The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Committee on Appropriations

BILL: CS/CS/SB 966

INTRODUCER: Appropriations Committee; Health Policy Committee; and Senator Bean

SUBJECT: Health Care

DATE: April 22, 2013 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Stovall	HP	**Fav/CS**
2.	Brown	Hansen	AP	**Fav/CS**
3.				
4.				
5.				
6.				

Please see Section VIII. for Additional Information:

A. COMMITTEE SUBSTITUTE.....	X	Statement of Substantial Changes
B. AMENDMENTS........................		Technical amendments were recommended
		Amendments were recommended
		Significant amendments were recommended

I. Summary:

CS/CS/SB 966 amends various sections of Florida law relating to health care.

The bill has fiscal impacts that can be absorbed within existing resources.

The bill amends the Florida Statutes to:

- Allow the Department of Highway Safety and Motor Vehicles (DHSMV) to share the digital image and signature of driver licensees with the Agency for Health Care Administration (AHCA) for the purpose of verifying photographs in the Care Provider Background Screening Clearinghouse (CPBSC or Clearinghouse);
- Revise the regulations for trauma centers to:
  - Repeal legislative findings and intent language;
  - Amend the definitions of “level II trauma center” and “trauma center” to conform to changes made in the bill;
  - Strike the requirement to have the number and location of needed trauma centers in local and regional trauma plans;
  - Require regional trauma plans reflect well established patient flow patterns; and

  - Require the Department of Health (DOH) to designate level II trauma centers that are certified by the American College of Surgeons and are located in an area with limited access to trauma center services;
  - Define the criteria for areas with limited access to trauma center services;
  - Allow current level I, II and pediatric trauma centers to retain their designations unless they are unable to comply with the adopted standards for such centers;
  - Allow provisionally approved trauma centers to complete their applications; and
  - Strike all requirements in current law establishing the number and location of trauma centers except for the designation of counties into trauma service areas.
- Amend the definition of "nurse registry" to comply with provisions in the insurance code.
- Exempt the delivery of home dialysis services provided by a federally certified end-stage renal disease provider from the licensure requirements for home health agencies;
- Exclude certain health care facilities from the definition of "clinic" under section 400.9905, F.S.;
- Revise the regulations for transitional living facilities to:
  - Provide for admission criteria, client evaluations, treatment plans, and discharge plans; and
  - Establish rights for clients in these facilities, screening requirements for facility employees, and penalties for violations.
- Add certain crimes to the list of offenses which disqualify an applicant subject to a Level 2 background check from employment;
- Authorize an agency head to grant an exemption to disqualification if 3 years have elapsed since the applicant has completed all nonmonetary conditions for a felony offense and the applicant has paid all monetary costs associated with a disqualifying felony or misdemeanor;
- Extend the requirement for Medicaid recipients with HIV/AIDS to be referred to certain specialty plans beyond the sunset date of October 1, 2014.
- Require Medicaid managed care plans to to continue enrollees on their current medication when the plan's formulary changes if a provider submits a written request demonstrating that the drug is medically necessary;
- Strengthen the enforcement of current regulations for Assisted Living Facilities (ALF or facility). The changes include:
  - Revising the fines imposed for licensure violations;
  - Clarifying existing enforcement tools; and
  - Requiring additional inspections for facilities with significant violations.
- Allow nurses to provide assistance with portable oxygen, colostomy care, and anti-embolism stockings in a standard license ALF;
- Preempt the regulation of pharmacies and pain management clinics to the state under certain circumstances;
- Authorize health care entities to use out of state prescription drug repackagers under certain circumstances;
- Update various sections of law with the most current names for CARF International and the Joint Commission and add the American Osteopathic Association/Healthcare Facilities Accreditation Program to those organizations specifically recognized as accrediting organizations;

- Designate the Florida Hospital Sanford-Burnham Translational Research Institute for Metabolism and Diabetes (Institute) as a resource for research in the prevention and treatment of diabetes;
- Delete language requiring drug-testing laboratories to submit a monthly report to the AHCA;
- Allow hospitals, ambulatory surgical centers, and mobile surgical facilities to pay inspection fees at times other than the time of inspection;
- Repeal s. 395.1046, F.S., which currently grants the AHCA duplicative authority to investigate complaints related to access to emergency services and care;
- Delete obsolete language regarding the AHCA's list of primary and comprehensive stroke centers;
- Exempt all state operated hospitals, rather than only hospitals run by the Department of Corrections (DOC), from the annual assessments on net operating revenues for inpatient and outpatient services to fund public medical assistance required by s. 395.701, F.S.;
- Repeal the Public Medical Assistance Trust Fund (PMATF) assessment on health care entities which was found to be unconstitutional;
- Exempt state-operated hospitals from filing the Florida Hospital Uniform Reporting System (FHURS) report; and
- Exempt state-operated hospitals from an assessment used to fund the data collection and analysis activities of the AHCA.

