 percent for percutaneous cardiac intervention procedures; and

d. 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.

Section 62. Subsection (4) of section 408.061, Florida Statutes, is amended to read:

408.061 Data collection; uniform systems of financial reporting; information relating to physician charges; confidential information; immunity.—

(4) Within 120 days after the end of its fiscal year, each health care facility, excluding continuing care facilities, hospitals operated by state agencies, and nursing homes as those terms are defined in s. 408.07 ~~s. 408.07(14) and (37)~~, shall file with the agency, on forms adopted by the agency and based on the uniform system of financial reporting, its actual financial experience for that fiscal year, including expenditures, revenues, and statistical measures. Such data may be based on internal financial reports which are certified to be complete and accurate by the provider. However, hospitals'

actual financial experience shall be their audited actual experience. Every nursing home shall submit to the agency, in a format designated by the agency, a statistical profile of the nursing home residents. The agency, in conjunction with the Department of Elderly Affairs and the Department of Health, shall review these statistical profiles and develop recommendations for the types of residents who might more appropriately be placed in their homes or other noninstitutional settings.

Section 63. Subsection (11) of section 408.07, Florida Statutes, is amended to read:

408.07 Definitions.—As used in this chapter, with the exception of ss. 408.031-408.045, the term:

~~(11) "Clinical laboratory" means a facility licensed under s. 483.091, excluding: any hospital laboratory defined under s. 483.041(6); any clinical laboratory operated by the state or a political subdivision of the state; any blood or tissue bank where the majority of revenues are received from the sale of blood or tissue and where blood, plasma, or tissue is procured from volunteer donors and donated, processed, stored, or distributed on a nonprofit basis; and any clinical laboratory which is wholly owned and operated by physicians who are licensed pursuant to chapter 458 or chapter 459 and who practice in the same group practice, and at which no clinical laboratory work is performed for patients referred by any health care~~

~~provider who is not a member of that same group practice.~~

Section 64. Subsection (4) of section 408.20, Florida Statutes, is amended to read:

408.20 Assessments; Health Care Trust Fund.—

(4) Hospitals operated by a state agency ~~the Department of Children and Families, the Department of Health, or the Department of Corrections~~ are exempt from the assessments required under this section.

Section 65. Section 408.7056, Florida Statutes, is repealed.

Section 66. Subsections (10), (11), and (27) of section 408.802, Florida Statutes, are amended to read:

408.802 Applicability.—The provisions of this part apply to the provision of services that require licensure as defined in this part and to the following entities licensed, registered, or certified by the agency, as described in chapters 112, 383, 390, 394, 395, 400, 429, 440, 483, and 765:

~~(10) Mobile surgical facilities, as provided under part I of chapter 395.~~

~~(11) Health care risk managers, as provided under part I of chapter 395.~~

~~(27) Clinical laboratories, as provided under part I of chapter 483.~~

Section 67. Subsections (12) and (13) of section 408.803, Florida Statutes, are redesignated as subsections (13) and (14),

respectively, and a new subsection (12) is added to that section, to read:

408.803 Definitions.—As used in this part, the term:

(12) "Relative" means an individual who is the father, mother, stepfather, stepmother, son, daughter, brother, sister, grandmother, grandfather, great-grandmother, great-grandfather, grandson, granddaughter, uncle, aunt, first cousin, nephew, niece, husband, wife, father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, sister-in-law, stepson, stepdaughter, stepbrother, stepsister, half-brother, or half-sister of a patient or client.

Section 68. Paragraph (c) of subsection (7) of section 408.806, Florida Statutes, is amended, and subsection (9) is added to that section, to read:

408.806 License application process.—

(7)(c) If an inspection is required by the authorizing statute for a license application other than an initial application, the inspection must be unannounced. This paragraph does not apply to inspections required pursuant to ss. 383.324, 395.0161(4) and~~,~~ 429.67(6)~~, and 483.061(2)~~.

(9) A licensee that holds a license for multiple providers licensed by the agency may request that all related license expiration dates be aligned. Upon such request, the agency may issue a license for an abbreviated licensure period with a prorated licensure fee.

Section 69. Paragraphs (d) and (e) of subsection (1) of section 408.809, Florida Statutes, are amended to read:

408.809 Background screening; prohibited offenses.—

(1) Level 2 background screening pursuant to chapter 435 must be conducted through the agency on each of the following persons, who are considered employees for the purposes of conducting screening under chapter 435:

(d) Any person who is a controlling interest ~~if the agency has reason to believe that such person has been convicted of any offense prohibited by s. 435.04. For each controlling interest who has been convicted of any such offense, the licensee shall submit to the agency a description and explanation of the conviction at the time of license application~~.

(e) Any person, as required by authorizing statutes, seeking employment with a licensee or provider who is expected to, or whose responsibilities may require him or her to, provide personal care or services directly to clients or have access to client funds, personal property, or living areas; and any person, as required by authorizing statutes, contracting with a licensee or provider whose responsibilities require him or her to provide personal care or personal services directly to clients, or contracting with a licensee or provider to work 20 hours a week or more who will have access to client funds, personal property, or living areas. Evidence of contractor screening may be retained by the contractor's employer or the

licensee.

Section 70. Subsection (8) of section 408.810, Florida Statutes, is amended, and subsections (11), (12), and (13) are added to that section, to read:

408.810 Minimum licensure requirements.—In addition to the licensure requirements specified in this part, authorizing statutes, and applicable rules, each applicant and licensee must comply with the requirements of this section in order to obtain and maintain a license.

(8) Upon application for initial licensure or change of ownership licensure, the applicant shall furnish satisfactory proof of the applicant's financial ability to operate in accordance with the requirements of this part, authorizing statutes, and applicable rules. The agency shall establish standards for this purpose, including information concerning the applicant's controlling interests. The agency shall also establish documentation requirements, to be completed by each applicant, that show anticipated provider revenues and expenditures, the basis for financing the anticipated cash-flow requirements of the provider, and an applicant's access to contingency financing. A current certificate of authority, pursuant to chapter 651, may be provided as proof of financial ability to operate. The agency may require a licensee to provide proof of financial ability to operate at any time if there is evidence of financial instability, including, but not limited

to, unpaid expenses necessary for the basic operations of the provider. An applicant applying for change of ownership licensure is exempt from furnishing proof of financial ability to operate if the provider has been licensed for at least 5 years, and:

(a) The ownership change is a result of a corporate reorganization under which the controlling interest is unchanged and the applicant submits organizational charts that represent the current and proposed structure of the reorganized corporation; or

(b) The ownership change is due solely to the death of a person holding a controlling interest, and the surviving controlling interests continue to hold at least 51 percent of ownership after the change of ownership.

(11) The agency may adopt rules that govern the circumstances under which a controlling interest, an administrator, an employee, or a contractor, or a representative thereof, who is not a relative of the client may act as an agent of the client in authorizing consent for medical treatment, assignment of benefits, and release of information. Such rules may include requirements related to disclosure, bonding, restrictions, and client protections.

(12) The licensee shall ensure that no person holds any ownership interest, either directly or indirectly, regardless of ownership structure, who:

(a) Has a disqualifying offense pursuant to s. 408.809; or

(b) Holds or has held any ownership interest, either directly or indirectly, regardless of ownership structure, in a provider that had a license revoked or an application denied pursuant to s. 408.815.

(13) If the licensee is a publicly traded corporation or is wholly owned, directly or indirectly, by a publicly traded corporation, subsection (12) does not apply to those persons whose sole relationship with the corporation is as a shareholder of publicly traded shares. As used in this subsection, a "publicly traded corporation" is a corporation that issues securities traded on an exchange registered with the United States Securities and Exchange Commission as a national securities exchange.

Section 71. Section 408.812, Florida Statutes, is amended to read:

408.812 Unlicensed activity.—

(1) A person or entity may not offer or advertise services that require licensure as defined by this part, authorizing statutes, or applicable rules to the public without obtaining a valid license from the agency. A licenseholder may not advertise or hold out to the public that he or she holds a license for other than that for which he or she actually holds the license.

(2) The operation or maintenance of an unlicensed provider or the performance of any services that require licensure

without proper licensure is a violation of this part and authorizing statutes. Unlicensed activity constitutes harm that materially affects the health, safety, and welfare of clients, and constitutes abuse and neglect, as defined in s. 415.102. The agency or any state attorney may, in addition to other remedies provided in this part, bring an action for an injunction to restrain such violation, or to enjoin the future operation or maintenance of the unlicensed provider or the performance of any services in violation of this part and authorizing statutes, until compliance with this part, authorizing statutes, and agency rules has been demonstrated to the satisfaction of the agency.

(3) It is unlawful for any person or entity to own, operate, or maintain an unlicensed provider. If after receiving notification from the agency, such person or entity fails to cease operation ~~and apply for a license under this part and authorizing statutes~~, the person or entity is ~~shall be~~ subject to penalties as prescribed by authorizing statutes and applicable rules. Each day of ~~continued~~ operation is a separate offense.

(4) Any person or entity that fails to cease operation after agency notification may be fined $1,000 for each day of noncompliance.

(5) When a controlling interest or licensee has an interest in more than one provider and fails to license a

provider rendering services that require licensure, the agency may revoke all licenses, ~~and~~ impose actions under s. 408.814, and regardless of correction, impose a fine of $1,000 per day, unless otherwise specified by authorizing statutes, against each licensee until such time as the appropriate license is obtained or the unlicensed activity ceases ~~for the unlicensed operation~~.

(6) In addition to granting injunctive relief pursuant to subsection (2), if the agency determines that a person or entity is operating or maintaining a provider without obtaining a license and determines that a condition exists that poses a threat to the health, safety, or welfare of a client of the provider, the person or entity is subject to the same actions and fines imposed against a licensee as specified in this part, authorizing statutes, and agency rules.

(7) Any person aware of the operation of an unlicensed provider must report that provider to the agency.

Section 72. Subsections (10), (11) and (26) of section 408.820, Florida Statutes, are amended, and subsections (12) through (25) and (27) and (28) are redesignated as subsections (10) through (23) and (24) and (25), respectively, to read:

408.820 Exemptions.—Except as prescribed in authorizing statutes, the following exemptions shall apply to specified requirements of this part:

~~(10) Mobile surgical facilities, as provided under part I of chapter 395, are exempt from s. 408.810(7)-(10).~~

~~(11) Health care risk managers, as provided under part I of chapter 395, are exempt from ss. 408.806(7), 408.810(4)-(10), and 408.811.~~

~~(26) Clinical laboratories, as provided under part I of chapter 483, are exempt from s. 408.810(5)-(10).~~

Section 73. Subsection (7) of section 409.905, Florida Statutes, is amended to read:

409.905 Mandatory Medicaid services.—The agency may make payments for the following services, which are required of the state by Title XIX of the Social Security Act, furnished by Medicaid providers to recipients who are determined to be eligible on the dates on which the services were provided. Any service under this section shall be provided only when medically necessary and in accordance with state and federal law. Mandatory services rendered by providers in mobile units to Medicaid recipients may be restricted by the agency. Nothing in this section shall be construed to prevent or limit the agency from adjusting fees, reimbursement rates, lengths of stay, number of visits, number of services, or any other adjustments necessary to comply with the availability of moneys and any limitations or directions provided for in the General Appropriations Act or chapter 216.

(7) INDEPENDENT LABORATORY SERVICES.—The agency shall pay for medically necessary diagnostic laboratory procedures ordered by a licensed physician or other licensed practitioner of the

healing arts which are provided for a recipient in a laboratory that meets the requirements for Medicare participation and is appropriately certified by the Centers for Medicare and Medicaid Services under the federal Clinical Laboratory Improvement Amendments and the federal rules adopted thereunder ~~licensed under chapter 483, if required~~.

Section 74. Subsection (10) of section 409.907, Florida Statutes, is amended to read:

409.907 Medicaid provider agreements.—The agency may make payments for medical assistance and related services rendered to Medicaid recipients only to an individual or entity who has a provider agreement in effect with the agency, who is performing services or supplying goods in accordance with federal, state, and local law, and who agrees that no person shall, on the grounds of handicap, race, color, or national origin, or for any other reason, be subjected to discrimination under any program or activity for which the provider receives payment from the agency.

(10) The agency may consider whether the provider, or any officer, director, agent, managing employee, or affiliated person, or any partner or shareholder having an ownership interest equal to 5 percent or greater in the provider if the provider is a corporation, partnership, or other business entity, has:

(a) Made a false representation or omission of any

material fact in making the application, including the submission of an application that conceals the controlling or ownership interest of any officer, director, agent, managing employee, affiliated person, or partner or shareholder who may not be eligible to participate;

(b) Been or is currently excluded, suspended, terminated from, or has involuntarily withdrawn from participation in, Florida's Medicaid program or any other state's Medicaid program, or from participation in any other governmental or private health care or health insurance program;

~~(c) Been convicted of a criminal offense relating to the delivery of any goods or services under Medicaid or Medicare or any other public or private health care or health insurance program including the performance of management or administrative services relating to the delivery of goods or services under any such program;~~

~~(d) Been convicted under federal or state law of a criminal offense related to the neglect or abuse of a patient in connection with the delivery of any health care goods or services;~~

~~(e) Been convicted under federal or state law of a criminal offense relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance;~~

~~(f) Been convicted of any criminal offense relating to~~

~~fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct;~~

~~(g) Been convicted under federal or state law of a crime punishable by imprisonment of a year or more which involves moral turpitude;~~

~~(h) Been convicted in connection with the interference or obstruction of any investigation into any criminal offense listed in this subsection;~~

~~(i) Been found to have violated federal or state laws, rules, or regulations governing Florida's Medicaid program or any other state's Medicaid program, the Medicare program, or any other publicly funded federal or state health care or health insurance program, and been sanctioned accordingly;~~

(c) ~~(j)~~ Been previously found by a licensing, certifying, or professional standards board or agency to have violated the standards or conditions relating to licensure or certification or the quality of services provided; or

(d) ~~(k)~~ Failed to pay any fine or overpayment properly assessed under the Medicaid program in which no appeal is pending or after resolution of the proceeding by stipulation or agreement, unless the agency has issued a specific letter of forgiveness or has approved a repayment schedule to which the provider agrees to adhere.

Section 75. Subsection (6) of section 409.9116, Florida Statutes, is amended to read:

409.9116 Disproportionate share/financial assistance program for rural hospitals.—In addition to the payments made under s. 409.911, the Agency for Health Care Administration shall administer a federally matched disproportionate share program and a state-funded financial assistance program for statutory rural hospitals. The agency shall make disproportionate share payments to statutory rural hospitals that qualify for such payments and financial assistance payments to statutory rural hospitals that do not qualify for disproportionate share payments. The disproportionate share program payments shall be limited by and conform with federal requirements. Funds shall be distributed quarterly in each fiscal year for which an appropriation is made. Notwithstanding the provisions of s. 409.915, counties are exempt from contributing toward the cost of this special reimbursement for hospitals serving a disproportionate share of low-income patients.

(6) This section applies only to hospitals that were defined as statutory rural hospitals, or their successor-in-interest hospital, prior to January 1, 2001. Any additional hospital that is defined as a statutory rural hospital, or its successor-in-interest hospital, on or after January 1, 2001, is not eligible for programs under this section unless additional funds are appropriated each fiscal year specifically to the rural hospital disproportionate share and financial assistance

programs in an amount necessary to prevent any hospital, or its successor-in-interest hospital, eligible for the programs prior to January 1, 2001, from incurring a reduction in payments because of the eligibility of an additional hospital to participate in the programs. A hospital, or its successor-in-interest hospital, which received funds pursuant to this section before January 1, 2001, and which qualifies under s. 395.602(2)(b) ~~s. 395.602(2)(c)~~, shall be included in the programs under this section and is not required to seek additional appropriations under this subsection.

Section 76. Paragraphs (a) and (b) of subsection (1) of section 409.975, Florida Statutes, are amended to read:

409.975 Managed care plan accountability.—In addition to the requirements of s. 409.967, plans and providers participating in the managed medical assistance program shall comply with the requirements of this section.

(1) PROVIDER NETWORKS.—Managed care plans must develop and maintain provider networks that meet the medical needs of their enrollees in accordance with standards established pursuant to s. 409.967(2)(c). Except as provided in this section, managed care plans may limit the providers in their networks based on credentials, quality indicators, and price.

(a) Plans must include all providers in the region that are classified by the agency as essential Medicaid providers, unless the agency approves, in writing, an alternative

arrangement for securing the types of services offered by the essential providers. Providers are essential for serving Medicaid enrollees if they offer services that are not available from any other provider within a reasonable access standard, or if they provided a substantial share of the total units of a particular service used by Medicaid patients within the region during the last 3 years and the combined capacity of other service providers in the region is insufficient to meet the total needs of the Medicaid patients. The agency may not classify physicians and other practitioners as essential providers. The agency, at a minimum, shall determine which providers in the following categories are essential Medicaid providers:

1. Federally qualified health centers.

2. Statutory teaching hospitals as defined in s. 408.07(44) ~~s. 408.07(45)~~.

3. Hospitals that are trauma centers as defined in s. 395.4001(14).

4. Hospitals located at least 25 miles from any other hospital with similar services.

Managed care plans that have not contracted with all essential providers in the region as of the first date of recipient enrollment, or with whom an essential provider has terminated its contract, must negotiate in good faith with such essential

providers for 1 year or until an agreement is reached, whichever is first. Payments for services rendered by a nonparticipating essential provider shall be made at the applicable Medicaid rate as of the first day of the contract between the agency and the plan. A rate schedule for all essential providers shall be attached to the contract between the agency and the plan. After 1 year, managed care plans that are unable to contract with essential providers shall notify the agency and propose an alternative arrangement for securing the essential services for Medicaid enrollees. The arrangement must rely on contracts with other participating providers, regardless of whether those providers are located within the same region as the nonparticipating essential service provider. If the alternative arrangement is approved by the agency, payments to nonparticipating essential providers after the date of the agency's approval shall equal 90 percent of the applicable Medicaid rate. Except for payment for emergency services, if the alternative arrangement is not approved by the agency, payment to nonparticipating essential providers shall equal 110 percent of the applicable Medicaid rate.

(b) Certain providers are statewide resources and essential providers for all managed care plans in all regions. All managed care plans must include these essential providers in their networks. Statewide essential providers include:

1. Faculty plans of Florida medical schools.

2. Regional perinatal intensive care centers as defined in s. 383.16(2).

3. Hospitals licensed as specialty children's hospitals as defined in s. 395.002(27) ~~s. 395.002(28)~~.

4. Accredited and integrated systems serving medically complex children which comprise separately licensed, but commonly owned, health care providers delivering at least the following services: medical group home, in-home and outpatient nursing care and therapies, pharmacy services, durable medical equipment, and Prescribed Pediatric Extended Care.

Managed care plans that have not contracted with all statewide essential providers in all regions as of the first date of recipient enrollment must continue to negotiate in good faith. Payments to physicians on the faculty of nonparticipating Florida medical schools shall be made at the applicable Medicaid rate. Payments for services rendered by regional perinatal intensive care centers shall be made at the applicable Medicaid rate as of the first day of the contract between the agency and the plan. Except for payments for emergency services, payments to nonparticipating specialty children's hospitals shall equal the highest rate established by contract between that provider and any other Medicaid managed care plan.

Section 77. Subsections (5) and (17) of section 429.02, Florida Statutes, are amended to read:

429.02 Definitions.—When used in this part, the term:

(5) "Assisted living facility" means any building or buildings, section or distinct part of a building, private home, boarding home, home for the aged, or other residential facility, regardless of whether operated for profit ~~or not~~, which ~~undertakes~~ through its ownership or management provides ~~to provide~~ housing, meals, and one or more personal services for a period exceeding 24 hours to one or more adults who are not relatives of the owner or administrator.

(17) "Personal services" means direct physical assistance with or supervision of the activities of daily living, ~~and~~ the self-administration of medication, or ~~and~~ other similar services which the department may define by rule. The term may ~~"Personal services" shall~~ not be construed to mean the provision of medical, nursing, dental, or mental health services.

Section 78. Paragraphs (b) and (d) of subsection (2) of section 429.04, Florida Statutes, are amended, and subsection (3) is added that section, to read:

429.04 Facilities to be licensed; exemptions.—

(2) The following are exempt from licensure under this part:

(b) Any facility or part of a facility licensed by the Agency for Persons with Disabilities under chapter 393, a mental health facility licensed under ~~or~~ chapter 394, a hospital licensed under chapter 395, a nursing home licensed under part

II of chapter 400, an inpatient hospice licensed under part IV of chapter 400, a home for special services licensed under part V of chapter 400, an intermediate care facility licensed under part VIII of chapter 400, or a transitional living facility licensed under part XI of chapter 400.

(d) Any person who provides housing, meals, and 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 person who provides the housing, meals, and personal services must own or rent the home and must have established the home as his or her permanent residence. For purposes of this paragraph, any person holding a homestead exemption at an address other than that at which the person asserts this exemption is presumed to not have established permanent residence ~~reside therein~~. This exemption does not apply to a person or entity that previously held a license issued by the agency which was revoked or for which renewal was denied by final order of the agency, or when the person or entity voluntarily relinquished the license during agency enforcement proceedings.

(3) Upon agency investigation of unlicensed activity, any person or entity that claims that it is exempt under this section must provide documentation substantiating entitlement to the exemption.

Section 79. Paragraphs (b) and (d) of subsection (1) of

section 429.08, Florida Statutes, are amended to read:

429.08 Unlicensed facilities; referral of person for residency to unlicensed facility; penalties.—

(1)(b) ~~Except as provided under paragraph (d),~~ Any person who owns, rents, or otherwise maintains a building or property used as ~~operates, or maintains~~ an unlicensed assisted living facility commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. Each day of continued operation is a separate offense.