The bill substantially amends the following sections of the Florida Statutes: 112.0455, 154.11, 322.142, 381.745, 381.75, 381.78, 394.4574, 394.741, 395.0161, 395.3038, 395.4001, 395.401, 395.4015, 395.402, 395.4025, 395.405, 395.701, 395.7016, 397.403, 400.0074, 400.0078, 400.462, 400.464, 400.925, 400.93, 400.9905, 400.9935, 402.7306, 408.061, 408.20, 408.802, 408.809, 408.820, 409.9122, 409.966, 409.967, 429.07, 429.075, 429.14, 429.178, 429.19, 429.26, 429.28, 429.34, 429.52, 430.80, 435.04, 435.07, 435.12, 440.102, 440.13, 465.1902, 499.003, 499.01, 499.01212, 499.041, 627.645, 627.668, 627.669, 627.736, 641.495, and 766.1015.

The bill creates the following sections of the Florida Statutes: 385.2035, 400.9970, 400.9971, 400.9972, 400.9973, 400.9974, 400.9975, 400.9976, 400.9977, 400.9978, 400.9979, 400.998, 400.9981, 400.9982, 400.9983, 400.9984, and 893.0552.

The bill creates two non-statutory provisions of Florida Law.

The bill repeals the following sections of the Florida Statutes: 395.1046, 395.40, 395.7015, and 400.805.

II. Present Situation:

Accrediting Organizations

In 2012, the Legislature enacted ch. 2012-66, L.O.F., which substantially amended the definition of "accrediting organizations" in s. 395.002, F.S. Prior to the passage of ch. 2012-66, L.O.F., the statutes defined "accrediting organizations" as the Joint Commission on Accreditation of Healthcare Organizations, the American Osteopathic Association, the Commission on Accreditation of Rehabilitation Facilities, and the Accreditation Association for Ambulatory

Health Care, Inc. Currently, the definition includes any national accreditation organizations that are approved by the federal Centers for Medicare and Medicaid Services[1] (CMS) and whose standards incorporate comparable licensure regulations required by the state.

The Joint Commission

The Joint Commission is a non-profit organization that accredits and certifies more than 20,000 health care organizations and programs in the United States.[2] The Joint Commission was established in 1951 as the Joint Commission on Accreditation of Hospitals. In 1987, the organization changed its name to the Joint Commission on Accreditation of Healthcare Organizations in order to reflect an expanded scope of activities. In 2007, the Joint Commission on Accreditation of Healthcare Organizations shorted its name to the Joint Commission in order to refresh its brand identity.[3] Currently, references to the Joint Commission on Accreditation of Healthcare Organizations remain in the Florida Statutes.

CARF International

What is now known as CARF International was founded in 1966 as the Commission on Accreditation of Rehabilitation Facilities when the National Association of Sheltered Workshops and Homebound Programs and the Association of Rehabilitation Centers agreed to pool their interests.[4] The CARF International is a non-profit accreditor of health and human services providers in multiple areas including aging services, behavioral health, and medical rehabilitation. The CARF family of organizations currently accredits close to 50,000 programs in countries across the globe.[5] Currently, the Florida Statutes still refer to CARF - the Commission on Accreditation of Rehabilitation Facilities or other similar monikers.