(d) In addition to the requirements of s. 408.812, any person who owns, operates, or maintains an unlicensed assisted living facility after receiving notice from the agency ~~due to a change in this part or a modification in rule within 6 months after the effective date of such change and who, within 10 working days after receiving notification from the agency, fails to cease operation or apply for a license under this part~~ commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. Each day of continued operation is a separate offense.

Section 80. Section 429.176, Florida Statutes, is amended to read:

429.176 Notice of change of administrator.—If, during the period for which a license is issued, the owner changes administrators, the owner must notify the agency of the change within 10 days and provide documentation within 90 days that the

new administrator has completed the applicable core educational requirements under s. 429.52. A facility may not be operated for more than 120 consecutive days without an administrator who has completed the core educational requirements.

Section 81. Subsection (7) of section 429.19, Florida Statutes, is amended to read:

429.19 Violations; imposition of administrative fines; grounds.—

(7) In addition to any administrative fines imposed, the agency may assess a survey fee, equal to the lesser of one half of the facility's biennial license and bed fee or $500, to cover the cost of conducting initial complaint investigations that result in the finding of a violation that was the subject of the complaint or monitoring visits conducted ~~under s. 429.28(3)(c)~~ to verify the correction of the violations.

Section 82. Subsection (2) of section 429.24, Florida Statutes, is amended to read:

429.24 Contracts.—

(2) Each contract must contain express provisions specifically setting forth the services and accommodations to be provided by the facility; the rates or charges; provision for at least 30 days' written notice of a rate increase; the rights, duties, and obligations of the residents, other than those specified in s. 429.28; and other matters that the parties deem appropriate. A new service or accommodation added to, or

implemented in, a resident's contract for which the resident was not previously charged does not require a 30-day written notice of a rate increase. Whenever money is deposited or advanced by a resident in a contract as security for performance of the contract agreement or as advance rent for other than the next immediate rental period:

(a) Such funds shall be deposited in a banking institution in this state that is located, if possible, in the same community in which the facility is located; shall be kept separate from the funds and property of the facility; may not be represented as part of the assets of the facility on financial statements; and shall be used, or otherwise expended, only for the account of the resident.

(b) The licensee shall, within 30 days of receipt of advance rent or a security deposit, notify the resident or residents in writing of the manner in which the licensee is holding the advance rent or security deposit and state the name and address of the depository where the moneys are being held. The licensee shall notify residents of the facility's policy on advance deposits.

Section 83. Paragraphs (e) and (j) of subsection (1) and paragraphs (c), (d), and (e) of subsection (3) of section 429.28, Florida Statutes, are amended to read:

429.28 Resident bill of rights.—

(1) No resident of a facility shall be deprived of any

civil or legal rights, benefits, or privileges guaranteed by law, the Constitution of the State of Florida, or the Constitution of the United States as a resident of a facility. Every resident of a facility shall have the right to:

(e) Freedom to participate in and benefit from community services and activities and to pursue ~~achieve~~ the highest possible level of independence, autonomy, and interaction within the community.

(j) Assistance with obtaining access to adequate and appropriate health care. For purposes of this paragraph, the term "adequate and appropriate health care" means the 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 which are consistent with established and recognized standards within the community.

(3) ~~(c) During any calendar year in which no survey is conducted, the agency shall conduct at least one monitoring visit of each facility cited in the previous year for a class I or class II violation, or more than three uncorrected class III violations.~~

~~(d) The agency may conduct periodic followup inspections as necessary to monitor the compliance of facilities with a history of any class I, class II, or class III violations that threaten the health, safety, or security of residents.~~

~~(c) The agency may conduct complaint investigations as warranted to investigate any allegations of noncompliance with requirements required under this part or rules adopted under this part.~~

Section 84. Subsection (1) of section 429.294, Florida Statutes, is amended to read:

429.294 Availability of facility records for investigation of resident's rights violations and defenses; penalty.—

(1) Failure to provide complete copies of a resident's records, including, but not limited to, all medical records and the resident's chart, within the control or possession of the facility ~~within 10 days,~~ in accordance with ~~the provisions of~~ s. 400.145, shall constitute evidence of failure of that party to comply with good faith discovery requirements and shall waive the good faith certificate and presuit notice requirements under this part by the requesting party.

Section 85. Subsection (2) of section 429.34, Florida Statutes, is amended to read:

429.34 Right of entry and inspection.—

(2)(a) In addition to the requirements of s. 408.811, the agency may inspect and investigate facilities as necessary to determine compliance with this part, part II of chapter 408, and rules adopted thereunder. ~~The agency shall inspect each licensed assisted living facility at least once every 24 months to determine compliance with this chapter and related rules.~~ If an

assisted living facility is cited for a class I violation or three or more class II violations arising from separate surveys within a 60-day period or due to unrelated circumstances during the same survey, the agency must conduct an additional licensure inspection within 6 months.

(b) During any calendar year in which a survey is not conducted, the agency may conduct monitoring visits of each facility cited in the previous year for a class I or class II violation or for more than three uncorrected class III violations.

Section 86. Subsection (4) of section 429.52, Florida Statutes, is amended to read:

429.52 Staff training and educational programs; core educational requirement.—

(4) Effective January 1, 2004, a new facility administrator must complete the required training and education, including the competency test, within 90 days after the date of employment ~~a reasonable time after being employed~~ as an administrator~~, as determined by the department~~. Failure to do so is a violation of this part and subjects the violator to an administrative fine as prescribed in s. 429.19. Administrators licensed in accordance with part II of chapter 468 are exempt from this requirement. Other licensed professionals may be exempted, as determined by the department by rule.

Section 87. Subsection (3) of section 435.04, Florida

Statutes, is amended, and subsection (4) is added to that section, to read:

435.04 Level 2 screening standards.—

(3) The security background investigations under this section must ensure that no person subject to this section has been arrested for and is awaiting final disposition of, been found guilty of, regardless of adjudication, or entered a plea of nolo contendere or guilty to, any offense that constitutes domestic violence as defined in s. 741.28, whether such act was committed in this state or in another jurisdiction.

(4) For the purpose of screening applicability to participate in the Medicaid program, the security background investigations under this section must ensure that a person subject to screening under this section has not been arrested for and is not awaiting final disposition of; has not been found guilty of, regardless of adjudication, or entered a plea of nolo contendere or guilty to; and has not been adjudicated delinquent and the record sealed or expunged for, any of the following offenses:

(a) Violation of a federal law or a law in any state which creates a criminal offense relating to:

1. The delivery of any goods or services under Medicaid or Medicare or any other public or private health care or health insurance program, including the performance of management or administrative services relating to the delivery of goods or

services under any such program;

2. Neglect or abuse of a patient in connection with the delivery of any health care good or service;

3. Unlawful manufacture, distribution, prescription, or dispensing of a controlled substance;

4. Fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct; or

5. Moral turpitude, if punishable by imprisonment of a year or more.

6. Interference with or obstruction of an investigation into any criminal offense identified in this subsection.

(b) Violation of the following state laws or laws of another jurisdiction:

1. Section 817.569, criminal use of a public record or information contained in a public record;

2. Section 838.016, unlawful compensation or reward for official behavior;

3. Section 838.021, corruption by threat against a public servant;

4. Section 838.022, official misconduct;

5. Section 838.22, bid tampering;

6. Section 839.13, falsifying records;

7. Section 839.26, misuse of confidential information; or

(c) Violation of a federal or state law, rule, or regulation governing the Florida Medicaid program or any other

state Medicaid program, the Medicare program, or any other publicly funded federal or state health care or health insurance program.

Section 88. Paragraph (a) of subsection (2) of section 435.12, Florida Statutes, is amended to read:

435.12 Care Provider Background Screening Clearinghouse.—

(2)(a) To ensure that the information in the clearinghouse is current, the fingerprints of an employee required to be screened by a specified agency and included in the clearinghouse must be:

1. Retained by the Department of Law Enforcement pursuant to s. 943.05(2)(g) and (h) and (3), and the Department of Law Enforcement must report the results of searching those fingerprints against state incoming arrest fingerprint submissions to the Agency for Health Care Administration for inclusion in the clearinghouse.

2. Retained by the Federal Bureau of Investigation in the national retained print arrest notification program as soon as the Department of Law Enforcement begins participation in such program. Arrest prints will be searched against retained prints at the Federal Bureau of Investigation and notification of arrests will be forwarded to the Florida Department of Law Enforcement and reported to the Agency for Health Care Administration for inclusion in the clearinghouse.

3. Resubmitted for a Federal Bureau of Investigation

national criminal history check every 5 years until such time as the fingerprints are retained by the Federal Bureau of Investigation.

4. Subject to retention on a 5-year renewal basis with fees collected at the time of initial submission or resubmission of fingerprints.

a. A person who passed a level 2 screening under s. 435.04 after December 31, 2012, by a specified agency may extend the screening renewal period until January 1, 2020, unless the Department of Law Enforcement begins participation in the national retained print arrest notification program before that date.

b. The retention of fingerprints by the Department of Law Enforcement pursuant to s. 943.05(2)(g) and (h) and (3) is extended until the earlier of January 1, 2021, or the date that the Department of Law Enforcement begins participation in the national retained print arrest notification program.

5. Submitted with a photograph of the person taken at the time the fingerprints are submitted.

Section 89. Subsection (4) of section 456.001, Florida Statutes, is amended to read:

456.001 Definitions.—As used in this chapter, the term:

(4) "Health care practitioner" means any person licensed under chapter 457; chapter 458; chapter 459; chapter 460; chapter 461; chapter 462; chapter 463; chapter 464; chapter 465;

chapter 466; chapter 467; part I, part II, part III, part V, part X, part XIII, or part XIV of chapter 468; chapter 478; chapter 480; part II or part III ~~or part IV~~ of chapter 483; chapter 484; chapter 486; chapter 490; or chapter 491.

Section 90. Subsection (3) of section 456.054, Florida Statutes, is redesignated as subsection (4), and a new subsection (3) is added to that section, to read:

456.054 Kickbacks prohibited.—

(3)(a) It is unlawful for any person or any entity to pay or receive, directly or indirectly, a commission, bonus, kickback, or rebate from, or to engage in any form of a split-fee arrangement with, a dialysis facility, health care practitioner, surgeon, person, or entity for referring patients to a clinical laboratory as defined in s. 483.803.

(b) It is unlawful for any clinical laboratory to:

1. Provide personnel to perform any functions or duties in a health care practitioner's office or dialysis facility for any purpose, including for the collection or handling of specimens, directly or indirectly through an employee, contractor, independent staffing company, lease agreement, or otherwise, unless the laboratory and the practitioner's office, or dialysis facility, are wholly owned and operated by the same entity.

2. Lease space within any part of a health care practitioner's office or dialysis facility for any purpose, including for the purpose of establishing a collection station

where materials or specimens are collected or drawn from patients.

Section 91. Paragraphs (h) and (i) of subsection (2) of section 456.057, Florida Statutes, are amended to read:

456.057 Ownership and control of patient records; report or copies of records to be furnished; disclosure of information.—

(2) As used in this section, the terms "records owner," "health care practitioner," and "health care practitioner's employer" do not include any of the following persons or entities; furthermore, the following persons or entities are not authorized to acquire or own medical records, but are authorized under the confidentiality and disclosure requirements of this section to maintain those documents required by the part or chapter under which they are licensed or regulated:

(h) Clinical laboratory personnel licensed under part II ~~III~~ of chapter 483.

(i) Medical physicists licensed under part III ~~IV~~ of chapter 483.

Section 92. Paragraph (j) of subsection (1) of section 456.076, Florida Statutes, is amended to read:

456.076 Impaired practitioner programs.—

(1) As used in this section, the term:

(j) "Practitioner" means a person licensed, registered, certified, or regulated by the department under part III of

chapter 401; chapter 457; chapter 458; chapter 459; chapter 460; chapter 461; chapter 462; chapter 463; chapter 464; chapter 465; chapter 466; chapter 467; part I, part II, part III, part V, part X, part XIII, or part XIV of chapter 468; chapter 478; chapter 480; part II or part III ~~or part IV~~ of chapter 483; chapter 484; chapter 486; chapter 490; or chapter 491; or an applicant for a license, registration, or certification under the same laws.

Section 93. Subsection (2) of section 458.307, Florida Statutes, is amended to read:

458.307 Board of Medicine.—

(2) Twelve members of the board must be licensed physicians in good standing in this state who are residents of the state and who have been engaged in the active practice or teaching of medicine for at least 4 years immediately preceding their appointment. One of the physicians must be on the full-time faculty of a medical school in this state, and one of the physicians must be in private practice and on the full-time staff of a statutory teaching hospital in this state as defined in s. 408.07. At least one of the physicians must be a graduate of a foreign medical school. The remaining three members must be residents of the state who are not, and never have been, licensed health care practitioners. One member must be a health care risk manager ~~licensed under s. 395.10974~~. At least one member of the board must be 60 years of age or older.

Section 94. Subsection (1) of section 458.345, Florida Statutes, is amended to read:

458.345 Registration of resident physicians, interns, and fellows; list of hospital employees; prescribing of medicinal drugs; penalty.—

(1) Any person desiring to practice as a resident physician, assistant resident physician, house physician, intern, or fellow in fellowship training which leads to subspecialty board certification in this state, or any person desiring to practice as a resident physician, assistant resident physician, house physician, intern, or fellow in fellowship training in a teaching hospital in this state as defined in s. 408.07 ~~s. 408.07(45)~~ or s. 395.805(2), who does not hold a valid, active license issued under this chapter shall apply to the department to be registered and shall remit a fee not to exceed $300 as set by the board. The department shall register any applicant the board certifies has met the following requirements:

(a) Is at least 21 years of age.

(b) Has not committed any act or offense within or without the state which would constitute the basis for refusal to certify an application for licensure pursuant to s. 458.331.

(c) Is a graduate of a medical school or college as specified in s. 458.311(1)(f).

Section 95. Subsection (1) of s. 459.021, Florida

Statutes, is amended to read:

459.021 Registration of resident physicians, interns, and fellows; list of hospital employees; penalty.—

(1) Any person who holds a degree of Doctor of Osteopathic Medicine from a college of osteopathic medicine recognized and approved by the American Osteopathic Association who desires to practice as a resident physician, intern, or fellow in fellowship training which leads to subspecialty board certification in this state, or any person desiring to practice as a resident physician, intern, or fellow in fellowship training in a teaching hospital in this state as defined in s. 408.07 ~~s. 408.07(45)~~ or s. 395.805(2), who does not hold an active license issued under this chapter shall apply to the department to be registered, on an application provided by the department, before commencing such a training program and shall remit a fee not to exceed $300 as set by the board.

Section 96. Part I of chapter 483, Florida Statutes, consisting of sections 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, and 483.26, is repealed.

Section 97. Section 483.294, Florida Statutes, is amended to read:

483.294 Inspection of centers.—In accordance with s. 408.811, the agency shall~~, at least once annually,~~ inspect the

premises and operations of all centers subject to licensure under this part.

Section 98. Subsections (3) and (5) of section 483.801, Florida Statutes, are amended, and subsection (6) is added to that section, to read:

483.801 Exemptions.—This part applies to all clinical laboratories and clinical laboratory personnel within this state, except:

(3) Persons engaged in testing performed by laboratories that are wholly owned and operated by one or more practitioners licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, or chapter 466 who practice in the same group practice, and in which no clinical laboratory work is performed for patients referred by any health care provider who is not a member of that group practice ~~regulated under s. 483.035(1) or exempt from regulation under s. 483.031(2)~~.

(5) Advanced registered nurse practitioners licensed under part I of chapter 464 who perform provider-performed microscopy procedures (PPMP) in a ~~an exclusive-use~~ laboratory setting pursuant to subsection (3).

(6) Persons performing laboratory testing within a physician office practice for patients referred by a health care provider who is a member of the same physician office practice, if the laboratory or entity operating the laboratory within a

physician office practice is under common ownership, directly or indirectly, with an entity licensed pursuant to chapter 395.

Section 99. Subsections (2), (3), and (4) of section 483.803, Florida Statutes, are amended to read:

483.803 Definitions.—As used in this part, the term:

(2) "Clinical laboratory" means the physical location in which one or more of the following services are performed to provide information or materials for use in the diagnosis, prevention, or treatment of a disease or the identification or assessment of a medical or physical condition:

(a) Clinical laboratory services, which entail the examination of fluids or other materials taken from the human body.

(b) Anatomic laboratory services, which entail the examination of tissue taken from the human body.

(c) Cytology laboratory services, which entail the examination of cells from individual tissues or fluid taken from the human body ~~a clinical laboratory as defined in s. 483.041~~.

(3) "Clinical laboratory examination" means a procedure performed to deliver the services identified in subsection (2), including the oversight or interpretation of such services ~~clinical laboratory examination as defined in s. 483.041~~.

(4) "Clinical laboratory personnel" includes a clinical laboratory director, supervisor, technologist, blood gas analyst, or technician who performs or is responsible for

laboratory test procedures, but the term does not include trainees, persons who perform screening for blood banks or plasmapheresis centers, phlebotomists, or persons employed by a clinical laboratory to perform manual pretesting duties or clerical, personnel, or other administrative responsibilities~~, or persons engaged in testing performed by laboratories regulated under s. 483.035(1) or exempt from regulation under s. 483.031(2)~~.

Section 100. Section 483.813, Florida Statutes, is amended to read:

483.813 Clinical laboratory personnel license.—A person may not conduct a clinical laboratory examination or report the results of such examination unless such person is licensed under this part to perform such procedures. However, this provision does not apply to any practitioner of the healing arts authorized to practice in this state ~~or to persons engaged in testing performed by laboratories regulated under s. 483.035(1) or exempt from regulation under s. 483.031(2)~~. The department may grant a temporary license to any candidate it deems properly qualified, for a period not to exceed 1 year.

Section 101. Subsection (2) of section 483.823, Florida Statutes, is amended to read:

483.823 Qualifications of clinical laboratory personnel.—

(2) Personnel qualifications may require appropriate education, training, or experience or the passing of an

examination in appropriate subjects or any combination of these, but a ~~no~~ practitioner of the healing arts licensed to practice in this state is not required to obtain any license ~~under this part~~ or to pay any fee under this part ~~hereunder except the fee required for clinical laboratory licensure~~.

Section 102. Paragraph (c) of subsection (7) and subsections (8) and (9) of section 491.003, Florida Statutes, are amended to read:

491.003 Definitions.—As used in this chapter:

(7) The "practice of clinical social work" is defined as the use of scientific and applied knowledge, theories, and methods for the purpose of describing, preventing, evaluating, and treating individual, couple, marital, family, or group behavior, based on the person-in-situation perspective of psychosocial development, normal and abnormal behavior, psychopathology, unconscious motivation, interpersonal relationships, environmental stress, differential assessment, differential planning, and data gathering. The purpose of such services is the prevention and treatment of undesired behavior and enhancement of mental health. The practice of clinical social work includes methods of a psychological nature used to evaluate, assess, diagnose, treat, and prevent emotional and mental disorders and dysfunctions (whether cognitive, affective, or behavioral), sexual dysfunction, behavioral disorders, alcoholism, and substance abuse. The practice of clinical social

work includes, but is not limited to, psychotherapy, hypnotherapy, and sex therapy. The practice of clinical social work also includes counseling, behavior modification, consultation, client-centered advocacy, crisis intervention, and the provision of needed information and education to clients, when using methods of a psychological nature to evaluate, assess, diagnose, treat, and prevent emotional and mental disorders and dysfunctions (whether cognitive, affective, or behavioral), sexual dysfunction, behavioral disorders, alcoholism, or substance abuse. The practice of clinical social work may also include clinical research into more effective psychotherapeutic modalities for the treatment and prevention of such conditions.

(c) The terms "diagnose" and "treat," as used in this chapter, when considered in isolation or in conjunction with ~~any provision of~~ the rules of the board, may ~~shall~~ not be construed to permit the performance of any act which clinical social workers are not educated and trained to perform, including, but not limited to, admitting persons to hospitals for treatment of the foregoing conditions, treating persons in hospitals without medical supervision, prescribing medicinal drugs as defined in chapter 465, authorizing clinical laboratory procedures ~~pursuant to chapter 483~~, or radiological procedures, or use of electroconvulsive therapy. In addition, this definition ~~shall~~ may not be construed to permit any person licensed,

provisionally licensed, registered, or certified pursuant to this chapter to describe or label any test, report, or procedure as "psychological," except to relate specifically to the definition of practice authorized in this subsection.

(8) The term "practice of marriage and family therapy" means ~~is defined as~~ the use of scientific and applied marriage and family theories, methods, and procedures for the purpose of describing, evaluating, and modifying marital, family, and individual behavior, within the context of marital and family systems, including the context of marital formation and dissolution, and is based on marriage and family systems theory, marriage and family development, human development, normal and abnormal behavior, psychopathology, human sexuality, psychotherapeutic and marriage and family therapy theories and techniques. The practice of marriage and family therapy includes methods of a psychological nature used to evaluate, assess, diagnose, treat, and prevent emotional and mental disorders or dysfunctions (whether cognitive, affective, or behavioral), sexual dysfunction, behavioral disorders, alcoholism, and substance abuse. The practice of marriage and family therapy includes, but is not limited to, marriage and family therapy, psychotherapy, including behavioral family therapy, hypnotherapy, and sex therapy. The practice of marriage and family therapy also includes counseling, behavior modification, consultation, client-centered advocacy, crisis intervention, and

the provision of needed information and education to clients, when using methods of a psychological nature to evaluate, assess, diagnose, treat, and prevent emotional and mental disorders and dysfunctions (whether cognitive, affective, or behavioral), sexual dysfunction, behavioral disorders, alcoholism, or substance abuse. The practice of marriage and family therapy may also include clinical research into more effective psychotherapeutic modalities for the treatment and prevention of such conditions.

(a) Marriage and family therapy may be rendered to individuals, including individuals affected by termination of marriage, to couples, whether married or unmarried, to families, or to groups.

(b) The use of specific methods, techniques, or modalities within the practice of marriage and family therapy is restricted to marriage and family therapists appropriately trained in the use of such methods, techniques, or modalities.

(c) The terms "diagnose" and "treat," as used in this chapter, when considered in isolation or in conjunction with ~~any provision of~~ the rules of the board, may ~~shall~~ not be construed to permit the performance of any act that ~~which~~ marriage and family therapists are not educated and trained to perform, including, but not limited to, admitting persons to hospitals for treatment of the foregoing conditions, treating persons in hospitals without medical supervision, prescribing medicinal

drugs as defined in chapter 465, authorizing clinical laboratory procedures ~~pursuant to chapter 483,~~ or radiological procedures~~,~~ or the use of electroconvulsive therapy. In addition, this definition may ~~shall~~ not be construed to permit any person licensed, provisionally licensed, registered, or certified pursuant to this chapter to describe or label any test, report, or procedure as "psychological," except to relate specifically to the definition of practice authorized in this subsection.

(d) The definition of "marriage and family therapy" contained in this subsection includes all services offered directly to the general public or through organizations, whether public or private, and applies whether payment is requested or received for services rendered.

(9) The term "practice of mental health counseling" means ~~is defined as~~ the use of scientific and applied behavioral science theories, methods, and techniques for the purpose of describing, preventing, and treating undesired behavior and enhancing mental health and human development and is based on the person-in-situation perspectives derived from research and theory in personality, family, group, and organizational dynamics and development, career planning, cultural diversity, human growth and development, human sexuality, normal and abnormal behavior, psychopathology, psychotherapy, and rehabilitation. The practice of mental health counseling includes methods of a psychological nature used to evaluate,

assess, diagnose, and treat emotional and mental dysfunctions or disorders, ~~(~~whether cognitive, affective, or behavioral~~)~~, ~~behavioral disorders,~~ interpersonal relationships, sexual dysfunction, alcoholism, and substance abuse. The practice of mental health counseling includes, but is not limited to, psychotherapy, hypnotherapy, and sex therapy. The practice of mental health counseling also includes counseling, behavior modification, consultation, client-centered advocacy, crisis intervention, and the provision of needed information and education to clients, when using methods of a psychological nature to evaluate, assess, diagnose, treat, and prevent emotional and mental disorders and dysfunctions (whether cognitive, affective, or behavioral), behavioral disorders, sexual dysfunction, alcoholism, or substance abuse. The practice of mental health counseling may also include clinical research into more effective psychotherapeutic modalities for the treatment and prevention of such conditions.

(a) Mental health counseling may be rendered to individuals, including individuals affected by the termination of marriage, and to couples, families, groups, organizations, and communities.

(b) The use of specific methods, techniques, or modalities within the practice of mental health counseling is restricted to mental health counselors appropriately trained in the use of such methods, techniques, or modalities.

(c) The terms "diagnose" and "treat," as used in this chapter, when considered in isolation or in conjunction with any provision of the rules of the board, may ~~shall~~ not be construed to permit the performance of any act that ~~which~~ mental health counselors are not educated and trained to perform, including, but not limited to, admitting persons to hospitals for treatment of the foregoing conditions, treating persons in hospitals without medical supervision, prescribing medicinal drugs as defined in chapter 465, authorizing clinical laboratory procedures ~~pursuant to chapter 483,~~ or radiological procedures, or the use of electroconvulsive therapy. In addition, this definition may ~~shall~~ not be construed to permit any person licensed, provisionally licensed, registered, or certified pursuant to this chapter to describe or label any test, report, or procedure as "psychological," except to relate specifically to the definition of practice authorized in this subsection.

(d) The definition of "mental health counseling" contained in this subsection includes all services offered directly to the general public or through organizations, whether public or private, and applies whether payment is requested or received for services rendered.

Section 103. Paragraph (h) of subsection (4) of section 627.351, Florida Statutes, is amended to read:

627.351 Insurance risk apportionment plans.—

(4) MEDICAL MALPRACTICE RISK APPORTIONMENT.—

(h) As used in this subsection:

1. "Health care provider" means hospitals licensed under chapter 395; physicians licensed under chapter 458; osteopathic physicians licensed under chapter 459; podiatric physicians licensed under chapter 461; dentists licensed under chapter 466; chiropractic physicians licensed under chapter 460; naturopaths licensed under chapter 462; nurses licensed under part I of chapter 464; midwives licensed under chapter 467; ~~clinical laboratories registered under chapter 483;~~ physician assistants licensed under chapter 458 or chapter 459; physical therapists and physical therapist assistants licensed under chapter 486; health maintenance organizations certificated under part I of chapter 641; ambulatory surgical centers licensed under chapter 395; other medical facilities as defined in subparagraph 2.; blood banks, plasma centers, industrial clinics, and renal dialysis facilities; or professional associations, partnerships, corporations, joint ventures, or other associations for professional activity by health care providers.

2. "Other medical facility" means a facility the primary purpose of which is to provide human medical diagnostic services or a facility providing nonsurgical human medical treatment, to which facility the patient is admitted and from which facility the patient is discharged within the same working day, and which facility is not part of a hospital. However, a facility existing for the primary purpose of performing terminations of pregnancy

or an office maintained by a physician or dentist for the practice of medicine may ~~shall~~ not be construed to be an "other medical facility."

3. "Health care facility" means any hospital licensed under chapter 395, health maintenance organization certificated under part I of chapter 641, ambulatory surgical center licensed under chapter 395, or other medical facility as defined in subparagraph 2.

Section 104. Paragraph (h) of subsection (1) of section 627.602, Florida Statutes, is amended to read:

627.602 Scope, format of policy.—

(1) Each health insurance policy delivered or issued for delivery to any person in this state must comply with all applicable provisions of this code and all of the following requirements:

(h) Section 641.312 and the provisions of the Employee Retirement Income Security Act of 1974, as implemented by 29 C.F.R. s. 2560.503-1, relating to internal grievances. This paragraph does not apply ~~to a health insurance policy that is subject to the Subscriber Assistance Program under s. 408.7056 or~~ to the types of benefits or coverages provided under s. 627.6513(1)-(14) issued in any market.

Section 105. Subsection (1) of section 627.6406, Florida Statutes, is amended to read:

627.6406 Maternity care.—

(1) Any policy of health insurance which ~~that~~ provides coverage for maternity care must also cover the services of certified nurse-midwives and midwives licensed pursuant to chapter 467, and the services of birth centers licensed under ss. 383.30-383.332 ~~383.30-383.335~~.

Section 106. Paragraphs (b) and (e) of subsection (1) of section 627.64194, Florida Statutes, are amended to read:

627.64194 Coverage requirements for services provided by nonparticipating providers; payment collection limitations.—

(1) As used in this section, the term:

(b) "Facility" means a licensed facility as defined in s. 395.002(16) and an urgent care center as defined in s. 395.002 ~~s. 395.002(30)~~.

(e) "Nonparticipating provider" means a provider who is not a preferred provider as defined in s. 627.6471 or a provider who is not an exclusive provider as defined in s. 627.6472. For purposes of covered emergency services under this section, a facility licensed under chapter 395 or an urgent care center defined in s. 395.002 ~~s. 395.002(30)~~ is a nonparticipating provider if the facility has not contracted with an insurer to provide emergency services to its insureds at a specified rate.

Section 107. Section 627.6513, Florida Statutes, is amended to read:

627.6513 Scope.—Section 641.312 and the provisions of the Employee Retirement Income Security Act of 1974, as implemented

by 29 C.F.R. s. 2560.503-1, relating to internal grievances, apply to all group health insurance policies issued under this part. This section does not apply to ~~a group health insurance policy that is subject to the Subscriber Assistance Program in s. 408.7056 or to~~:

(1) Coverage only for accident insurance, or disability income insurance, or any combination thereof.

(2) Coverage issued as a supplement to liability insurance.

(3) Liability insurance, including general liability insurance and automobile liability insurance.

(4) Workers' compensation or similar insurance.

(5) Automobile medical payment insurance.

(6) Credit-only insurance.

(7) Coverage for onsite medical clinics, including prepaid health clinics under part II of chapter 641.

(8) Other similar insurance coverage, specified in rules adopted by the commission, under which benefits for medical care are secondary or incidental to other insurance benefits. To the extent possible, such rules must be consistent with regulations adopted by the United States Department of Health and Human Services.

(9) Limited scope dental or vision benefits, if offered separately.

(10) Benefits for long-term care, nursing home care, home

health care, or community-based care, or any combination thereof, if offered separately.

(11) Other similar, limited benefits, if offered separately, as specified in rules adopted by the commission.

(12) Coverage only for a specified disease or illness, if offered as independent, noncoordinated benefits.

(13) Hospital indemnity or other fixed indemnity insurance, if offered as independent, noncoordinated benefits.

(14) Benefits provided through a Medicare supplemental health insurance policy, as defined under s. 1882(g)(1) of the Social Security Act, coverage supplemental to the coverage provided under 10 U.S.C. chapter 55, and similar supplemental coverage provided to coverage under a group health plan, which are offered as a separate insurance policy and as independent, noncoordinated benefits.

Section 108. Subsection (1) of section 627.6574, Florida Statutes, is amended to read:

627.6574 Maternity care.—

(1) Any group, blanket, or franchise policy of health insurance which ~~that~~ provides coverage for maternity care must also cover the services of certified nurse-midwives and midwives licensed pursuant to chapter 467, and the services of birth centers licensed under ss. 383.30-383.332 ~~383.30-383.335~~.

Section 109. Paragraph (j) of subsection (1) of section 641.185, Florida Statutes, is amended to read:

641.185 Health maintenance organization subscriber protections.—

(1) With respect to the provisions of this part and part III, the principles expressed in the following statements ~~shall~~ serve as standards to be followed by the commission, the office, the department, and the Agency for Health Care Administration in exercising their powers and duties, in exercising administrative discretion, in administrative interpretations of the law, in enforcing its provisions, and in adopting rules:

~~(j) A health maintenance organization should receive timely and, if necessary, urgent review by an independent state external review organization for unresolved grievances and appeals pursuant to s. 408.7056.~~

Section 110. Paragraph (a) of subsection (18) of section 641.31, Florida Statutes, is amended to read:

641.31 Health maintenance contracts.—

(18)(a) Health maintenance contracts that provide coverage, benefits, or services for maternity care must provide, as an option to the subscriber, the services of nurse-midwives and midwives licensed pursuant to chapter 467, and the services of birth centers licensed pursuant to ss. 383.30-383.332 ~~383.30-383.335~~, if such services are available within the service area.

Section 111. Section 641.312, Florida Statutes, is amended to read:

641.312 Scope.—The Office of Insurance Regulation may

adopt rules to administer ~~the provisions of~~ the National Association of Insurance Commissioners' Uniform Health Carrier External Review Model Act, issued by the National Association of Insurance Commissioners and dated April 2010. This section does not apply to ~~a health maintenance contract that is subject to the Subscriber Assistance Program under s. 408.7056 or to~~ the types of benefits or coverages provided under s. 627.6513(1)-(14) issued in any market.

Section 112. Subsection (4) of section 641.3154, Florida Statutes, is amended to read:

641.3154 Organization liability; provider billing prohibited.—

(4) A provider or any representative of a provider, regardless of whether the provider is under contract with the health maintenance organization, may not collect or attempt to collect money from, maintain any action at law against, or report to a credit agency a subscriber of an organization for payment of services for which the organization is liable, if the provider in good faith knows or should know that the organization is liable. This prohibition applies during the pendency of any claim for payment made by the provider to the organization for payment of the services and any legal proceedings or dispute resolution process to determine whether the organization is liable for the services if the provider is informed that such proceedings are taking place. It is presumed

that a provider does not know and should not know that an organization is liable unless:

(a) The provider is informed by the organization that it accepts liability;

(b) A court of competent jurisdiction determines that the organization is liable; or

~~(c) The office or agency makes a final determination that the organization is required to pay for such services subsequent to a recommendation made by the Subscriber Assistance Panel pursuant to s. 408.7056; or~~

(c) ~~(d)~~ The agency issues a final order that the organization is required to pay for such services subsequent to a recommendation made by a resolution organization pursuant to s. 408.7057.

Section 113. Paragraph (c) of subsection (5) of section 641.51, Florida Statutes, is amended to read:

641.51 Quality assurance program; second medical opinion requirement.—

(5)(c) For second opinions provided by contract physicians the organization is prohibited from charging a fee to the subscriber in an amount in excess of the subscriber fees established by contract for referral contract physicians. The organization shall pay the amount of all charges, which are usual, reasonable, and customary in the community, for second opinion services performed by a physician not under contract

with the organization, but may require the subscriber to be responsible for up to 40 percent of such amount. The organization may require that any tests deemed necessary by a noncontract physician shall be conducted by the organization. The organization may deny reimbursement rights granted under this section in the event the subscriber seeks in excess of three such referrals per year if such subsequent referral costs are deemed by the organization to be evidence that the subscriber has unreasonably overutilized the second opinion privilege. A subscriber ~~thus~~ denied reimbursement under this section has ~~shall have~~ recourse to grievance procedures as specified in ss. ~~408.7056,~~ 641.495~~,~~ and 641.511. The organization's physician's professional judgment concerning the treatment of a subscriber derived after review of a second opinion is ~~shall be~~ controlling as to the treatment obligations of the health maintenance organization. Treatment not authorized by the health maintenance organization is ~~shall be~~ at the subscriber's expense.

Section 114. Subsection (1), paragraph (e) of subsection (3), paragraph (d) of subsection (4), paragraphs (g) and (h) of subsection (6), and subsections (7) through (12) of section 641.511, Florida Statutes, are amended to read:

641.511 Subscriber grievance reporting and resolution requirements.—

(1) Every organization must have a grievance procedure

available to its subscribers for the purpose of addressing complaints and grievances. Every organization must notify its subscribers that a subscriber must submit a grievance within 1 year after the date of occurrence of the action that initiated the grievance~~, and may submit the grievance for review to the Subscriber Assistance Program panel as provided in s. 408.7056 after receiving a final disposition of the grievance through the organization's grievance process~~. An organization shall maintain records of all grievances and shall report annually to the agency the total number of grievances handled, a categorization of the cases underlying the grievances, and the final disposition of the grievances.

(3) Each organization's grievance procedure, as required under subsection (1), must include, at a minimum:

(e) A notice that a subscriber may voluntarily pursue binding arbitration in accordance with the terms of the contract if offered by the organization, after completing the organization's grievance procedure ~~and as an alternative to the Subscriber Assistance Program~~. Such notice shall include an explanation that the subscriber may incur some costs if the subscriber pursues binding arbitration, depending upon the terms of the subscriber's contract.

(4)~~(d) In any case when the review process does not resolve a difference of opinion between the organization and the subscriber or the provider acting on behalf of the subscriber,~~

~~the subscriber or the provider acting on behalf of the subscriber may submit a written grievance to the Subscriber Assistance Program.~~

(6) ~~(g) In any case when the expedited review process does not resolve a difference of opinion between the organization and the subscriber or the provider acting on behalf of the subscriber, the subscriber or the provider acting on behalf of the subscriber may submit a written grievance to the Subscriber Assistance Program.~~

(g) ~~(h)~~ An organization shall not provide an expedited retrospective review of an adverse determination.

~~(7) Each organization shall send to the agency a copy of its quarterly grievance reports submitted to the office pursuant to s. 408.7056(12).~~

(7) ~~(8)~~ The agency shall investigate all reports of unresolved quality of care grievances received from~~:~~

~~(a)~~ annual and quarterly grievance reports submitted by the organization to the office.

~~(b) Review requests of subscribers whose grievances remain unresolved after the subscriber has followed the full grievance procedure of the organization.~~

~~(9)(a) The agency shall advise subscribers with grievances to follow their organization's formal grievance process for resolution prior to review by the Subscriber Assistance Program. The subscriber may, however, submit a copy of the grievance to~~

~~the agency at any time during the process.~~

~~(b) Requiring completion of the organization's grievance process before the Subscriber Assistance Program panel's review does not preclude the agency from investigating any complaint or grievance before the organization makes its final determination.~~

~~(10) Each organization must notify the subscriber in a final decision letter that the subscriber may request review of the organization's decision concerning the grievance by the Subscriber Assistance Program, as provided in s. 408.7056, if the grievance is not resolved to the satisfaction of the subscriber. The final decision letter must inform the subscriber that the request for review must be made within 365 days after receipt of the final decision letter, must explain how to initiate such a review, and must include the addresses and toll-free telephone numbers of the agency and the Subscriber Assistance Program.~~

(8)~~(11)~~ Each organization, as part of its contract with any provider, must require the provider to post a consumer assistance notice prominently displayed in the reception area of the provider and clearly noticeable by all patients. The consumer assistance notice must state the addresses and toll-free telephone numbers of the Agency for Health Care Administration~~, the Subscriber Assistance Program,~~ and the Department of Financial Services. The consumer assistance notice must also clearly state that the address and toll-free telephone

number of the organization's grievance department shall be provided upon request. The agency may adopt rules to implement this section.

(9) ~~(12)~~ The agency may impose administrative sanction, in accordance with s. 641.52, against an organization for noncompliance with this section.

Section 115. Subsection (1) of section 641.515, Florida Statutes, is amended to read:

641.515 Investigation by the agency.—

(1) The agency shall investigate further any quality of care issue contained in recommendations and reports submitted pursuant to s. ~~ss. 408.7056 and~~ 641.511. The agency shall also investigate further any information that indicates that the organization does not meet accreditation standards or the standards of the review organization performing the external quality assurance assessment pursuant to reports submitted under s. 641.512. Every organization shall submit its books and records and take other appropriate action as may be necessary to facilitate an examination. The agency shall have access to the organization's medical records of individuals and records of employed and contracted physicians, with the consent of the subscriber or by court order, as necessary to administer ~~carry out the provisions of~~ this part.

Section 116. Subsection (2) of section 641.55, Florida Statutes, is amended to read:

641.55 Internal risk management program.—

(2) The risk management program shall be the responsibility of the governing authority or board of the organization. Every organization which has an annual premium volume of $10 million or more and which directly provides health care in a building owned or leased by the organization shall hire a risk manager~~, certified under ss. 395.10971-395.10975~~, who is ~~shall be~~ responsible for implementation of the organization's risk management program required by this section. A part-time risk manager may ~~shall~~ not be responsible for risk management programs in more than four organizations or facilities. Every organization that ~~which~~ does not directly provide health care in a building owned or leased by the organization and every organization with an annual premium volume of less than $10 million shall designate an officer or employee of the organization to serve as the risk manager.

The gross data compiled under this section or s. 395.0197 shall be furnished by the agency upon request to organizations to be utilized for risk management purposes. The agency shall adopt rules necessary to administer ~~carry out the provisions of~~ this section.

Section 117. Section 641.60, Florida Statutes, is repealed.

Section 118. Section 641.65, Florida Statutes, is

repealed.

Section 119. Section 641.67, Florida Statutes, is repealed.

Section 120. Section 641.68, Florida Statutes, is repealed.

Section 121. Section 641.70, Florida Statutes, is repealed.

Section 122. Section 641.75, Florida Statutes, is repealed.

Section 123. Paragraph (b) of subsection (6) of section 766.118, Florida Statutes, is amended to read:

766.118 Determination of noneconomic damages.—

(6) LIMITATION ON NONECONOMIC DAMAGES FOR NEGLIGENCE OF A PRACTITIONER PROVIDING SERVICES AND CARE TO A MEDICAID RECIPIENT.—Notwithstanding subsections (2), (3), and (5), with respect to a cause of action for personal injury or wrongful death arising from medical negligence of a practitioner committed in the course of providing medical services and medical care to a Medicaid recipient, regardless of the number of such practitioner defendants providing the services and care, noneconomic damages may not exceed $300,000 per claimant, unless the claimant pleads and proves, by clear and convincing evidence, that the practitioner acted in a wrongful manner. A practitioner providing medical services and medical care to a Medicaid recipient is not liable for more than $200,000 in

noneconomic damages, regardless of the number of claimants, unless the claimant pleads and proves, by clear and convincing evidence, that the practitioner acted in a wrongful manner. The fact that a claimant proves that a practitioner acted in a wrongful manner does not preclude the application of the limitation on noneconomic damages prescribed elsewhere in this section. For purposes of this subsection:

(b) The term "practitioner," in addition to the meaning prescribed in subsection (1), includes any hospital or~~,~~ ambulatory surgical center~~, or mobile surgical facility~~ as defined and licensed under chapter 395.

Section 124. Subsection (4) of section 766.202, Florida Statutes, is amended to read:

766.202 Definitions; ss. 766.201-766.212.—As used in ss. 766.201-766.212, the term:

(4) "Health care provider" means any hospital or~~,~~ ambulatory surgical center~~, or mobile surgical facility~~ as defined and licensed under chapter 395; a birth center licensed under chapter 383; any person licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, part I of chapter 464, chapter 466, chapter 467, part XIV of chapter 468, or chapter 486; ~~a clinical lab licensed under chapter 483;~~ a health maintenance organization certificated under part I of chapter 641; a blood bank; a plasma center; an industrial clinic; a renal dialysis facility; or a professional

association partnership, corporation, joint venture, or other association for professional activity by health care providers.