The American Osteopathic Association / Healthcare Facilities Accreditation Program

The Healthcare Facilities Accreditation Program (HFAP) is a program that is authorized by the CMS to survey hospitals for compliance with the Medicare Conditions of Participation. HFAP has maintained its authority to survey hospitals for compliance with the Medicare Conditions of Participation and Coverage since 1965 and meets or exceeds the standards required by CMS to provide accreditation to hospitals, ambulatory care/surgical facilities, mental health facilities, physical rehabilitation facilities, clinical laboratories, and critical access hospitals. The HFAP also provides certification reviews for Primary Stroke Centers.[6] The HFAP facility accreditation process consists of five basic steps including application, survey, reporting deficiencies, creating a plan of corrections/correct action response, and accreditation.[7]

[1] The Centers for Medicare and Medicaid Services is a division of the U.S. Department of Health and Human Services that oversees the Medicare and Medicaid programs at the federal level.
[2] About the Joint Commission, found at: http://www.jointcommission.org/about_us/about_the_joint_commission_main.aspx, last visited on Mar. 4, 2013.
[3] The Joint Commission History, found at: http://www.jointcommission.org/assets/1/6/Joint_Commission_History.pdf, last visited on Mar. 4, 2013
[4] History of CARF International, found at: http://www.carf.org/About/History/, last visited on Mar. 4, 2013.
[5] CARF International, found at: http://www.carf.org/About/WhoWeAre/, last visited on Mar. 4, 2013.
[6] HFAP Overview, found at http://www.hfap.org/about/overview.aspx, last visited on Mar. 14, 2013.
[7] Accreditation by HFAP, found at http://www.hfap.org/WhyHfap/workingwithhfap.aspx, last visited on Mar. 14, 2013.

Trauma Centers

The regulation of trauma centers in Florida is established under part II of ch. 395, F.S. Trauma centers treat individuals who have incurred single or multiple injuries because of blunt or penetrating means or burns, and who require immediate medical intervention or treatment.

Pursuant to s. 395.402, F.S., Florida is divided into 19 “trauma service areas.” A trauma service area is determined based on population density and an ability to respond to a specified number of patients in a trauma center environment. For purposes of medical response time, the trauma service area should have at least one Level I or Level II trauma center, and DOH is required to allocate, by rule, the number of trauma centers for each trauma service area. There cannot be more than 44 trauma centers in the state.

On November 30, 2012, the Florida First District Court of Appeal upheld a circuit court ruling which invalidated DOH Rule 64J-2.010, F.A.C.[8] The rule mirrored exactly the allocation of trauma service areas in s. 395.402(4), F.S., even though the statute required the DOH to review the assignment of counties to trauma service areas annually. In its opinion the court stated that the trauma statutes were substantially amended in 2004 but the rule remained unchanged since 1992. As such, the rule continued to implement the outdated provisions of these statutes.[9] In response to this ruling, the DOH began a series of nine workshops to gather input from the public in order to rewrite Rule 64J-2.010, F.A.C. These workshops concluded on March 28, 2013 and the DOH is currently working on a new rule using the input from these workshops and the upcoming final report of the American College of Surgeons Committee on Trauma systems consultation team which is scheduled to be available in early May, 2013.[10]

Section 395.401, F.S., requires local and regional trauma agencies to develop and submit plans for local and regional trauma service systems to DOH. The plans must include, among other things:

- The organizational structure of the trauma system;
- Pre-hospital care management guidelines for triage and transportation of trauma cases;
- Flow patterns of trauma cases and transportation system design and resources; and
- The number and location of needed trauma centers based on local needs, population, and location of resources.

Section 395.4025, F.S., provides a scheduled application process and specific trauma center selection criteria. Standards for verification and approval are based on national guidelines established by the American College of Surgeons.[11] Standards for verification and approval as a pediatric center are developed in conjunction with Children's Medical Services.

[8] *Department of Health v. Bayfront Medical Center, Inc.*, Fla. App. 1 Dist., 2012, on file with Health Policy Committee.
[9] Id., p. 5
[10] DOH press release, dated March 28, 2013, found at: http://www.doh.state.fl.us/demo/trauma/PDFs/032813PressRelease-TraumaRuleWorkshopsConclude.pdf, last visited on April 16, 2013.
[11] The ACS requirements for Level I, Level II, and pediatric trauma centers are available at: http://www.facs.org/trauma/verifivisitoutcomes.html, last visited on April 19, 2013.

The DOH has adopted rules pertaining to the procedures and process by which it will select trauma centers.

Clinics

Currently, clinics in the State of Florida must be licensed by the Agency for Health Care Administration (AHCA).[12] However, there are numerous exclusions from the definition of "clinic" under s. 400.9905(a)-(n), F.S.