Section 125. Section 945.36, Florida Statutes, is amended to read:

945.36 ~~Exemption from health testing regulations for~~ Law enforcement personnel authorized to conduct ~~conducting~~ drug tests on inmates and releasees.—

(1) Any law enforcement officer, state or county probation officer, employee of the Department of Corrections, or employee of a contracted community correctional center who is certified by the Department of Corrections pursuant to subsection (2) may administer~~, is exempt from part I of chapter 483, for the limited purpose of administering~~ a urine screen drug test to:

(a) Persons during incarceration;

(b) Persons released as a condition of probation for either a felony or misdemeanor;

(c) Persons released as a condition of community control;

(d) Persons released as a condition of conditional release;

(e) Persons released as a condition of parole;

(f) Persons released as a condition of provisional release;

(g) Persons released as a condition of pretrial release; or

(h) Persons released as a condition of control release.

(2) The Department of Corrections shall develop a procedure for certification of any law enforcement officer, state or county probation officer, employee of the Department of Corrections, or employee of a contracted community correctional center to perform a urine screen drug test on the persons specified in subsection (1).

Section 126. Paragraph (b) of subsection (2) of section 1009.65, Florida Statutes, is amended to read:

1009.65 Medical Education Reimbursement and Loan Repayment Program.—

(2) From the funds available, the Department of Health shall make payments to selected medical professionals as follows:

(b) All payments are ~~shall be~~ contingent on continued proof of primary care practice in an area defined in s. 395.602(2)(b) ~~s. 395.602(2)(c)~~, or an underserved area designated by the Department of Health, provided the practitioner accepts Medicaid reimbursement if eligible for such reimbursement. Correctional facilities, state hospitals, and other state institutions that employ medical personnel shall be designated by the Department of Health as underserved locations. Locations with high incidences of infant mortality, high morbidity, or low Medicaid participation by health care professionals may be designated as underserved.

Section 127. Subsection (2) of section 1011.52, Florida

Statutes, is amended to read:

1011.52 Appropriation to first accredited medical school.—

(2) In order for a medical school to qualify under ~~the provisions of~~ this section and to be entitled to the benefits herein, such medical school:

(a) Must be primarily operated and established to offer, afford, and render a medical education to residents of the state qualifying for admission to such institution;

(b) Must be operated by a municipality or county of this state, or by a nonprofit organization heretofore or hereafter established exclusively for educational purposes;

(c) Must, upon the formation and establishment of an accredited medical school, transmit and file with the Department of Education documentary proof evidencing the facts that such institution has been certified and approved by the council on medical education and hospitals of the American Medical Association and has adequately met the requirements of that council in regard to its administrative facilities, administrative plant, clinical facilities, curriculum, and all other such requirements as may be necessary to qualify with the council as a recognized, approved, and accredited medical school;

(d) Must certify to the Department of Education the name, address, and educational history of each student approved and accepted for enrollment in such institution for the ensuing

school year; and

(e) Must have in place an operating agreement with a government-owned hospital that is located in the same county as the medical school and that is a statutory teaching hospital as defined in s. 408.07(44) ~~s. 408.07(45)~~. The operating agreement must ~~shall~~ provide for the medical school to maintain the same level of affiliation with the hospital, including the level of services to indigent and charity care patients served by the hospital, which was in place in the prior fiscal year. Each year, documentation demonstrating that an operating agreement is in effect shall be submitted jointly to the Department of Education by the hospital and the medical school prior to the payment of moneys from the annual appropriation.

Section 128. This act shall take effect July 1, 2018.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 673 Reporting Of Adverse Incidents In Planned Out-Of-Hospital Births
SPONSOR(S): Magar
TIED BILLS: **IDEN./SIM. BILLS:** CS/SB 510

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	13 Y, 0 N	Siples	McElroy
2) Health Care Appropriations Subcommittee		Mielke BW	Pridgeon
3) Health & Human Services Committee			

SUMMARY ANALYSIS

When planning for the birth of child, prospective parents may make a number of decisions about their childbirth experience, including where they want the child to be born and who they want to provide obstetrical care. There are several types of health care practitioners who may provide obstetric care: a physician, a physician assistant, a certified nurse midwife (an advanced registered nursing practitioner (ARNP) with specialized training in obstetric care), or a licensed midwife. A prospective parent may choose to have labor and childbirth occur in a hospital, birthing center, or home setting.

HB 673 requires a physician, certified nurse midwife, or licensed midwife attending a planned out-of-hospital birth to submit an adverse incident report to the Department of Health (DOH), within 15 days of the occurrence of the incident.

The bill defines an adverse incident as an event over which the physician, certified nurse midwife, or licensed midwife could exercise control and one of the following occurs during the process of childbirth:

- A maternal death that occurs after delivery or within 42 days after delivery;
- A maternal patient is transferred to a hospital intensive care unit;
- A maternal patient experiences hemorrhagic shock or requires a transfusion of more than four units of blood or blood products;
- A fetal or newborn death, including a still birth, attributable to an obstetrical delivery;
- A newborn patient is transferred to a hospital neonatal intensive care unit (NICU) due to a traumatic birth injury;
- A newborn patient is transferred to a hospital NICU 72 hours after birth if the newborn remains in the NICU for more than 72 hours; or
- Any other injury as determined by department rules.

The attending health care practitioner must provide a medical summary of the events in the adverse incident report. DOH must review each adverse incident report to determine whether the incident involves conduct for which the health care practitioner may be subject to disciplinary action by the appropriate regulatory board or if there is no board, DOH.

The bill authorizes DOH to adopt rules to develop the adverse incident form and to implement the provisions of the bill.

The bill will have an indeterminate, negative fiscal impact on the DOH related to the review of the adverse incident reports and any subsequent investigation and disciplinary cases that may result; however, current department resources can absorb the additional workload. The bill has no fiscal impact on local governments.

The bill takes effect upon becoming a law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Prior to giving birth, expectant parents will make a number of decisions in planning their childbirth experience. The parents may decide the location at which they would like to give birth, as well as the type of health care practitioner they would like to provide obstetrical services.[1] The decision on the type of practitioner may dictate the place where the birth may occur, and vice versa. In Florida, the health care practitioners that may attend a childbirth include a physician,[2] certified nurse midwife (CNM), and licensed midwife. Typically, there are three settings in which childbirths occur: hospitals, birthing centers, and home.[3]

Regulation of Health Care Practitioners

The Department of Health (DOH), Division of Medical Quality Assurance (MQA), is charged with the regulation of health care practitioners in this state.[4] MQA works in conjunction with regulatory boards to adopt rules and regulate health care practitioners.[5] For all health care professions regulated by MQA or regulatory boards, ch. 456, F.S., provides the general framework for licensure and regulation; however, the individual practice acts provide greater specificity for the regulation of a health care profession.

Each practice act provides licensure requirements, the scope of practice in which the health care practitioner may engage, as well disciplinary guidelines. To be licensed in this state, an applicant must meet the minimum licensure standards as provided in the practice act and any rules adopted by the regulatory board or DOH, if there is no board.

Physicians

Both allopathic and osteopathic physicians have a broad scope of practice; they may diagnose, treat, operate, or prescribe for any human disease, pain, injury, deformity, or other physical or mental condition.[6] However, a physician may be required to meet additional standards to practice in certain settings or perform certain medical acts. For example, physicians who wish to practice in a pain management clinic must meet certain training requirements.[7]

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[1] American Pregnancy Association, *Birthing Choices: Health Care Providers and Birth Locations*, (Sept. 6, 2016), available at http://americanpregnancy.org/labor-and-birth/birthing-choices/ (last visited on December 14, 2017).
[2] A physician may delegate the performance of medical acts to a physician assistant under his or her supervision unless such delegation is expressly prohibited by law. (Sections 458.347(4), and 459.022(e), F.S.) The physician remains liable for any acts or omissions of the physician assistant acting under his or her supervision or control. *See* ss. 458.347(15), and 459.022(15), F.S.
[3] Centers for Disease Control and Prevention, *Trends in Out-of-Hospital Births in the United States, 1990-2012*, (March 4, 2014), available at https://www.cdc.gov/nchs/products/databriefs/db144.htm (last visited December 18, 2017).
[4] Pursuant to s. 456.001(4), F.S., health care practitioners are defined to include acupuncturists, physicians, physician assistants, chiropractors, podiatrists, naturopaths, dentists, dental hygienists, optometrists, nurses, nursing assistants, pharmacists, midwives, speech language pathologists, nursing home administrators, occupational therapists, respiratory therapists, dieticians, athletic trainers, orthotists, prosthetists, electrologists, massage therapists, clinical laboratory personnel, medical physicists, dispensers of optical devices or hearing aids, physical therapists, psychologists, social workers, counselors, and psychotherapists, among others.
[5] Section 456.001(1), F.S.
[6] Sections 458.305(3), and 459.003(3), F.S. However, an osteopathic physician's practice is based in part on education which emphasizes the importance of the musculoskeletal structure and manipulative therapy in the maintenance and restoration of health.
[7] Rules 64B8-9.0131 and 6415-14.0051, F.A.C.

A physician is expected to practice in a safe and competent manner.[8] A physician who fails to do so may be subject to discipline against his or her license to practice in this state.[9] For example, a physician's license may be disciplined for, among other things:

- Committing medical malpractice;[10]
- Practicing outside his or her scope of practice or performing professional responsibilities that he or she knows or has reason to know that he or she cannot perform competently;[11]
- Delegating a professional responsibility to a person he or she knows or has reason to know that such person is not qualified to perform;[12] or
- Failing to adequately supervise a physician assistant, advanced registered nurse practitioner (ARNP), or other health care practitioner acting under his or her supervision.[13]

Adverse Incident Reporting

A physician or physician assistant is required to report to DOH, any adverse incident occurring in an office practice setting within 15 days after the occurrence of the adverse incident.[14] DOH must review each report to determine if discipline against the practitioner's license is warranted.[15]

An adverse incident in an office setting is defined as an event over which the physician or licensee could exercise control and which is associated with a medical intervention and results in one of the following patient injuries:[16]

- The death of a patient;
- Brain or spinal damage to a patient;
- The performance of a surgical procedure on the wrong patient;
- If the procedure results in death; brain or spinal damage; permanent disfigurement; the fracture or dislocation of bones or joints; a limitation of neurological, physical, or sensory functions; or any condition that required the transfer of a patient, the performance of:
    - A wrong-site surgical procedure;
    - A wrong surgical procedure; or
    - A surgical repair of damage to a patient resulting from a planned surgical procedure where the damage is not a recognized specific risk as disclosed to the patient and documented through the informed consent process;
- A procedure to remove unplanned foreign objects remaining from a surgical procedure; or
- Any condition that required the transfer of a patient to a hospital from an ambulatory surgical center or any facility or any office maintained by a physician for the practice of medicine which is not licensed under ch. 395, F.S.

There is no statutory requirement for a physician to report an adverse incident that occurs outside of an office or hospital setting.

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[8] Sections 458.301 and 459.001, F.S.
[9] Sections 458.331 and 459.015, F.S., provide the grounds for which disciplinary action may be taken against a physician's license. Section 456.072, F.S., provides grounds for discipline that apply to all licensed health care practitioners.
[10] Sections 456.331(1)(t), and 459.015(1)(x), F.S. Medical malpractice is the failure to practice medicine in accordance with the care, skill, and treatment recognized in general law related to health care licensure (s. 456.50(1)(g), F.S.
[11] Sections 458.331(1)(v) and 459.015(1)(z), F.S.
[12] Sections 458.331(1)(w) and 459.015(1)(aa), F.S.
[13] Sections 458.331(1)(dd) and 459.015(1)(hh), F.S.
[14] Sections 458.351 and 459.026, F.S.
[15] Sections 458.351(5) and 459.026(5), F.S.
[16] Sections 458.351(4) and 459.026(4), F.S.

Certified Nurse Practitioners

An advanced registered nurse practitioner (ARNP) may perform advanced-level nursing acts approved by the Board of Nursing which, by virtue of post-basic specialized education, training, and experience are appropriately performed by an ARNP, in addition to the professional nursing acts that registered nurses are authorized to perform.[17] In addition to advanced or specialized nursing practices, ARNPs are authorized to practice certain medical acts, as opposed to nursing acts, as authorized within the framework of an established supervisory physician's protocol.[18]

To be eligible to be certified as an ARNP, the applicant must be licensed as a registered nurse, and have a master's degree in a nursing clinical specialty area with preparation in specialized practitioner skills or submit proof that the applicant holds a current national advanced practice certification from a board-approved nursing specialty board.[19] In Florida, an ARNP may be categorized as a certified nurse practitioner (CNP), certified nurse midwife (CNM), or certified registered nurse anesthetist (CRNA).[20]

A CNM may, to the extent authorized under a supervisory protocol, perform the following acts in a healthcare facility where midwifery services are performed or in the patient's home:[21]

- Superficial minor surgical procedures;
- Manage the patient's labor and delivery to include amniotomy, episiotomy, and repair;
- Order, initiate, perform appropriate anesthetic procedures;
- Perform postpartum examinations;
- Order appropriate medications;
- Provide family-planning services and well-woman care; and
- Manage the medical care of the normal obstetrical patient and the initial care of a newborn patient.

An ARNP is expected to practice in a safe and competent manner.[22] An ARNP who fails to do so may be subject to discipline against his or her license to practice in this state.[23] For example, an ARNP may be disciplined for failing to meet the minimum standard of care for nursing practice, including engaging in acts for which he or she is not qualified by training or experience.[24]

There is no statutory requirement for an ARNP or a CNM to report adverse incidents to DOH.

Licensed Midwives

DOH is responsible for the licensure and regulation of the practice of midwifery in this state. The Council of Licensed Midwifery assists and advises DOH on midwifery, including the development of rules relating to regulatory requirements, including but not limited to training requirements, the licensure examination, responsibilities of midwives, emergency care plans, and reports and records to be filed by licensed midwives.[25]

To be licensed as a midwife, an applicant must graduate from an approved midwifery program, and pass the licensure examination.[26] Along with an application for licensure or licensure renewal, a

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[17] Section 464.003(2)-(3), F.S.
[18] Id.
[19] Section 464.012(1), F.S., and Rule 64B9-4.002, F.A.C.
[20] Section 464.012(4), F.S.
[21] Section 464.012(4)(b), F.S.
[22] Section 464.002, F.S.
[23] Section 464.018, F.S., provide the grounds for which disciplinary action may be taken against the license. Section 456.072, F.S., provides grounds for discipline that apply to all licensed health care practitioners.
[24] Section 464.018(1)(n), F.S.
[25] Section 467.004, F.S.
[26] Section 467.011, F.S. Section 467.0125, F.S., provides for licensure by endorsement for applicants who hold a valid license to practice midwifery in another state.

licensed midwife must submit a general emergency care plan which addresses consultation with other health care providers, emergency transfer protocols, and access to neonatal intensive care units and obstetrical units or other patient care areas.[27]

A licensed midwife is responsible for ensuring the following conditions are met:[28]

- Accepting only those patients who are expect to have a normal pregnancy, labor, and delivery;
- Ensuring that each patient has signed an informed consent form developed by DOH, which informs the patient of the qualifications of the licensed midwife, the nature and risk of the procedures to be performed by the licensed midwife, and to obtain the patient's consent for the provision of midwifery services;
- Determining if the home is safe and hygienic if the patient is delivering at home;
- Voluntarily entering into a collaborative agreement with a physician for prenatal and postpartal care to women who are not expected to have a normal pregnancy, labor, and delivery within the framework of a written protocol;
- Administering prophylactic ophthalmic medication, oxygen, postpartum oxytocin, vitamin K, rho immune globulin, local anesthetic, or other medicinal drugs pursuant to a prescription issued by a practitioner licensed under ch. 458, F.S., or ch. 459, F.S.;
- Providing care to mothers and infants throughout the prenatal, intrapartal, and postpartal periods in compliance with the law;
- Preparing a written plan of action with the family to ensure continuity of medical care throughout labor and delivery and to provide for immediate medical care if an emergency arises;
- Instructing the patient and family regarding the preparation of the environment and ensure the availability of equipment and supplies needed for delivery and infant care if a home birth is planned;
- Instructing the patient in the hygiene of pregnancy and nutrition as it relates to prenatal care;
- Maintaining appropriate equipment and supplies, as required by rule;
- Determining the progress of labor, and when birth is imminent, be immediately available until delivery is accomplished, including:
    - Maintaining a safe and hygienic environment;
    - Monitoring the progress of labor and the status of the fetus;
    - Recognizing the early signs of distress or complications; and
    - Enacting the written emergency plan when indicated;
- Remaining with the postpartal mother until the mother and neonate are stabilized; and
- Instilling a prophylactic into each eye of the newborn infant within one hour after birth for the prevention of neonatal ophthalmia.[29]

Annually, licensed midwives must file an "Annual Report of Midwifery Practice," by July 31.[30] The report requires each licensed midwife to detail information regarding the number of clients seen in the previous fiscal year (July 1 to June 30), the types of births performed, maternal and newborn transfers, fetal deaths (stillbirths and neonatal), and maternal deaths.

There is no statutory requirement for a licensed midwife to report adverse incidents to DOH. However, by rule, a licensed midwife must report maternal and fetal deaths, as well as maternal and newborn transfers as a part of the annual report.

[27] Section 467.017, F.S.
[28] Section 467.015, F.S.
[29] Section 383.04, F.S.
[30] Rule 64B24-7.014, F.A.C.

Childbirth Settings

In 1900, almost all childbirths in the United States occurred outside of hospital; however, by 1969 that figure had fallen to one percent of all births.[31] In 2015, 1.5 percent of all births in the U.S. occurred outside of a hospital.[32] Of those, 63.1 percent occurred in a home or residence, and 30.9 percent occurred in a freestanding birthing center.[33] In Florida, 0.9 percent of births occurred at home in 2015.[34]

Hospitals

Hospitals are licensed and regulated under ch. 395, F.S., and part II of ch. 408, F.S., by the Agency for Health Care Administration (AHCA).

Every licensed hospital is required to establish and maintain an internal risk management program that is overseen by a health care risk manager.[35] As a part of its risk management program, a hospital must have an incident reporting system which places an affirmative duty on all health care providers, as well the agents and employees of the hospital, to report adverse incidents to the risk manager within 3 business days after their occurrence.[36] The hospital must annually submit a report to AHCA summarizing the incident reports filed in the facility for that year.[37]

An adverse incident is defined as an event over which health care personnel could exercise control and which is associated with a medical intervention which results in:[38]

- One of the following patient injuries:
  - Death;
  - Brain or spinal damage;
  - Permanent disfigurement;
  - Fracture or dislocation of bones or joints;
  - A resulting limitation of neurological, physical, or sensory functions which continue after discharge from the facility
  - Any condition that requires specialized medical attention or surgical intervention resulting from a nonemergency medical intervention to which the patient has not given his or her informed consent; or
  - Any condition that required the transfer of a patient, within or outside the facility, to a unit providing a more acute level of care due to the adverse incident, rather than the patient's condition prior to the adverse incident;
- The performance of a surgical procedure on the wrong patient, a wrong surgical procedure, a wrong-site surgical procedure, or a surgical procedure otherwise unrelated to the patient's medical condition;
- Required surgical repair of damage resulting from a planned surgical procedure, where the damage was not a recognized specific risk, as disclosed to the patient through the informed consent process; or
- A procedure to remove unplanned foreign objects remaining from a surgical procedure.

Any of the following adverse incidents, whether occurring in the hospital or arising from health care prior to admission, must be reported to AHCA within 15 calendar days after occurrence:[39]

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[31] National Center for Health Statistics, *Trends in Out-Of-Hospital Births in the United States, 1990-2012,* NCHS DATA BRIEF, No. 144, (March 2014), available

[32] Joyce A. Martin, et. al., *Births: Final Data for 2015*, NATIONAL VITAL STATISTICS REPORTS, 66:1 (Jan. 5, 2017), available at https://www.cdc.gov/nchs/data/nvsr/nvsr66/nvsr66_01.pdf (last visited December 18, 2017).

[33] Id

[34] Id.

[35] Section 395.0197, F.S.

[36] Section 395.0197(1)(e), F.S.

[37] Section 395.0197(6), F.S.

[38] Section 395.0197(5), F.S.

[39] Section 395.0197(7), F.S.

- Death of a patient;
- Brain or spinal damage to a patient;
- The performance of a surgical procedure on the wrong patient;
- The performance of a wrong-site surgical procedure;
- The performance of a wrong surgical procedure;
- The performance of a surgical procedure that is medically unnecessary or otherwise unrelated to the patient's medical condition;
- The surgical repair of damage resulting to a patient from a planned surgical procedure, where the damage was not a recognized specific risk, as disclosed to the patient through the informed consent process; or
- The performance of a procedure to remove unplanned foreign objects remaining from a surgical procedure.

Birth Centers

A birth center is any facility, institution, or place, which is not an ambulatory surgical center, a hospital or in a hospital, in which births are planned to occur away from the mother's usual residence following a normal, uncomplicated, low-risk pregnancy.[40] Birth centers are licensed and regulated by AHCA under ch. 383, F.S., and part II of ch. 408, F.S.

A birth center may only accept those patients who are expected to have normal pregnancies and deliveries; and prior to being accepted for care, the patient must sign an informed consent form.[41] A mother and her infant must be discharged from a birth center within 24 hours after giving birth, except when:[42]

- The mother is in a deep sleep at the end of the 24-hour period; in which case, the mother must be discharged as soon after waking as feasible; or
- The 24-hour period is completed during the middle of the night.

If a mother or infant must remain in the birth center for longer than 24 hours after giving birth for a reason other than those listed above, the birth center must file a report with AHCA within 48 hours of the birth describing the circumstances and the reasons for the decision.[43]

A birth center is required for maintaining the quality of care by:[44]

- Having at least one clinical staff[45] member for every two clients in labor;
- Having a clinical staff member or qualified personnel[46] available on site during the entire time a client is in the birth center. Services during labor and delivery must be provided by a physician, certified nurse midwife, or licensed midwife, assisted by at least one other staff member under protocols developed by clinical staff;
- Ensuring all qualified personnel and clinical staff are trained in infant and adult resuscitation and requiring qualified personnel or clinical staff who is able to perform neonatal resuscitation to be present during each birth;
- Maintaining complete and accurate medical records;

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[40] Section 383.302(2), F.S.
[41] Section 383.31, F.S. The informed consent form must advise the patient of the qualifications of the clinical staff, the risks related to out-of-hospital births, the benefits of out-of-hospital births, and the possibility of referral or transfer if complications arise during pregnancy or childbirth with additional costs for services rendered (r. 59A-11.010, F.A.C.)
[42] Section 383.318(1), F.S., and Rule 59A-11.016(6), F.A.C.
[43] Section 383.318(1), F.S.
[44] Rule 59A-11.005(3), F.A.C.
[45] Section 383.302(3), F.S., defines "clinical staff" as individuals employed full-time or part-time by a birth center who are licensed or certified to provide care at childbirth.
[46] Rule 59A-11.002(6), F.A.C., defines "qualified staff" as an individual who is trained and competent in the services that he or she provides and is licensed or certified when required by statute or professional standard.

- Evaluating the quality of care by reviewing clinical records;
- Reviewing admissions with respect to eligibility, course of pregnancy and outcome, evaluation of services, condition of mother and newborn on discharge, or transfer to other providers; and
- Surveillance of infection risk and cases and the promotion of preventive and corrective program designed to minimize hazards.

A birth center must be equipped with those items needed to provide low-risk maternity care and readily available equipment to initiate emergency procedures in life-threatening events to a mother and baby.[47] Each facility must have an arrangement with a local ambulance service for the transport of emergency patients to a hospital, which must be documented in the facilities policy and procedures manual.[48]

A birth center must submit an annual report to AHCA by July 30 of each year that details, among other things:[49]

- The number of deliveries by birth weight;
- The number of maternity clients accepted for care and length of stay;
- The number of surgical procedures performed at the birth center by type;
- Maternal transfers, including the reason for the transfer, whether it occurred intrapartum or postpartum, and the length of the hospital stay;
- Newborn transfers, including the reason for the transfer, birth weight, days in hospital, and APGAR score at five and ten minutes;
- Newborn deaths; and
- Stillborn/Fetal deaths.

Home Births

The home delivery setting is not regulated. However, the health care practitioners who perform such services, including physicians, physician assistants, certified nurse midwives, and licensed midwives are regulated by their respective regulatory boards, or in the case of licensed midwives, DOH.

Effect of Proposed Changes

HB 673 requires that a physician, certified nurse midwife, or licensed midwife attending a planned out-of-hospital birth submit an adverse incident report to the Department of Health (DOH) within 15 days of the occurrence of the incident.

The bill defines an adverse incident as an event over which the physician, certified nurse midwife, or licensed midwife could exercise control and one of the following occurs during the process of childbirth:

- A maternal death that occurs after delivery or within 42 days after delivery;
- A maternal patient is transferred to a hospital intensive care unit;
- A maternal patient experiences hemorrhagic shock or requires a transfusion of more than four units of blood or blood products;
- A fetal or newborn death, including a still birth, attributable to an obstetrical delivery;
- A newborn patient is transferred to a hospital neonatal intensive care unit (NICU) due to a traumatic birth injury;
- A newborn patient is transferred to a hospital NICU 72 hours after birth if the newborn remains in the NICU for more than 72 hours; or
- Any other injury as determined by department rules.

[47] Section 383.308(2)(a), F.S.
[48] Section 383.316, F.S.
[49] Rule 59A-11.019, F.A.C., and AHCA Form 3130-3004, (Feb. 2015).

In the adverse injury report, the attending health care practitioner must provide a medical summary of the events. DOH must review each adverse incident report to determine whether the incident involves conduct for which the health care practitioner may be subject to disciplinary action by the appropriate regulatory board or if there is no board, DOH.

The adverse incident reports required by the bill would be exempt from disclosure under public record laws pursuant to s. 456.057, F.S., which protects patient records obtained by the DOH.

The bill authorizes DOH to adopt rules to develop the adverse incident form and to implement the provisions of the bill.

The bill takes effect upon becoming law.

B. SECTION DIRECTORY:

Section 1: Creates s. 456.0495, F.S., relating to reporting adverse incidents occurring in planned out-of-hospital births.
Section 2: Provides that the act takes effect upon becoming law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   DOH will incur a recurring, indeterminate negative fiscal impact related to the increase in workload associated with the review of adverse incident reports required to be submitted under the provisions of the bill and any complaints and investigations that may be generated.[50] It is estimated current resources are adequate to absorb the increase in workload.

   DOH will incur an insignificant, nonrecurring negative fiscal impact for developing the adverse incident report form and rulemaking; however, current resources are adequate to absorb such costs.[51]

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Health care practitioners who provide planned childbirth services outside of a hospital may incur administrative costs to comply with the adverse incident reporting required by the bill.

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[50] DOH, *2018 Agency Legislative Bill Analysis for House Bill 673* (Nov. 15, 2017), on file with the Health Quality Subcommittee.
[51] Id.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill provides DOH with sufficient rulemaking authority to adopt rules relating to the reporting of adverse incidents that occur in planned out-of-hospital births, as well as a form for reporting such adverse incidents.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to reporting of adverse incidents in planned out-of-hospital births; creating s. 456.0495, F.S.; defining the term "adverse incident"; requiring licensed physicians, certified nurse midwives, or licensed midwives to report an adverse incident and a medical summary of events to the Department of Health within a specified timeframe; requiring the department to review adverse incident reports and determine if conduct occurred that is subject to disciplinary action; requiring the appropriate regulatory board or the department to take disciplinary action under certain circumstances; requiring the department to adopt rules; requiring the department to develop a form to be used for the reporting of adverse incidents; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 456.0495, Florida Statutes, is created to read:

456.0495 Reporting adverse incidents occurring in planned out-of-hospital births.—

(1) For purposes of this section, the term "adverse incident" means an event over which a physician licensed under

chapter 458 or chapter 459, a nurse midwife certified under part I of chapter 464, or a midwife licensed under chapter 467 could exercise control and which is associated with an attempted or completed planned out-of-hospital birth, and results in one or more of the following injuries or conditions:

(a) A maternal death that occurs during delivery or within 42 days after delivery;

(b) The transfer of a maternal patient to a hospital intensive care unit;

(c) A maternal patient who experiences hemorrhagic shock or who requires a transfusion of more than 4 units of blood or blood products;

(d) A fetal or newborn death, including a stillbirth, associated with an obstetrical delivery;

(e) A transfer of a newborn to a neonatal intensive care unit due to a traumatic physical or neurological birth injury, including any degree of a brachial plexus injury;

(f) A transfer of a newborn to a neonatal intensive care unit within the first 72 hours after birth if the newborn remains in such unit for more than 72 hours; or

(g) Any other injury as determined by department rule.

(2) A physician licensed under chapter 458 or chapter 459, a nurse midwife certified under part I of chapter 464, or a midwife licensed under chapter 467 who performs an attempted or completed planned out-of-hospital birth must report an adverse

incident, along with a medical summary of events, to the department within 15 days after the adverse incident occurs.

(3) The department shall review each incident report and determine whether the incident involves conduct by a health care practitioner which is subject to disciplinary action under s. 456.073. Disciplinary action, if any, must be taken by the appropriate regulatory board or by the department if no such board exists.

(4) The department shall adopt rules to implement this section and shall develop a form to be used for the reporting of adverse incidents.

Section 2. This act shall take effect upon becoming a law.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 1099 Advanced Birth Centers
SPONSOR(S): Health Quality Subcommittee; Magar
TIED BILLS: HB 1101 **IDEN./SIM. BILLS:** SB 1564

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

SUMMARY ANALYSIS

A birth center is any facility, institution, or place, which is not an ambulatory surgical center, a hospital or in a hospital, in which births are planned to occur away from the mother's usual residence following a normal, uncomplicated, low-risk pregnancy. Birth centers are licensed and regulated by the Agency for Health Care Administration (AHCA) under ch. 383. F.S., and part II of ch. 408, F.S.

A birth center may only accept those patients who are expected to have normal pregnancies and deliveries. Birth centers may not perform operative obstetrics or caesarean sections.

A mother and her infant must be discharged from a birth center within 24 hours after giving birth, except when:

- The mother is in a deep sleep at the end of the 24-hour period; in which case, the mother must be discharged as soon after waking as feasible; or
- The 24-hour period is completed during the middle of the night.

CS/HB 1099 creates a new licensure program within AHCA for advanced birth centers. An advanced birth center is a birth center that may perform trial of labor after cesarean deliveries for screened patients that qualify, planned low risk cesarean deliveries, and anticipated vaginal delivery of laboring patients at the beginning of the 37th week of gestation to the end of the 41st week of gestation.

The bill requires advanced birth centers to be operated and staffed 24 hours per day, 7 days per week. The bill requires a mother and her infant to be discharged from the advanced birth center within 48 hours after the birth of the infant for a vaginal delivery and within 72 hours when delivery is by cesarean section, except in unusual circumstances as defined by rule.

The new advanced birth center license is modeled after the current licensure program for birth centers, subjecting advanced birth centers to similar regulatory standards, inspections and rules.

The bill has an indeterminate, but likely insignificant, fiscal impact on state government.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Birth Centers

A birth center is any facility, institution, or place, which is not an ambulatory surgical center, a hospital or in a hospital, in which births are planned to occur away from the mother's usual residence following a normal, uncomplicated, low-risk pregnancy.[1] Birth centers are licensed and regulated by the Agency for Health Care Administration (AHCA) under ch. 383. F.S., and part II of ch. 408, F.S.

Birth centers must have a governing body responsible for the overall operation and maintenance of the birth center.[2] The governing body must develop and make available to all staff, clinicians, consultants, and licensing authorities, a manual that documents the policies, procedures, and protocols of the birth center.[3]

A birth center may only accept those patients who are expected to have normal pregnancies and deliveries; and prior to being accepted for care, the patient must sign an informed consent form.[4] A mother and her infant must be discharged from a birth center within 24 hours after giving birth, except when:[5]

- The mother is in a deep sleep at the end of the 24-hour period; in which case, the mother must be discharged as soon after waking as feasible; or
- The 24-hour period is completed during the middle of the night.

A birth center must file a report with AHCA within 48 hours of the birth describing the circumstances and the reasons for the decision, if a mother or infant must remain in the birth center for longer than 24 hours after giving birth for a reason other than those listed above.[6]

AHCA is required to adopt rules establishing minimum standards for birth centers, which ensure:[7]

- Sufficient numbers and qualified types of personnel and occupational disciplines are available at all times to provide necessary and adequate patient care and safety.
- Infection control, housekeeping, sanitary conditions, disaster plan, and medical record procedures that will adequately protect patient care and provide safety are established and implemented.
- Licensed facilities are established, organized, and operated consistent with established programmatic standards.

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[1] Section 383.302(2), F.S.; Section 383.302(8), F.S. defines "low-risk pregnancy" as a pregnancy which is expected to result in an uncomplicated birth, as determined through risk criteria developed by rule of the department, and which is accompanied by adequate prenatal care.
[2] Section 383.307, F.S.
[3] Id.
[4] Section 383.31, F.S. The informed consent form must advise the patient of the qualifications of the clinical staff, the risks related to out-of-hospital births, the benefits of out-of-hospital births, and the possibility of referral or transfer if complications arise during pregnancy or childbirth with additional costs for services rendered (r. 59A-11.010, F.A.C.)
[5] Section 383.318(1), F.S., and Rule 59A-11.016(6), F.A.C.
[6] Section 383.318(1), F.S.
[7] Section 383.309, F.S.; The minimum standards for birth centers are contained in Chapter 59A-11, F.A.C.

A birth center is required to maintain the quality of care by:[8]

- Having at least one clinical staff[9] member for every two clients in labor;
- Having a clinical staff member or qualified personnel[10] available on site during the entire time a client is in the birth center. Services during labor and delivery must be provided by a physician, certified nurse midwife, or licensed midwife, assisted by at least one other staff member under protocols developed by clinical staff;
- Ensuring all qualified personnel and clinical staff are trained in infant and adult resuscitation and requiring qualified personnel or clinical staff who are able to perform neonatal resuscitation to be present during each birth;
- Maintaining complete and accurate medical records;
- Evaluating the quality of care by reviewing clinical records;
- Reviewing admissions with respect to eligibility, course of pregnancy and outcome, evaluation of services, condition of mother and newborn on discharge, or transfer to other providers; and
- Surveillance of infection risk and cases and the promotion of preventive and corrective program designed to minimize hazards.

Birth centers must ensure that its patients have adequate prenatal care and must maintain records of prenatal care for each client and must make the records available during labor and delivery.[11]

Birth centers may perform simple laboratory tests and collect specimens for tests that are requested pursuant to its protocol.[12] Birth centers are exempt from the clinical laboratory licensure requirements under chapter 483 if the birth center employs no more than five physicians and testing is conducted exclusively in connection with the diagnosis and treatment of patients of the birth center.[13]

Birth centers may perform surgical procedures that are normally performed during uncomplicated childbirths, such as episiotomies and repairs. Birth centers may not perform operative obstetrics or caesarean sections.[14]

Birth centers may not administer general and conduction anesthesia. Systemic analgesia and local anesthesia for pudendal block and episiotomy repair may be administered if procedures are outlined by the clinical staff and performed by personnel with statutory authority to do so.[15]

Birth centers may not inhibit, simulate, or augment labor with chemical agents during the first or second stage of labor unless prescribed by personnel with the statutory authority to do so and in connection with and prior to an emergency transport.[16]

Birth centers must provide postpartum care and evaluation that includes physical examination of the infant, metabolic screening tests, referral to pediatric care sources, maternal postpartum assessment, family planning, referral to secondary or tertiary care, and instruction in child care, including immunization, breastfeeding, safe sleep practices, and possible causes of Sudden Unexpected Infant Death.[17]

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[8] Rule 59A-11.005(3), F.A.C.
[9] Section 383.302(3), F.S., defines "clinical staff" as individuals employed full-time or part-time by a birth center who are licensed or certified to provide care at childbirth.
[10] Rule 59A-11.002(6), F.A.C., defines "qualified staff" as an individual who is trained and competent in the services that he or she provides and is licensed or certified when required by statute or professional standard.
[11] Section 383.312, F.S.
[12] Section 383.313, F.S.
[13] Id.
[14] Id.
[15] Id.
[16] Id.
[17] Section 383.313(3), F.S.

Birth centers must be designed to assure adequate provision for birthing rooms, bath and toilet facilities, storage areas for supplies and equipment, examination areas, and reception or family areas.[18] Birth centers must comply with provisions of the Florida Building Code and Florida Fire Prevention Code applicable to birth centers.[19] AHCA may enforce the special-occupancy provisions of the Florida Building Code and the Florida Fire Prevention Code that apply to birth centers when conducting inspections.[20]

Birth centers must have the equipment necessary to provide low-risk maternity care and readily available equipment to initiate emergency procedures in life-threatening events to a mother and baby.[21] A birth center must transfer the patient to a hospital if unforeseen complications arise during labor.[22] Each facility must have an arrangement with a local ambulance service for the transport of emergency patients to a hospital, which must be documented in the facilities policy and procedures manual.[23]

Birth centers must submit an annual report to AHCA that details, among other things:[24]

- The number of deliveries by birth weight;
- The number of maternity clients accepted for care and length of stay;
- The number of surgical procedures performed at the birth center by type;
- Maternal transfers, including the reason for the transfer, whether it occurred intrapartum or postpartum, and the length of the hospital stay;
- Newborn transfers, including the reason for the transfer, birth weight, days in hospital, and APGAR score at five and ten minutes;
- Newborn deaths; and
- Stillborn/Fetal deaths.

Birth centers must have written consultation agreements with each consultant who has agreed to provide advice and services to the birth center.[25] A consultant must be a licensed medical doctor or licensed osteopathic physician who is either certified or eligible for certification by the American Board of Obstetrics and Gynecology, or has hospital obstetrical privileges.[26] Consultation may be provided onsite or by telephone.[27]

Birth centers must adopt a protocol that provides information about adoption procedures. The protocol must be provided upon request to any birth parent or prospective adoptive parent of a child born in the facility.[28]

AHCA may impose an administrative fine not to exceed $500 per violation per day for the violation of any provision of the Birth Center Licensure Act, part II of chapter 408, or applicable rules.[29] AHCA may also impose an immediate moratorium on elective admissions to any birth center when it determines that any condition in the facility presents a threat to the public health or safety.[30]

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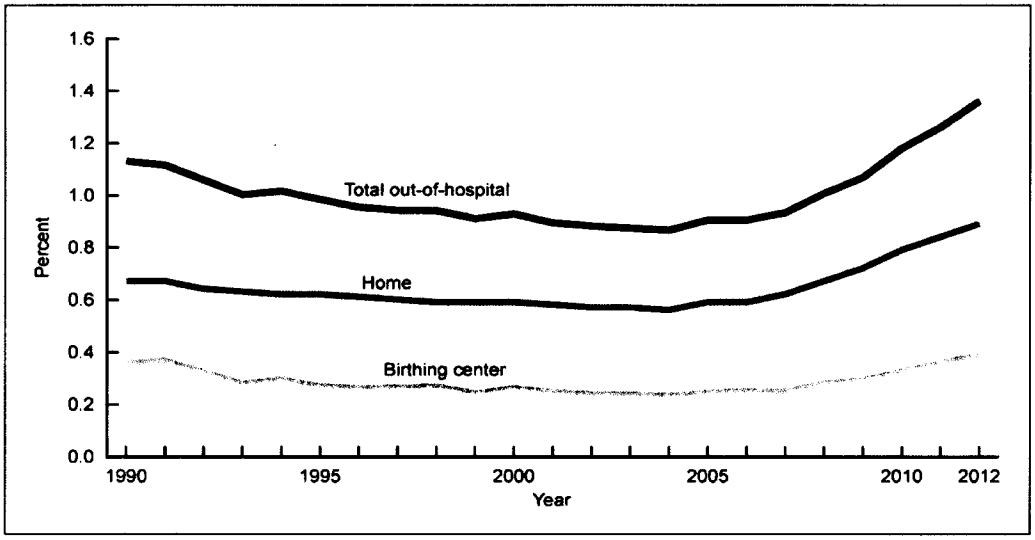
[18] Section 383.308(1), F.S.
[19] Section 383.309(2), F.S.; Section 452 of the Florida Building Code provides requirements for birth centers.
[20] Id.
[21] Section 383.308(2)(a), F.S.
[22] Section 383.316, F.S.
[23] Id.
[24] Rule 59A-11.019, F.A.C., and AHCA Form 3130-3004, (Feb. 2015).
[25] Section 383.315(1), F.S.
[26] Section 383.302(4), F.S.
[27] Section 383.315(2), F.S.
[28] Section 383.3105, F.S.
[29] Section 383.33, F.S.
[30] Id.

Out-Hospital-Births at Birth Centers

Out-of-hospital births have increased from 0.87% of U.S. births in 2004 to 1.36% of U.S. births in 2012, its highest level since 1975.[31] In 2012, 66% of out-of-hospital births occurred at home and 29% occurred in a freestanding birth center.[32]

Figure 1. Percentage of births occurring out-of-hospital: United States, 1990-2012[33]



NOTE: Out-of-hospital births include those occurring in a home, birthing center, clinic or doctor's office, or other location.
SOURCE: CDC/NCHS, National Vital Statistics System, birth certificate data.

A 2013 study of 13,030 births at 79 birth centers in 33 states found that the cesarean section rate for women who entered labor planning a birth center birth was 6% compared to the national cesarean section rate of 27%.[34] Out of the women who planned to give at a birth center, 4.5% were referred to a hospital before being admitted to the birth center, 11.9% transferred to the hospital during labor, 2.0% transferred after giving birth, and 2.2% had their babies transferred after birth. Fewer than 2% of the women required emergency transfer to a hospital.[35] Out of the 1,851 women who transferred to hospitals during labor, 54% ended up with a vaginal birth, 38% had a Cesarean, and 8% had a forceps or vacuum-assisted vaginal birth.[36] The study also found that 0.47 stillbirths per 1,000 women (.047%) and 0.40 newborn deaths per 1,000 women (.04%) occurred out of the births planned at the birth centers.[37]

The study also estimated $30 million in savings from the births that occurred at the birth centers based on Medicare facility reimbursement rates at the time of the study.[38] The Medicare facility reimbursement for an uncomplicated vaginal birth in a hospital was $3,998 compared to $1,907 in a birth center.[39]

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[31] Marian F. MacDorman, Ph.D.; T.J. Mathews, M.S.; and Eugene Declercq, Ph.D, *Trends in Out-of-Hospital Births in the United States, 1990–2012*. NCHS Data Brief No. 144, March, 2014. Available at: https://www.cdc.gov/nchs/products/databriefs/db144.htm (Last visited January 12, 2017).
[32] Id.
[33] Id.
[34] Susan Rutledge Stapleton, CNM, DNP; Cara Osborne, SD, CNM; Jessica Illuzzi, M.D., M.S., *Outcomes of Care in Birth Centers: Demonstration of a Durable Model*. Journal of Midwifery & Women's Health. Vol. 58, No. 1, January/February 2013. Available at: http://nacpm.org/documents/Birth%20Center%20Study%202013.pdf (Last visited January 12, 2017).
[35] Id.
[36] Id.
[37] Id.
[38] Id.
[39] Id.

Wesley Medical Center (Center) in Kansas is a licensed hospital that operates a freestanding, physician-led, birth center linked to the hospital through a service tunnel.[40] The birth center is equipped equivalent to the hospital's labor and delivery unit and contains two operating rooms. A study comparing births at the Center's birth center to the hospital found that deliveries at its birth center were associated with a lower rate of cesarean sections without an increased rate of operative vaginal delivery compared to births at the hospital.[41] The study also found that maternal length of stays longer than 72 hours were less frequent in the birth center, the rate of infants requiring transfer to the high-risk were less than those born in the hospital, and adverse maternal and infant outcomes were not increased in the birth center.[42] The study also found that only 2.2% of all deliveries were transferred to the hospital, and infants of mothers that were transferred were not more likely to need transfer to the high-risk nursery.[43]

Practice of Pharmacy

The Florida Pharmacy Act (act) regulates the practice of pharmacy in Florida and contains the minimum requirements for safe practice.[44] The Board of Pharmacy (board) is tasked with adopting rules to implement the provisions of the chapter and setting standards of practice within the state.[45] Any person who operates a pharmacy in Florida must have a permit. The following permits are issued by the Department of Health (DOH):

- Community pharmacy – A permit is required for each location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis.[46]
- Institutional pharmacy – A permit is required for every location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility where medicinal drugs are compounded, dispensed, stored, or sold.[47]
- Nuclear pharmacy – A permit is required for every location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold. The term "nuclear pharmacy" does not include hospitals licensed under ch. 395, F.S., or the nuclear medicine facilities of such hospitals.[48]
- Special pharmacy – A permit is required for every location where medicinal drugs are compounded, dispensed, stored, or sold if the location does not otherwise meet an applicable pharmacy definition in s. 465.003, F.S.[49]
- Internet pharmacy – A permit is required for a location not otherwise licensed or issued a permit under this chapter, within or outside this state, which uses the Internet to communicate with or obtain information from consumers in this state to fill or refill prescriptions or to dispense, distribute, or otherwise practice pharmacy in this state.[50]
- Nonresident sterile compounding pharmacy – A permit is required for a registered nonresident pharmacy or an outsourcing facility to ship, mail, deliver, or dispense, in any manner, a compounded sterile product into this state.[51]

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[40] Margaret H. O'Hara, MD, Linda M. Frazier, MD, MPH, Travis W. Stembridge, MD, Robert S. McKay, MD, Sandra N. Mohr, MD, MPH, and Stuart L. Shalat, ScD, *Physician-led, hospital-linked, birth care centers can decrease Cesarean section rates without increasing rates of adverse events.* Birth Issues in Perinatal Care Vol. 40 Issue 3, September 2013. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4321785/ (Last visited January 12, 2012).
[41] Id.
[42] Id.
[43] Id.
[44] Chapter 465, F.S.
[45] Sections 465.005, 465.0155, and 465.022, F.S.
[46] Sections 465.003(11)(a)1. and 465.018, F.S.
[47] Sections 465.003(11)(a)2. and 465.019, F.S.
[48] Sections 465.003(11)(a)3. and 465.0193, F.S.
[49] Sections 465.003(11)(a)4. and 465.0196, F.S.
[50] Sections 465.003(11)(a)5. and 465.0197, F.S.
[51] Section 465.0158, F.S.

- Special sterile compounding – A separate permit is required for a pharmacy holding an active pharmacy permit that engages in sterile compounding.[52]

DOH issues three different classes of permits for institutional pharmacies[53]:

- Institutional Class I: An Institutional Class I pharmacy is a pharmacy in which all medicinal drugs are administered from individual prescription containers to the individual patient and in which medicinal drugs are not dispensed on the premises. No medicinal drugs may be dispensed in a Class I Institutional pharmacy. A Special- Closed System Pharmacy Permit, Special Parenteral and Enteral Pharmacy Permit, or Community Pharmacy Permit provide the individual patient prescriptions.
- Institutional Class II: An Institutional Class II pharmacy is a pharmacy, which employs the services of a registered pharmacist or pharmacists who, in practicing institutional pharmacy, provide dispensing and consulting services on the premises to patients of that institution, for use on the premises of that institution. An Institutional Class II pharmacy is required be open sufficient hours to meet the needs of the hospital facility. A consultant pharmacist of record shall also be responsible for establishing written policy and procedure manual for the implementation of the general requirements set forth in Rule 64B16- 28.702, F.A.C.
- Modified Class II: Modified Institutional Class II pharmacies are those pharmacies in short-term, primary care treatment centers that meet all the requirements for a Class II permit, except space and equipment requirements.

Ambulatory Surgical Centers

An ambulatory surgical center (ASC) is a facility that is not part of a hospital, the primary purpose of which is to provide elective surgical care, in which the patient is admitted and discharged within the same working day and is not permitted to stay overnight.[54] ASCs are licensed and regulated by AHCA under the same regulatory framework as hospitals.[55]

AHCA is authorized to adopt rules for minimum standards for ASCs that ensure:[56]

- A sufficient number of qualified types of personnel and occupational disciplines are on duty and available at all times to provide necessary and adequate patient care;
- Infection control, housekeeping, sanitary conditions, and medical record procedures are established and implemented to adequately protect patients;
- A comprehensive emergency management plan is prepared and updated annually;
- Licensed facilities are established, organized, and operated consistent with established standards and rules; and
- Licensed facility beds conform to minimum space, equipment, and furnishing standards

ASCs must comply with provisions of the Florida Building Code and Florida Fire Prevention Code applicable to ASCs.[57]

Effect of the Bill

CS/HB 1099 creates a new licensure program within AHCA for advanced birth centers. The advanced birth center license is modeled after the current licensure program for birth centers in Chapters 383 and 408, F.S. The bill requires advanced birth centers to meet the same licensure, inspection and administrative penalty requirements for birth centers in Chapter 383. The bill also requires advanced

[52] Rules 64B16-2.100 and 64B16-28.802, F.A.C. An outsourcing facility is considered a pharmacy and need to hold a special sterile compounding permit if it engages in sterile compounding.
[53] S. 465.109, F.S.
[54] S. 395.002(3), F.S.
[55] SS. 395.001-.1065, F.S., and Part II, Chapter 408, F.S.
[56] S. 395.1055, F.S.; The minimum standards for ASCs are contained in Chapter 59A-5, F.A.C.
[57] Section 395.1063, F.S.; Section 451 of the Florida Building Code provides requirements for ASCs.

birth centers to provide prenatal and postpartum care and establish a governing body, an adoption protocol, a transfer agreement with an ambulance service, and consultation agreements with consultants in the same manner as birth centers.

The bill defines an advanced birth center as a birth center that may perform trial of labor after cesarean deliveries for screened patients that qualify, planned low risk cesarean deliveries, and anticipated vaginal delivery of laboring patients at the beginning of the 37th week of gestation to the end of the 41st week of gestation.

The bill requires advanced birth centers to be operated and staffed 24 hours per day, 7 days per week. The bill requires a mother and her infant to be discharged from the advanced birth center within 48 hours after the birth of the infant for a vaginal delivery and within 72 hours when delivery is by cesarean section, except in unusual circumstances defined by rule by AHCA. The bill requires an advanced birth center to file a report with AHCA describing the reasons and circumstances for not discharging a mother or infant within the required timeframes.

Section 383.309, F.S., F.S. directs AHCA to adopt rules establishing minimum standards for:

- Sufficient numbers and qualified types of personnel and occupational disciplines are available at all times to provide necessary and adequate patient care and safety.
- Infection control, housekeeping, sanitary conditions, disaster plan, and medical record procedures that will adequately protect patient care and provide safety are established and implemented.
- Licensed facilities are established, organized, and operated consistent with established programmatic standards.

The bill authorizes AHCA to adopt, by rule, appropriate standards for advanced birth centers pursuant to s. 383.309, F.S. The bill also requires AHCA to establish minimum standards for food handling and service. The bill requires the minimum standards adopted for advanced birth centers be equivalent to the minimum standards adopted for ambulatory surgical centers.

The bill requires advanced birth centers to have at least one, properly equipped, dedicated surgical suite for the performance of caesarean deliveries.

The bill requires advanced birth centers to, at a minimum, comply with the Florida Building Code and Florida Fire Prevention Code requirements for ambulatory surgical centers. The bill authorizes AHCA to enforce the special-occupancy provisions of the Florida Building Code and the Florida Fire Prevention Code that apply to advanced birth centers when conducting inspections.

The bill authorizes advanced birth centers to perform laboratory tests as permitted by AHCA rule and requires a laboratory in an advanced birth center to be licensed as a clinical laboratory pursuant to chapter 483.

The bill authorizes advanced birth centers to perform uncomplicated cesarean deliveries, surgical management of immediate complications, postpartum sterilization, and circumcisions, in addition to the surgical procedures authorized to be performed at birth centers.

The bill allows advanced birth centers to administer general, conduction, and local anesthesia if such services are provided in accordance with established protocol required by state law. The bill requires an anesthesiologist or a certified registered nurse anesthetist to administer all general anesthesia. The bill requires a physician or a certified registered nurse anesthetist to be present in the advanced birth center during the anesthesia and postanesthesia recovery period until the patient is fully alert.

The bill authorizes an advanced birth center to inhibit, stimulate, or augment labor with chemical agents during the first or second stage of labor if prescribed by personnel with statutory authority to do so. The

bill authorizes an advanced birth center to electively induce labor at 39 weeks' gestation or later for a patient with a documented Bishop score[58] of 8 or greater.

The bill requires an advanced birth center to either employ or maintain an agreement with an obstetrician who is available to attend and available to perform cesarean deliveries, when necessary.

The bill requires a patient be transferred to a hospital if unforeseen complications arise during labor, delivery, or postpartum.

The bill requires an advanced birth center with a pharmacy to obtain a Modified Class II institutional pharmacy permit from DOH.

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

B. SECTION DIRECTORY:

Section 1: Amends s. 383.30, F.S., relating to Birth Center Licensure Act; short title.
Section 2: Amends s. 383.301, F.S., relating to licensure and regulation of birth centers; legislative intent.
Section 3: Amends s. 383.302, F.S., relating to definitions of terms used in ss. 383.30-383.335.
Section 4: Amends s. 383.305, F.S., relating to licensure; fees.
Section 5: Amends s. 383.307, F.S., relating to administration of birth center.
Section 6: Creates s. 383.3081, F.S., relating to advanced birth center facility and equipment; requirements.
Section 7: Amends s. 383.309, F.S., relating to minimum standards for birth centers.
Section 8: Amends s. 383.31, F.S., relating to selection of clients; informed consent.
Section 9: Amends s. 383.3105, F.S., relating to patients consenting to adoptions; protocols.
Section 10: Amends s. 383.311, F.S., relating to education and orientation for birth center clients and their families.
Section 11: Amends s. 383.312, F.S., relating to prenatal care of birth center clients.
Section 12: Amends s. 383.313, F.S., relating to performance of laboratory and surgical services; use of anesthetic and chemical agents.
Section 13: Creates s. 383.3131, F.S., relating to advanced birth center performance of laboratory and surgical services; use of anesthetic and chemical agents.
Section 14: Amends s. 383.315, F.S., relating to agreements with consultants for advice or services; maintenance.
Section 15: Amends s. 383.316, F.S., relating to transfer and transport of clients to hospitals.
Section 16: Amends s. 383.318, F.S., relating postpartum care for birth center clients and infants.
Section 17: Amends s. 383.324, F.S., relating to inspections and investigations; inspection fees.
Section 18: Amends s. 383.327, F.S., relating to birth and death records; reports.
Section 19: Amends s. 383.33, F.S., relating to administrative penalties; moratorium on admissions.
Section 20: Amends s. 383.332, F.S., relating to establishing, managing, or operating a birth center without a license; penalty.
Section 21: Amends s. 465.003, F.S., relating to definitions.
Section 22: Amends s. 465.019, F.S., relating to institutional pharmacies; permits.
Section 23: Provides an effective date of July 1, 2018.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

[58] Health care professionals use the Bishop score to rate the readiness of the cervix for labor. With this scoring system, a number ranging from 0–13 is given to rate the condition of the cervix. A Bishop score of less than 6 means that your cervix may not be ready for labor. The American College of Obstetricians and Gynecologists, *Frequently Asked Questions*. Available at: https://www.acog.org/Patients/FAQs/Labor-Induction#score (Last visited January 14, 2018).

1. Revenues:

   AHCA will experience an increase in revenues from licensure fees for the new licensure program. Section 408.805, F.S., requires AHCA to set license fees that are reasonably calculated to cover the cost of regulation. By using the available resources, the AHCA estimates the biennial licensure fees for advanced birth centers would need to be $1,500 and $500 per inspection.[59]

   Applicants for licensure as an advanced birth center will be subject to the Plans and Construction project review fee of $2,000 plus $100 per hour for building plan reviews. These are non-recurring fees.[60]

   DOH may experience an increase in revenues from advanced birth centers that apply for licensure as a Modified Class II institutional pharmacy.[61] Applicants for such permits must pay a $250 application fee.[62]

2. Expenditures:

   AHCA will experience costs associated with administering the new licensure program. However, due to the common requirements for birth centers and advanced birth centers, AHCA expects to absorb implementation costs using current resources and revenues from the new licensure fees.

   DOH may experience an increase in costs and workload associated inspections, licensure, regulation, and enforcement of advanced birth centers that apply to be licensed as Modified Class II institutional pharmacies. It is unknown how many advanced birth centers will seek licensure; therefore, the fiscal impact is indeterminate, but likely insignificant. [63] Current DOH resources can absorb the increased workload.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Applicants for licensure as advanced birth centers will be subject to biennial licensure fees and a one-time Plans and Construction project review fee. Applicants for licensure as advanced birth centers that have a pharmacy will be subject to the Modified Class II institutional pharmacy permit fee.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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[59] Agency for Health Care Administration, *2018 Agency Legislative Bill Analysis-HB 1099, January 11, 2018* (on file with Health Quality Subcommittee staff).
[60] Id.
[61] Department of Health, *2018 Agency Bill Analysis-HB 1099, January 12, 2018* (on file with Health Quality Subcommittee Staff).
[62] Rule 61-28.100, F.A.C.
[63] Supra, FN 51.

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

Not applicable.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On January 16, 2018, the Health Quality Subcommittee adopted an amendment that:

- Requires minimum standards established by AHCA for the staffing, infection control, housekeeping, medical records, disaster plans, organization, and operation of advanced birth centers be equivalent to minimum standards established for ambulatory surgical centers.
- Requires minimum standards include standards for food handling and service.
- Requires at a minimum, advanced birth centers meet Florida Building Code and Florida Fire Prevention Code requirements for ambulatory surgical centers.
- Authorizes AHCA to enforce the special-occupancy provisions of the Florida Building Code and the Florida Fire Prevention Code that apply to advanced birth centers when conducting inspections.
- Authorizes advanced birth centers to collect specimens for laboratory tests and perform laboratory tests permitted by AHCA rule.
- Removes minimum staffing requirements and requires AHCA to set staffing requirements in rule.
- Removes requirement that a board-certified anesthesiologist to be on call and available at all times when a certified registered nurse anesthetist performs anesthesia services.
- Requires advanced birth centers to either employ or maintain an agreement with an obstetrician to be available to attend and available to perform cesarean section deliveries, when necessary.

The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute.

A bill to be entitled

An act relating to advanced birth centers; amending s. 383.30, F.S.; revising the short title; amending s. 383.301, F.S.; providing applicability of licensure requirements under pt. II of ch. 408, F.S., to advanced birth centers; amending s. 383.302, F.S.; defining the term "advanced birth center"; revising definitions; amending s. 383.305, F.S.; providing applicability of licensure fee requirements to advanced birth centers; amending s. 383.307, F.S.; providing for administration of advance birth centers; creating s. 383.3081, F.S.; providing requirements for advanced birth center facilities and equipment; amending s. 383.309, F.S.; providing minimum standards for advanced birth centers; authorizing the Agency for Health Care Administration to enforce specified provisions of the Florida Building Code and the Florida Fire Prevention Code; amending s. 383.3105, F.S.; providing applicability of adoption protocols for staff of an advanced birth center; amending s. 383.311, F.S.; providing for the education and orientation of advanced birth center clients and their families; amending s. 383.312, F.S.; providing for an advanced birth center to offer prenatal care; amending s. 383.313, F.S.; providing for laboratory and

surgical services at a birth center; creating s. 383.3131, F.S.; providing requirements for laboratory and surgical services at an advanced birth center; providing conditions for administration of anesthesia; authorizing the intrapartal use of chemical agents; amending s. 383.315, F.S.; requiring an advanced birth center to employ or maintain an agreement with an obstetrician under certain circumstances; amending s. 383.316, F.S.; requiring an advanced birth center to provide for transport of emergency patients to a hospital; amending s. 383.318, F.S.; providing protocols for postpartum care of clients and infants; providing requirements for followup care; amending s. 383.324, F.S.; requiring an advanced birth center to pay an inspection fee to the agency; amending s. 383.327, F.S.; requiring an advanced birth center to provide reports of all births and deaths occurring at the center; requiring reports to the agency; amending s. 383.33, F.S.; providing for fines, administrative penalties, and moratoriums; amending s. 383.332, F.S.; providing a criminal penalty for operating an unlicensed advanced birth center; amending s. 465.003, F.S.; revising the definition of the term "institutional pharmacy" to include pharmacies located in advanced birth centers; amending s. 465.019, F.S.;

revising the definition of the term "modified Class II institutional pharmacies" to include pharmacies located in advanced birth centers; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 383.30, Florida Statutes, is amended to read:

383.30 Birth Center and Advanced Birth Center Licensure Act; short title.—Sections 383.30-383.335 shall be known and may be cited as the "Birth Center and Advanced Birth Center Licensure Act."

Section 2. Section 383.301, Florida Statutes, is amended to read:

383.301 Licensure and regulation of birth centers and advanced birth centers; legislative intent.—It is the intent of the Legislature to provide for the protection of public health and safety in the establishment, maintenance, and operation of birth centers and advanced birth centers by providing for licensure of birth centers and advanced birth centers and for the development, establishment, and enforcement of minimum standards with respect to birth centers and advanced birth centers. The requirements of part II of chapter 408 shall apply to the provision of services that require licensure pursuant to

ss. 383.30-383.335 and part II of chapter 408 and to entities licensed by or applying for such licensure from the Agency for Health Care Administration pursuant to ss. 383.30-383.335. A license issued by the agency is required in order to operate a birth center or an advanced birth center in this state.

Section 3. Subsections (1) through (10) of section 383.302, Florida Statutes, are renumbered as subsections (2) through (11), respectively, present subsections (3), (4), and (5) are amended, and a new subsection (1) is added to that section, to read:

383.302 Definitions of terms used in ss. 383.30-383.335.—As used in ss. 383.30-383.335, the term:

(1) "Advanced birth center" means a birth center that may perform trial of labor after cesarean deliveries for screened patients that qualify, planned low-risk cesarean deliveries, and anticipated vaginal deliveries for laboring patients from the beginning of the 37th week of gestation through the end of the 41st week of gestation.

(4) ~~(3)~~ "Clinical staff" means individuals employed full time or part time by a birth center or an advanced birth center who are licensed or certified to provide care at childbirth.

(5) ~~(4)~~ "Consultant" means a physician licensed pursuant to chapter 458 or chapter 459 who agrees to provide advice and services to a birth center or an advanced birth center and who either:

(a) Is certified or eligible for certification by the American Board of Obstetrics and Gynecology, or

(b) Has hospital obstetrical privileges.

(6) ~~(5)~~ "Governing body" means any individual, group, corporation, or institution which is responsible for the overall operation and maintenance of a birth center or an advanced birth center.

Section 4. Section 383.305, Florida Statutes, is amended to read:

383.305 Licensure; fees.—

(1) In accordance with s. 408.805, an applicant for licensure as a birth center or an advanced birth center or a licensee shall pay a fee for each license application submitted under ss. 383.30-383.335 and part II of chapter 408. The amount of the fee shall be established by rule.

(2) Each applicant for licensure and each licensee must comply with the requirements of this chapter and part II of chapter 408.

Section 5. Section 383.307, Florida Statutes, is amended to read:

383.307 Administration of birth center and advanced birth center.—

(1) Each birth center and advanced birth center shall have a governing body which is responsible for the overall operation and maintenance of the ~~birth~~ center.

(a) The governing body shall develop and display a table of organization which shows the structure of the birth center or advanced birth center and identifies the governing body, the ~~birth center~~ director, the clinical director, the clinical staff, and the medical consultant.

(b) The governing body shall develop and make available to staff, clinicians, consultants, and licensing authorities a manual which documents policies, procedures, and protocols, including the roles and responsibilities of all personnel.

(2) There shall be an adequate number of licensed personnel to provide clinical services needed by mothers and newborns and a sufficient number of qualified personnel to provide services for families and to maintain the birth center or the advanced birth center.

(3) All clinical staff members and consultants shall hold current licenses from this state to practice their respective disciplines.

(4) Clinical staff members and consultants shall adopt bylaws which are subject to the approval of the governing body and which shall include recommendations for clinical staff or consultation appointments, delineation of clinical privileges, and the organization of the clinical staff.

Section 6. Section 383.3081, Florida Statutes, is created to read:

383.3081 Advanced birth center facility and equipment;

requirements.—

(1) An advanced birth center shall meet all of the requirements of s. 383.308.

(2) An advanced birth center shall be operated and staffed 24 hours per day, 7 days per week.

(3) Each advanced birth center shall have at least one properly equipped, dedicated surgical suite for the performance of cesarean deliveries.

Section 7. Section 383.309, Florida Statutes, is amended to read:

383.309 Minimum standards for birth centers and advanced birth centers; rules and enforcement.—

(1) The agency shall adopt and enforce rules to administer ss. 383.30-383.335 and part II of chapter 408, which rules shall include, but are not limited to, reasonable and fair minimum standards for ensuring that:

(a) Sufficient numbers and qualified types of personnel and occupational disciplines are available at all times to provide necessary and adequate patient care and safety.

(b) Infection control, housekeeping, sanitary conditions, disaster plan, and medical record procedures that will adequately protect patient care and provide safety are established and implemented.

(c) Licensed facilities are established, organized, and operated consistent with established programmatic standards.

(2) Minimum standards adopted by rule for advanced birth centers must be equivalent to the minimum standards adopted for ambulatory surgical centers pursuant to s. 395.1055 and shall include sanitary conditions for food handling and food service.

(3) ~~(2)~~ The agency may not establish any rule governing the design, construction, erection, alteration, modification, repair, or demolition of birth centers or advanced birth centers. It is the intent of the Legislature to preempt that function to the Florida Building Commission and the State Fire Marshal through adoption and maintenance of the Florida Building Code and the Florida Fire Prevention Code. However, the agency shall provide technical assistance to the commission and the State Fire Marshal in updating the construction standards of the Florida Building Code and the Florida Fire Prevention Code which govern birth centers and advanced birth centers. In addition, the agency may enforce the special-occupancy provisions of the Florida Building Code and the Florida Fire Prevention Code which apply to birth centers or advanced birth centers in conducting any inspection authorized under this chapter or part II of chapter 408. At a minimum, advanced birth centers must comply with the Florida Building Code and Florida Fire Prevention Code standards for ambulatory surgical centers.

Section 8. Section 383.3105, Florida Statutes, is amended to read:

383.3105 Patients consenting to adoptions; protocols.—

(1) Each licensed birth center and advanced birth center ~~facility~~ shall adopt a protocol that at a minimum provides for birth center and advanced birth center ~~facility~~ staff to be knowledgeable of the waiting periods, revocation and the contents of the consent to adoption as contained in s. 63.082(4), and describes the supportive and unbiased manner in which ~~facility~~ staff will interact with birth parents and prospective adoptive parents regarding the adoption, in particular during the waiting period required in s. 63.082(4)(b) before consenting to an adoption.

(2) The protocol shall be in writing and be provided upon request to any birth parent or prospective adoptive parent of a child born in the birth center and advanced birth center ~~facility~~.

Section 9. Section 383.311, Florida Statutes, is amended to read:

383.311 Education and orientation for birth center and advanced birth center clients and their families.—

(1) The clients and their families shall be fully informed of the policies and procedures of the birth center or advanced birth center, including, but not limited to, policies and procedures on:

(a) The selection of clients.

(b) The expectation of self-help and family/client relationships.

(c) The qualifications of the clinical staff.

(d) The transfer to secondary or tertiary care.

(e) The philosophy of childbirth care and the scope of services.

(f) The customary length of stay after delivery.

(2) The clients shall be prepared for childbirth and childbearing by education in:

(a) The course of pregnancy and normal changes occurring during pregnancy.

(b) The need for prenatal care.

(c) Nutrition, including encouragement of breastfeeding.

(d) The effects of smoking and substance abuse.

(e) Labor and delivery.

(f) The care of the newborn to include safe sleep practices and the possible causes of Sudden Unexpected Infant Death.

Section 10. Section 383.312, Florida Statutes, is amended to read:

383.312 Prenatal care of birth center and advanced birth center clients.—

(1) A birth center and an advanced birth center shall ensure that their ~~its~~ clients have adequate prenatal care, as defined by the agency, and shall ensure that serological tests are administered as required by this chapter.

(2) Records of prenatal care shall be maintained for each

client and shall be available during labor and delivery.

Section 11. Section 383.313, Florida Statutes, is amended to read:

383.313 Birth center performance of laboratory and surgical services; use of anesthetic and chemical agents.—

(1) LABORATORY SERVICES.—A birth center may collect specimens for those tests that are requested under protocol. A birth center may perform simple laboratory tests, as defined by rule of the agency, and is exempt from the requirements of chapter 483, provided no more than five physicians are employed by the birth center and testing is conducted exclusively in connection with the diagnosis and treatment of clients of the birth center.

(2) SURGICAL SERVICES.—Surgical procedures shall be limited to those normally performed during uncomplicated childbirths, such as episiotomies and repairs and may ~~shall~~ not include operative obstetrics or caesarean sections.

(3) ADMINISTRATION OF ANALGESIA AND ANESTHESIA.—General and conduction anesthesia may not be administered at a birth center. Systemic analgesia may be administered, and local anesthesia for pudendal block and episiotomy repair may be performed if procedures are outlined by the clinical staff and performed by personnel with statutory authority to do so.

(4) INTRAPARTAL USE OF CHEMICAL AGENTS.—Labor may not be inhibited, stimulated, or augmented with chemical agents during

the first or second stage of labor unless prescribed by personnel with statutory authority to do so and unless in connection with and prior to emergency transport.

Section 12. Section 383.3131, Florida Statutes, is created to read:

383.3131 Advanced birth center performance of laboratory and surgical services; use of anesthetic and chemical agents.—

(1) LABORATORY SERVICES.—An advanced birth center may collect specimens for those tests that are requested under protocol. An advanced birth center may perform laboratory tests, as defined by rule of the agency. Laboratories located in advanced birth centers must be licensed as a clinical laboratory under chapter 483.

(2) SURGICAL SERVICES.—In addition to surgical procedures authorized pursuant to s. 383.313(2), surgical procedures are limited to uncomplicated cesarean section deliveries and surgical management of immediate complications. Postpartum sterilization may be performed prior to discharge of the patient who has given birth during that admission. Circumcisions may be performed prior to discharge of the newborn infant.

(3) ADMINISTRATION OF ANALGESIA AND ANESTHESIA.—General, conduction, and local anesthesia may be administered at an advanced birth center if administered by personnel with the statutory authority to do so. All general anesthesia shall be administered by an anesthesiologist or a certified registered

nurse anesthetist in accordance with s. 464.012. When general anesthesia is administered, a physician or a certified registered nurse anesthetist shall be present in the advanced birth center during the anesthesia and postanesthesia recovery period until the patient is fully alert.

(4) INTRAPARTAL USE OF CHEMICAL AGENTS.—Labor may be inhibited, stimulated, or augmented with chemical agents during the first or second stage of labor at an advanced birth center if prescribed by personnel with statutory authority to do so. Labor may be electively induced beginning at the 39th week of gestation for a patient with a documented Bishop score of 8 or greater.

Section 13. Section 383.315, Florida Statutes, is amended to read:

383.315 Agreements with consultants for advice or services; maintenance.—

(1) A birth center and an advanced birth center shall maintain in writing a consultation agreement, signed within the current license period, with each consultant who has agreed to provide advice and services to the birth center and advanced birth center as requested.

(2) Consultation may be provided onsite or by telephone, as required by clinical and geographic conditions.

(3) An advanced birth center shall either employ or maintain an agreement with an obstetrician to be available to

attend and available to perform cesarean section deliveries, when necessary.

Section 14. Section 383.316, Florida Statutes, is amended to read:

383.316 Transfer and transport of clients to hospitals.—

(1) If unforeseen complications arise during labor, delivery, or postpartum recovery, the client shall be transferred to a hospital.

(2) Each licensed birth center or advanced birth center ~~facility~~ shall make arrangements with a local ambulance service licensed under chapter 401 for the transport of emergency patients to a hospital. Such arrangements shall be documented in the policy and procedures center's manual ~~of the facility~~ if the birth center or advanced birth center does not own or operate a licensed ambulance. The policy and procedures manual shall also contain specific protocols for the transfer of any patient to a licensed hospital.

(3) A licensed birth center or advanced birth center ~~facility~~ shall identify neonatal-specific transportation services, including ground and air ambulances; list their particular qualifications; and have the telephone numbers for access to these services clearly listed and immediately available.

(4) The birth center or advanced birth center shall assess and document ~~Annual assessments of~~ the transportation services

and transfer protocols annually ~~shall be made and documented~~.

Section 15. Section 383.318, Florida Statutes, is amended to read:

383.318 Postpartum care for birth center and advanced birth center clients and infants.—

(1) A mother and her infant shall be dismissed from a ~~the~~ birth center within 24 hours after the birth of the infant, except in unusual circumstances as defined by rule of the agency. If a mother or an infant is retained at the birth center for more than 24 hours after the birth, a report shall be filed with the agency within 48 hours of the birth describing the circumstances and the reasons for the decision.

(2)(a) A mother and her infant shall be discharged from an advanced birth center within 48 hours after the birth of the infant for a vaginal delivery and within 72 hours when delivery is by cesarean section, except in unusual circumstances defined by rule of the agency.

(b) If a mother or an infant is retained at the advanced birth center for more than the timeframes set forth in paragraph (a), a report shall be filed with the agency within 48 hours after the scheduled discharge time describing the circumstances and the reasons for the decision.

(3) ~~(2)~~ A prophylactic shall be instilled in the eyes of each newborn in accordance with s. 383.04.

(4) ~~(3)~~ Postpartum evaluation and followup care shall be

provided, which shall include:

(a) Physical examination of the infant.

(b) Metabolic screening tests required by s. 383.14.

(c) Referral to sources for pediatric care.

(d) Maternal postpartum assessment.

(e) Instruction in child care, including immunization, breastfeeding, safe sleep practices, and possible causes of Sudden Unexpected Infant Death.

(f) Family planning services.

(g) Referral to secondary or tertiary care, as indicated.

Section 16. Section 383.324, Florida Statutes, is amended to read:

383.324 Inspections and investigations; inspection fees.—Each birth center and advanced birth center ~~facility~~ licensed under s. 383.305 shall pay to the agency an inspection fee established by rule of the agency. In addition to the requirements of part II of chapter 408, the agency shall coordinate all periodic inspections for licensure made by the agency to ensure that the cost to the birth center and advanced birth center ~~facility~~ of such inspections and the disruption of services by such inspections is minimized.

Section 17. Section 383.327, Florida Statutes, is amended to read:

383.327 Birth and death records; reports.—Each licensed birth center and advanced birth center shall:

(1) File a completed certificate of birth ~~shall be filed~~ with the local registrar within 5 days of each birth in accordance with chapter 382.

(2) Immediately report each maternal death, newborn death, and stillbirth ~~shall be reported immediately~~ to the medical examiner.

(3) ~~The licensee shall~~ Comply with all requirements of this chapter and rules promulgated hereunder.

(4) Annually submit a report ~~shall be submitted annually~~ to the agency. The contents of the report shall be prescribed by rule of the agency.

Section 18. Section 383.33, Florida Statutes, is amended to read:

383.33 Administrative penalties; moratorium on admissions.—

(1) In addition to the requirements of part II of chapter 408, the agency may impose an administrative fine not to exceed $500 per violation per day for the violation of any provision of ss. 383.30-383.335, part II of chapter 408, or applicable rules.

(2) In determining the amount of the fine to be levied for a violation, as provided in this section, the following factors shall be considered:

(a) The severity of the violation, including the probability that death or serious harm to the health or safety of any person will result or has resulted; the severity of the

actual or potential harm; and the extent to which the provisions of ss. 383.30-383.335, part II of chapter 408, or applicable rules were violated.

(b) Actions taken by the licensee to correct the violations or to remedy complaints.

(c) Any previous violations by the licensee.

(3) In accordance with part II of chapter 408, the agency may impose an immediate moratorium on elective admissions to any licensed birth center or advanced birth center ~~facility~~, building or portion thereof, or service when the agency determines that any condition in the center ~~facility~~ presents a threat to the public health or safety.

Section 19. Section 383.332, Florida Statutes, is amended to read:

383.332 Establishing, managing, or operating a birth center or an advanced birth center without a license; penalty.—Any person who establishes, conducts, manages, or operates any birth center or advanced birth center ~~facility~~ without a license issued under s. 383.305 and part II of chapter 408 commits a misdemeanor and, upon conviction, shall be fined not more than $100 for the first offense and not more than $500 for each subsequent offense; and each day of continuing violation after conviction shall be considered a separate offense.

Section 20. Subsection (11) of section 465.003, Florida Statutes, is amended to read:

465.003 Definitions.—As used in this chapter, the term:

(11)(a) "Pharmacy" includes a community pharmacy, an institutional pharmacy, a nuclear pharmacy, a special pharmacy, and an Internet pharmacy.

1. The term "community pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis.

2. The term "institutional pharmacy" includes every location in a hospital, clinic, advanced birth center, nursing home, dispensary, sanitarium, extended care facility, or other facility, hereinafter referred to as "health care institutions," where medicinal drugs are compounded, dispensed, stored, or sold.

3. The term "nuclear pharmacy" includes every location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold. The term "nuclear pharmacy" does not include hospitals licensed under chapter 395 or the nuclear medicine facilities of such hospitals.

4. The term "special pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold if such locations are not otherwise defined in this subsection.

5. The term "Internet pharmacy" includes locations not otherwise licensed or issued a permit under this chapter, within

or outside this state, which use the Internet to communicate with or obtain information from consumers in this state and use such communication or information to fill or refill prescriptions or to dispense, distribute, or otherwise engage in the practice of pharmacy in this state. Any act described in this definition constitutes the practice of pharmacy as defined in subsection (13).

(b) The pharmacy department of any permittee shall be considered closed whenever a Florida licensed pharmacist is not present and on duty. The term "not present and on duty" shall not be construed to prevent a pharmacist from exiting the prescription department for the purposes of consulting or responding to inquiries or providing assistance to patients or customers, attending to personal hygiene needs, or performing any other function for which the pharmacist is responsible, provided that such activities are conducted in a manner consistent with the pharmacist's responsibility to provide pharmacy services.

Section 21. Paragraph (c) of subsection (2) of section 465.019, Florida Statutes, is amended to read:

465.019 Institutional pharmacies; permits.—

(2) The following classes of institutional pharmacies are established:

(c) "Modified Class II institutional pharmacies" are those institutional pharmacies in short-term, primary care treatment

centers and advanced birth centers that meet all the requirements for a Class II permit, except space and equipment requirements.

Section 22. This act shall take effect July 1, 2018.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 6057 Office of Public and Professional Guardians Direct-Support Organization
SPONSOR(S): Fischer
TIED BILLS: **IDEN./SIM. BILLS:** SB 498

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Children, Families & Seniors Subcommittee	12 Y, 0 N	Beattie	Brazzell
2) Health Care Appropriations Subcommittee		Clark	Pridgeon
3) Health & Human Services Committee			

SUMMARY ANALYSIS

A guardian is someone who is appointed by the court to act on behalf of a ward (an individual who has been adjudicated incapacitated) regarding his or her person or property or both. The Office of Public and Private Guardians (OPPG) under the Department of Elder Affairs (DOEA) appoints local public guardian offices to provide guardianship services to individuals who do not have adequate income or assets to afford a private guardian and have no willing family or friend to serve.

Direct-support organizations (DSOs) are statutorily authorized entities that are generally required to be non-profit organizations and may carry out specific tasks in support of public entities or public causes. In 2014, the Legislature created s. 20.058, F.S., which establishes a comprehensive set of transparency and reporting requirements for DSOs and sets a repeal date of October 1 of the fifth year after the DSO's enactment unless the DSO is reenacted by the Legislature.

Section 744.2105, F.S., authorizes a DSO to support the OPPG. This section requires the OPPG DSO to be:

- A non-profit under Chapter 617, F.S.;
- Organized and operated to conduct programs and activities and generate funding for the OPPG; and
- Determined by the OPPG to be consistent with the goals, of the office, in the best interest of the state, and in accordance with the adopted goals and mission of the DOEA and the OPPG.

The Foundation for Indigent Guardianship, Inc. (FIG) is a DSO established in 2002 to support the OPPG. In 2006, FIG founded the Florida Guardianship Pooled Special Needs Trust (Trust). The Trust provides support to the OPPG by directing residual funds from the trust account of a deceased beneficiary to the OPPG. The OPPG uses this revenue to assist its local Offices of Public Guardianship with non-recurring expenses such as emergency funding and technological upgrades. Since inception in 2006, FIG has distributed over $1,000,000.00 to public guardianship programs through the pooled special needs trust. The amount of money received by the Trust varies from year to year, depending on how many Trust beneficiaries die and what assets they have. Removing the repeal will allow the local Offices of Public Guardianship to continue receiving this supplemental revenue from FIG.

HB 6057 removes the scheduled repeal date of October 1, 2018 for the OPPG's DSO.

This bill has a positive fiscal impact on the OPPG and the local Offices of Public Guardianship.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Guardianship

When an individual is unable to make legal decisions regarding his or her person or property, a guardian may be appointed to act on his or her behalf. A guardian is someone who is appointed by the court to act on behalf of a ward (an individual who has been adjudicated incapacitated) regarding his or her person or property or both.[1] Adjudicating a person totally incapacitated and in need of a guardian deprives a person of his or her civil and legal rights.[2] The Legislature has recognized that the least restrictive form of guardianship should be used to ensure the most appropriate level of care and the protection of that person's rights.[3]

The process to determine an individual's incapacity and the subsequent appointment of a guardian begins with a verified petition detailing the factual information supporting the reasons the petitioner believes the individual to be incapacitated, including the rights the alleged incapacitated person is incapable of exercising.[4] Once a person has been adjudicated incapacitated (termed a "ward"), the court appoints a guardian and the letters of guardianship are issued.[5] The order appointing a guardian must be consistent with the ward's welfare and safety, must be the least restrictive appropriate alternative, and must reserve to the ward the right to make decisions in all matters commensurate with his or her ability to do so.[6]

Who Can Be Appointed Guardian

The following may be appointed guardian of a ward:

- Any resident of Florida who is 18 years of age or older and has full legal rights and capacity;
- A nonresident if he or she is related to the ward by blood, marriage, or adoption;
- A trust company, a state banking corporation, or state savings association authorized and qualified to exercise fiduciary powers in this state, or a national banking association or federal savings and loan association authorized and qualified to exercise fiduciary powers in Florida;
- A nonprofit corporation organized for religious or charitable purposes and existing under the laws of Florida;
- A judge who is related to the ward by blood, marriage, or adoption, or has a close relationship with the ward or the ward's family, and serves without compensation;
- A provider of health care services to the ward, whether direct or indirect, when the court specifically finds that there is no conflict of interest with the ward's best interests; or
- A for-profit corporation that meets certain qualifications, including being wholly owned by the person who is the circuit's public guardian in the circuit where the corporate guardian is appointed.[7]

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[1] s. 744.102(9), F.S.
[2] s. 744.101(1), F.S.
[3] s. 744.101(2), F.S
[4] s. 744.3201, F.S.
[5] ss. 744.3371-744.345
[6] s. 744.2005, F.S.
[7] s. 744.309, F.S.

Relationship Between Guardian and Ward

The relationship between a guardian and his or her ward is a fiduciary one.[8] A fiduciary relationship exists between two persons when one of them is under a duty to act for or to give advice for the benefit of another upon matters within the scope of that relationship.[9] The guardian, as fiduciary, must:

- Act within the scope of the authority granted by the court and as provided by law;
- Act in good faith;
- Not act in a manner contrary to the ward's best interests under the circumstances; and
- Use any special skills or expertise the guardian possesses when acting on behalf of the ward.[10]

Additionally, s. 744.446, F.S., states that there is a fiduciary relationship between the guardian and the ward and that such relationship may not be used for the private gain of the guardian other than the remuneration for fees and expenses provided by law. As such, the guardian must act in the best interest of the ward and carry out his or her responsibilities in an informed and considered manner. Should a guardian breach his or her fiduciary duty to the ward, the court is authorized to intervene.[11]

Guardians are subject to the requirements of ch. 744, F.S. There are three main types of guardians: family or friends of the ward, professional guardians, and public guardians.[12] The two types of guardians overseen by the Department of Elder Affairs (DOEA) are public and professional guardians.[13]

Public Guardianship

In 1999 the Legislature created the "Public Guardianship Act" and established the Statewide Public Guardianship Office.[14] By December 2013, the OPPG expanded public guardianship services to cover all 67 counties.[15] In 2016, the Legislature renamed the Statewide Public Guardianship Office within the DOEA as the Office of Public and Professional Guardians (OPPG). The OPPG appoints local public guardians offices to provide guardianship services to people who do not have adequate income or assets to afford a private guardian and there is no willing family or friend to serve.[16] The executive director of the OPPG is responsible for the oversight of all public guardians.[17]

The executive director appoints a public guardian for each Office of the Public Guardian that is established under the OPPG.[18] There are currently 17 local offices throughout Florida that contract with the OPPG.[19] The public guardian must maintain a staff or contract with professionally qualified individuals to carry out the guardianship functions.[20]

The OPPG monitors the public guardians by conducting in-depth investigations into the local programs'[21] administration and use of financial resources.[22] The OPPG's fiscal monitoring includes

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[8] *Lawrence v. Norris,* 563 So. 2d 195, 197 (Fla. 1st DCA 1990); s. 744.361(1), F.S.
[9] *Doe v. Evans,* 814 So. 2d 370, 374 (Fla. 2002).
[10] s. 744.361(1), F.S.
[11] s. 744.446(4), F.S.
[12] ch. 744, F.S.
[13] s. 744.2001, F.S.
[14] s. 744.701, F.S. (1999).
[15] Florida is the only state, except for Delaware (which has three counties), to provide public guardian services in every county. Florida Department of Elder Affairs, Summary of Programs and Services, February, 2014, *available at* http://elderaffairs.state.fl.us/doea/pubs/pubs/sops2014/2014%20SOPS_complete.pdf (last visited March 16, 2016).
[16] Department of Elder Affairs, *Office of Public and Professional Guardians*, available at http://elderaffairs.state.fl.us/doea/spgo.php (last visited January 8, 2018).
[17] s. 744.7021(2), F.S.
[18] s. 744.2006(1), F.S.
[19] Department of Elder Affairs, *Office of Public and Professional Guardians*, available at http://elderaffairs.state.fl.us/doea/spgo.php (last visited January 8, 2018).
[20] Id.
[21] These are entities that have contracted with OPPG to provide public guardian services.

investigating whether public guardians are spending state resources and wards' assets reasonably.[23] The OPPG reviews the case files and notes if there are any show cause orders or other issues that need to be addressed; additionally, the OPPG conducts random site visits for at least 20% of the wards belonging to each public guardian.[24]

A public guardian may serve as a guardian of a person adjudicated incapacitated under Chapter 744, F.S. if there is no other family member or friend, bank, or corporation willing to serve as a guardian.[25] Public guardians primarily serve incapacitated persons who are of limited financial means, as defined by contract or rule with the DOEA.[26] A public guardian may serve incapacitated persons of greater financial means at the DOEA's discretion.[27]

Powers and Duties of the Guardian

The guardian of an incapacitated person may exercise only those rights that have been removed from the ward and delegated to the guardian.[28] The guardian has a great deal of power when it comes to managing the ward's estate. Some of these powers require court approval before they may be exercised.

Examples of Powers That May Be Exercised By a Guardian	
Upon Court Approval[29]	**Without Court Approval[30]**
• Enter into contracts that are appropriate for, and in the best interest of, the ward. • Perform, compromise, or refuse performance of a ward's existing contracts. • Alter the ward's property ownership interests, including selling, mortgaging, or leasing any real property (including the homestead), personal property, or any interest therein • Borrow money to be repaid from the property of the ward or the ward's estate. • Renegotiate, extend, renew, or modify the terms of any obligation owing to the ward. • Prosecute or defend claims or proceedings in any jurisdiction for the protection of the estate. • Exercise any option contained in any policy of insurance payable to the ward. • Make gifts of the ward's property members of the ward's family in estate and income tax planning. • Pay reasonable funeral, interment, and grave marker expenses for the ward.	• Retain assets owned by the ward. • Receive assets from fiduciaries or other sources. • Insure the assets of the estate against damage, loss, and liability. • Pay taxes and assessments on the ward's property. • Pay reasonable living expenses for the ward, taking into consideration the ward's current finances. • Pay incidental expenses in the administration of the estate. • Prudently invest liquid assets belonging to the ward. • Sell or exercise stock subscription or conversion rights. • Consent to the reorganization, consolidation, merger, dissolution, or liquidation of a corporation or other business enterprise of the ward. • Employ, pay, or reimburse persons, including attorneys, auditors, investment advisers, care managers, or agents, even if they are associated with the guardian, to advise or assist the guardian in the performance of his or her duties.

[22] Email from Department of Elder Affairs, *FW: DOEA Summary of Programs and Services (override)*, March 16, 2015. (on file with Children, Families, and Seniors Subcommittee staff).
[23] Id.
[24] Id.
[25] s. 744.2007(1), F.S.
[26] s. 744.2007(3), F. S.
[27] *Id.*
[28] s. 744.361(1), F.S.
[29] s. 744.441, F.S.
[30] s. 744.444, F.S.

Direct Support Organizations (DSOs)

Direct-support organizations (DSOs) are statutorily sanctioned entities that are generally required to be non-profit organizations[31] and are authorized to carry out specific tasks in support of public entities or public causes. In 2014, the Legislature conducted a review of the relationships between DSOs and the government entities they support.[32] The review prompted the creation of s. 20.058, F.S. This section serves two important functions: it establishes a comprehensive set of transparency and reporting requirements for DSOs, and it sets a repeal date of October 1 of the fifth year after enactment unless the DSO is reenacted by the Legislature.[33]

Reporting and Audit Requirements for DSOs

The law specifically requires each DSO to annually submit by August 1st the following information to the agency it supports:[34]

- The name, mailing address, telephone number, and website address of the DSO;
- The statutory authority or executive order that created the DSO;
- A brief description of the mission of, and results obtained by, the DSO;
- A brief description of the DSO's plans for the next three fiscal years;
- A copy of the DSO's code of ethics; and
- A copy of the DSO's most recent Internal Revenue Service (IRS) Form 990.

This information must be made available by the agency receiving the information through its website.[35] The agency must also provide a link to the organization's website, if one exists.[36] Any contract between an agency and a DSO is contingent upon the DSO's submission of this information and the subsequent online posting by the agency.[37] The agency head can terminate a contract if an organization fails to submit the required information for two consecutive years.[38]

By August 15th every year, the agency must report the information provided by the DSO to the Governor, the President of the Senate, the Speaker of the House of Representatives, and the Office of Program Policy Analysis and Government Accountability.[39] The agency report must also include the agency's recommendation, with supporting rationale, to continue, terminate, or modify the agency's association with each DSO.[40]

In addition to these reporting requirements, DSOs are subject to audits by the Auditor General[41] and are subject to public records requirements.

The Department of Elder Affairs' DSO Authorization

Section 744.2105, F.S., authorizes a direct-support organization to support the OPPG. This section requires the DSO to be:

- A non-profit under Chapter 617, F.S.;
- Organized and operated to conduct programs and activities and generate funding for the OPPG; and

[31] Chapter 617, F.S.
[32] s. 20.058, F.S.
[33] *Id.*
[34] s. 20.058(1), F.S.
[35] s. 20.058(2), F.S.
[36] *Id.*
[37] s. 20.058(4), F.S.
[38] *Id.*
[39] s. 20.058(3), F.S.
[40] *Id.*
[41] s. 11.45(3), F.S.

- Determined by the OPPG to be consistent with the goals, of the office, in the best interest of the state, and in accordance with the adopted goals and mission of the DOEA and the OPPG.[42]

The DSO operates under a written contract with the OPPG that ensures that the DSO is complying with the intended goals and purposes of the office and in the best interest of the state.[43] If the DSO ceases to exist, the money and property it holds in trust must be reverted to the OPPG.[44] The DOEA Secretary appoints the board of directors for the DSO from a list of nominees submitted by the executive director of the OPPG.[45] The DOEA may allow the DSO to use its facilities at the agency's discretion.[46] All money held by the DSO must be held in a separate account in the name of the DSO, and must be expressly used to support the OPPG, and not for lobbying.[47] The DSO must provide for an annual financial audit in accordance with Section 215.981, F.S.[48] The DSO is repealed October 1, 2018, unless it is reviewed and saved from repeal.[49]

The Foundation for Indigent Guardianship, Inc. (FIG)

The Foundation for Indigent Guardianship, Inc. (FIG) is a DSO established in 2002 to support the OPPG within the DOEA. In 2006, FIG founded the Florida Guardianship Pooled Special Needs Trust (Trust). The Trust provides support to the OPPG by directing residual funds from the trust account of a deceased beneficiary to the OPPG.[50]

Pooled Special Needs Trusts

Special needs trusts are established under federal law specifically for the benefit of beneficiaries who have a mental illness or are disabled and are under age 65.[51] These trusts are designed to sequester the assets of beneficiaries so they are still financially eligible for government assistance such as Medicaid and SSI benefits. The beneficiary's own money, or money given by a family member or other person, may be included in a special needs trust.[52] The funds held in special needs trusts may only be used to provide beneficiaries with comforts that Medicaid and SSI do not offer.[53] When a beneficiary dies, the remaining funds in their special needs trust account is used to off-set the Medicare and SSI money that states provided to the beneficiary during his or her life.[54]

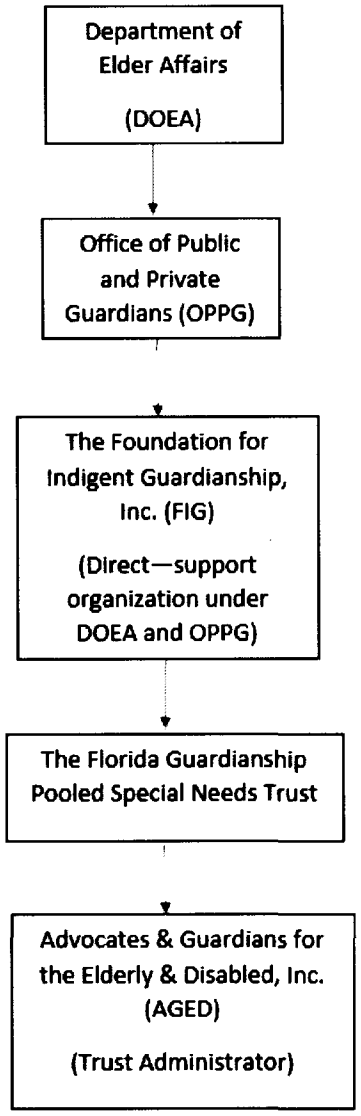
To reduce the administrative costs related to operating a trust, a beneficiary may choose to keep his or her money in a pooled special needs trust. These trusts are administered by non-profit organizations, and manage separate accounts for each beneficiary (called "trust sub accounts" or "TSAs").[55] Each beneficiary also has his or her own trustee, who manages the assets and disbursements related to the trust account.[56]

The Florida Guardianship Pooled Special Needs Trust

The Florida Guardianship Pooled Special Needs Trust has two purposes: to ensure that Trust beneficiaries qualify for government assistance, and to enable FIG to further its not-for-profit purpose of

[42] s. 744.2105(1), F.S.
[43] s. 744.2105(2), F.S.
[44] *Id.*
[45] s. 744.2105(3), F.S.
[46] s. 744.2105(4), F.S.
[47] s. 744.2105(5), F.S.
[48] s. 744.2105(7), F.S.
[49] s. 744.2105(8), F.S.
[50] s. 744.2105, F.S.
[51] 42 U.S.C. § 1396p(d)(4)
[52] *Id.*
[53] National Academy of Elder Law Attorneys, Inc., *Special Needs Trust Fairness Act (H.R. 670/S. 349)*, https://www.naela.org/NAELADocs/114th%20SNTFA%20Updated%201pger.pdf (last visited 1/11/2018).
[54] 42 U.S.C. § 1396p(d)(4).
[55] 42 U.S.C. § 1396p(d)(4)(C).
[56] *Id.*

providing funding to the OPPG.[57] FIG is the Founding Trustee.[58] As of November 28, 2016, the Administrative Trustee became the Advocates & Guardians for the Elderly & Disabled, Inc., (AGED), a non-profit organization under Chapter 617, F.S.[59] In this capacity, AGED is authorized to manage and administer the Trust and its separate TSAs.[60] The amount of fees, costs, and expenses associated with each TSA are determined by AGED and set out in its fee schedule.[61] There are currently 70 beneficiaries in the Trust.



Funds Provided to OPPG

When a beneficiary in the Florida Guardianship Pooled Special Needs Trust dies, AGED uses the remainder of the funds in his or her personal account to pay back the State for the government

[57] *Amended and Restated Master Trust Declaration of The Florida Public Guardianship Pooled Special Needs Trust*, Art.2 Sec.8 Purpose, Intent and Design (on file with Children, Families, and Seniors Subcommittee staff).
[58] *Amended and Restated Master Trust Declaration of The Florida Public Guardianship Pooled Special Needs Trust*, Art.1 Sec.4 Purpose, Intent and Design (on file with Children, Families, and Seniors Subcommittee staff).
[59] *Amended and Restated Master Trust Declaration of The Florida Public Guardianship Pooled Special Needs Trust*, Art.1 Sec.1 Purpose, Intent and Design (on file with Children, Families, and Seniors Subcommittee staff).
[60] *Amended and Restated Master Trust Declaration of The Florida Public Guardianship Pooled Special Needs Trust*, Art.2 Sec.6 Purpose, Intent and Design (on file with Children, Families, and Seniors Subcommittee staff).
[61] *Amended and Restated Master Trust Declaration of The Florida Public Guardianship Pooled Special Needs Trust*, Art.6 Sec.4 Purpose, Intent and Design (on file with Children, Families, and Seniors Subcommittee staff).

assistance paid to the beneficiary during life.[62] Any residual funds after this pay-back are deposited in the FIG Operating Account.[63] Of these residual funds, 10% remain in the operating account, 10% are transferred to the emergency account, and 80% are awarded to OPPG.[64]

Residual Trust Awards

Once residual funds become available, FIG notifies the local Office of Public Guardianship in the circuit where the residual funds originated of the available funds and requests information as to how the local office proposes to use the funds.[65] The local Office of Public Guardianship then responds to FIG with an itemization of how the funds would be spent.[66] The FIG Board of Directors reviews the itemized request to ensure funds are being used to help provide non-recurring "public guardianship" services.[67] After the FIG Board approves the expenditure, it forwards the itemized request to the OPPG Director for final review and approval. After the OPPG Director approves the request, FIG requests for a check for the award to be mailed to the local Office of Public Guardianship.[68] One example of these awards is a disbursement of $5,487.59 to Seniors First, Inc., to modernize their equipment and expand the capacity of the guardianship department.[69] FIG's trust income in found on its 990 tax filings.[70] FIG's trust income since 2009 is as follows:[71]

- 2009: $136,338
- 2010: $687,217
- 2011: $433,055
- 2012: $200,062
- 2013: $103,280
- 2014: $18,681
- 2015: $274,597

Emergency Fund Awards

Beginning in Fiscal Year 2016-2017, FIG established a new Emergency Fund Award opportunity to help local Offices of Public Guardianship when an unbudgeted need arises.[72] A local Office of Public Guardianship may request an Emergency Fund Award from FIG at any time by providing an itemized request of how funds will be spent.[73] Examples of these requests are travel for educational purposes, hurricane relief, and equipment failure.[74] The FIG Board of Directors also reviews these itemized requests.[75]

Other Services Provided by FIG

FIG provides other resources to OPPG besides funds from the special needs trust.[76] These include complimentary educational opportunities for the staff of public guardianship programs, as well as other educational projects to educate the public about the needs of public guardians and those they serve.[77]

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[62] Email from Jon Conley, Director of Legislative Affairs, Department of Elder Affairs, RE: DSO Follow-up (override), (Dec. 21, 2017) (on file with Children, Families, and Seniors Subcommittee staff).
[63] *Id.*
[64] *Id.*
[65] *Id.*
[66] *Id.*
[67] *Id.*
[68] *Id.*
[69] Letter from OPPG to FIG President, December 14, 2017 (on file with Children, Families, and Seniors Subcommittee staff).
[70] On file with the Children, Families, and Seniors Subcommittee.
[71] *Id.*
[72] Email from Jon Conley, Director of Legislative Affairs, Department of Elder Affairs, FW: DSO Follow-up (override), (Dec. 21, 2017) (on file with Children, Families, and Seniors Subcommittee staff).
[73] *Id.*
[74] *Id.*
[75] *Id.*
[76] Department of Elder Affairs, Agency Analysis of 2018 House Bill 6057, p. 4 (Dec. 14, 2017).

Oversight of FIG: Audits

FIG has been audited every year since its inception, and copies of its audits are provided to the DOEA as required by statute.[78] No issues or findings by the auditing firms have been reported thus far.[79] Since the Amended and Restated Master Trust Declaration went into effect in 2016 and FIG transferred to its current trust administrator (AGED), the FIG Board has not seen a need to conduct an audit of the special needs trust account.[80] To facilitate oversight of the trust administrator, since 2017, AGED provides monthly reports to all FIG Board members.[81] These monthly reports list each subaccount by name and account number as well as county of origin and total cash value.[82]

Effect of Proposed Changes

HB 6057 removes the scheduled repeal date for the DSO for the OPPG within the DOEA. This will allow the OPPG's DSO to continue in existence and thus facilitate the provision of additional funds to the local public guardian programs.

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

B. SECTION DIRECTORY:

Section 1: Amends s. 744.2105, F.S., relating to direct-support organization; definition; use of property; board of directors; audit; dissolution.
Section 2: Provides an effective date of July 1, 2018.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None. However, entities contracting with DOEA will receive additional revenue. See Fiscal Comments.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

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[77] *Id.*
[78] Email from Vicki Simmons, FIG Executive Director, January 5, 2018, FW: Additional Information for House Staff RE DSO Re-authorization (OVERRIDE), (Jan. 5, 2018).
[79] *Id.*
[80] *Id.*
[81] *Id.*
[82] *Id.*

The contracted entities serving as local public guardians will continue to receive additional revenue. See Fiscal Comments.

D. FISCAL COMMENTS:

Since inception in 2006, FIG has distributed over $1,000,000 to public guardianship programs through revenues generated by the pooled special needs trust.[83] Of the residual funds from trust accounts that are collected by FIG when a beneficiary dies, 10% remain in the operating account, 10% are transferred to the emergency account, and 80% are awarded to OPPG.[84] The amount of money received by FIG varies from year to year, depending on how many trust beneficiaries die and what assets they have. FIG's trust income since 2009 is as follows:[85]

- 2009: $136,338
- 2010: $687,217
- 2011: $433,055
- 2012: $200,062
- 2013: $103,280
- 2014: $18,681
- 2015: $274,597

Removing the repeal will allow the local Offices of Public Guardianship to continue receiving this revenue from FIG.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not Applicable. This bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

[83] Department of Elder Affairs, Agency Analysis of 2018 House Bill 6057, p. 4 (Dec. 14, 2017)(on file with Children, Families, and Seniors staff).
[84] *Id.*
[85] *Id.*

A bill to be entitled

An act relating to the Office of Public and Professional Guardians direct-support organization; amending s. 744.2105, F.S.; abrogating the scheduled repeal of provisions governing a direct-support organization established under the Office of Public and Professional Guardians within the Department of Elderly Affairs; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 744.2105, Florida Statutes, is amended to read:

744.2105 Direct-support organization; definition; use of property; board of directors; audit; dissolution.—

(1) DEFINITION.—As used in this section, the term "direct-support organization" means an organization whose sole purpose is to support the Office of Public and Professional Guardians and is:

(a) A not-for-profit corporation incorporated under chapter 617 and approved by the Department of State;

(b) Organized and operated to conduct programs and activities; to raise funds; to request and receive grants, gifts, and bequests of moneys; to acquire, receive, hold, invest, and administer, in its own name, securities, funds,

objects of value, or other property, real or personal; and to make expenditures to or for the direct or indirect benefit of the Office of Public and Professional Guardians; and

(c) Determined by the Office of Public and Professional Guardians to be consistent with the goals of the office, in the best interests of the state, and in accordance with the adopted goals and mission of the Department of Elderly Affairs and the Office of Public and Professional Guardians.

(2) CONTRACT.—The direct-support organization shall operate under a written contract with the Office of Public and Professional Guardians. The written contract must provide for:

(a) Certification by the Office of Public and Professional Guardians that the direct-support organization is complying with the terms of the contract and is doing so consistent with the goals and purposes of the office and in the best interests of the state. This certification must be made annually and reported in the official minutes of a meeting of the direct-support organization.

(b) The reversion of moneys and property held in trust by the direct-support organization:

1. To the Office of Public and Professional Guardians if the direct-support organization is no longer approved to operate for the office;

2. To the Office of Public and Professional Guardians if the direct-support organization ceases to exist;

3. To the Department of Elderly Affairs if the Office of Public and Professional Guardians ceases to exist; or

4. To the state if the Department of Elderly Affairs ceases to exist.

The fiscal year of the direct-support organization shall begin on July 1 of each year and end on June 30 of the following year.

(c) The disclosure of the material provisions of the contract, and the distinction between the Office of Public and Professional Guardians and the direct-support organization, to donors of gifts, contributions, or bequests, including such disclosure on all promotional and fundraising publications.

(3) BOARD OF DIRECTORS.—The Secretary of Elderly Affairs shall appoint a board of directors for the direct-support organization from a list of nominees submitted by the executive director of the Office of Public and Professional Guardians.

(4) USE OF PROPERTY.—The Department of Elderly Affairs may permit, without charge, appropriate use of fixed property and facilities of the department or the Office of Public and Professional Guardians by the direct-support organization. The department may prescribe any condition with which the direct-support organization must comply in order to use fixed property or facilities of the department or the Office of Public and Professional Guardians.

(5) MONEYS.—Any moneys may be held in a separate

depository account in the name of the direct-support organization and subject to the provisions of the written contract with the Office of Public and Professional Guardians. Expenditures of the direct-support organization shall be expressly used to support the Office of Public and Professional Guardians. The expenditures of the direct-support organization may not be used for the purpose of lobbying as defined in s. 11.045.

(6) PUBLIC RECORDS.—Personal identifying information of a donor or prospective donor to the direct-support organization who desires to remain anonymous is confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

(7) AUDIT.—The direct-support organization shall provide for an annual financial audit in accordance with s. 215.981.

(8) DISSOLUTION.—A not-for-profit corporation incorporated under chapter 617 that is determined by a circuit court to be representing itself as a direct-support organization created under this section, but that does not have a written contract with the Office of Public and Professional Guardians in compliance with this section, is considered to meet the grounds for a judicial dissolution described in s. 617.1430(1)(a). The Office of Public and Professional Guardians shall be the recipient for all assets held by the dissolved corporation which accrued during the period that the dissolved corporation represented itself as a direct-support organization created

under this section.

~~(9) REPEAL.—This section is repealed October 1, 2018, unless reviewed and saved from repeal by the Legislature.~~

Section 2. This act shall take effect July 1, 2018.