Brain and Spinal Cord Injuries

The human spinal cord operates much like a telephone line, relaying messages from the brain to the rest of the body. Spinal cord injuries are caused by bruising, crushing, or tearing of the delicate cord tissue. After an injury, the "messages" sent between the brain and the other parts of the body no longer flow through the damaged area. Many times the functions of the body which are located above the injury point will continue to work properly without impairment. However, the area below the injury point will be impaired to some degree, which will include any combination of the following: motor deficit, sensory deficit, initial breathing difficulty, and/or bowel and bladder dysfunction.13

The Brain and Spinal Cord Injury Program (BSCIP) is administered by the Florida Department of Health (DOH). The program is funded through a percentage of traffic related fines and surcharges for driving or boating under the influence, fees on temporary license tags, and a percentage of fees from the motorcycle specialty tag.14

The BSCIP is operated through a statewide system of case managers and rehabilitation technicians. Children receive services from the Children's Medical Services nurse care coordinators and human services counselors. The program also employs regional managers who supervise staff in their region and who oversee locally the operation, development, and evaluation of the program's services and supports. Services include: case management, acute care, inpatient and outpatient rehabilitation, transitional living, assistive technology, home and vehicle modifications, nursing home transition facilitation; and long-term supports for survivors and families through contractual agreements with community-based agencies.

In addition to providing resource facilitation and funding for the services above, the program funds education, prevention, and research activities. It expands its services by funding a contract with the Brain Injury Association of Florida and the Florida Disabled Outdoors Association. Other services are provided through working relationships with the Florida Centers for Independent Living and the Florida Department of Education, Division of Vocational Rehabilitation.

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[12] s. 400.991, F.S.

[13] Florida Spinal Cord Injury Resource Center, *Family and Survivor's Guide*, *available at* http://fscirc.com/what-is-a-sci (last visited April 3, 2013).

[14] Florida Department of Health website, *available at* http://www.doh.state.fl.us/demo/BrainSC/index.html/ (last visited April 3, 2013).

Section 381.76, F.S., requires an individual to be a legal Florida resident who has sustained a moderate-to-severe traumatic brain or spinal cord injury meeting the state's definition of such injuries, be referred to the BSCIP Central Registry, be medically stable, and be reasonably expected to achieve reintegration into the community through the services provided to be eligible for services.

The state definition of a brain injury is an insult to the skull, brain or its covering, resulting from external trauma that produces an altered state of consciousness or anatomic, motor, sensory, cognitive or behavioral deficit. The state definition of a spinal cord injury is a lesion to the spinal cord or cauda equina resulting from external trauma with evidence of significant involvement of two of the following-motor deficit, sensory deficit, or bowel and bladder dysfunction.[15]

Transitional Living Facilities

Transitional living facilities provide specialized health care services, including, but not limited to, rehabilitative services, community reentry training, aids for independent living, and counseling to spinal-cord-injured persons and head-injured persons. There are currently 13 facilities located in the state.[16] Most of the facilities have between 5 and 10 beds, however, the Florida Institute for Neurologic Rehabilitation in Wauchula is licensed for 127 beds.[17] Most facilities are located in Central Florida and the Agency for Health Care Administration (AHCA) licenses and is one of the regulators of transitional living facilities.[18] The current licensure fee is $4,588, and $90 per bed fee per biennium.

The AHCA governs the physical plant and fiscal management of these facilities and adopts rules in conjunction with the DOH, which monitors services for persons with traumatic brain and spinal cord injuries. The Department of Children and Families (DCF) investigates allegations of abuse and neglect of children and vulnerable adults.[19]

Section 400.805, F.S., creates requirements for transitional living facilities. Section 400.805(2), F.S., provides the licensure requirements and fees for operation of a transitional living facility as well as the requirement to obtain a Level 2 background screening for all facility personnel. Section 400.805(3)(a), F.S., requires the AHCA, in consultation with the DOH, to adopt rules governing the physical plant and the fiscal management of transitional living facilities.

The Brain and Spinal Cord Injury Advisory Council has the right to entry and inspection of transitional living facilities granted under s. 400.805(4), F.S. In addition, designated representatives of AHCA, the local fire marshal, and other agencies have access to the facilities and clients.

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[15] S. 381.745, F.S.

[16] Agency for Health Care Administration, *2013 Bill Analysis and Economic Impact Statement SB 1724*, (on file with the Senate Health Policy Committee).

[17] Florida Institute for Neurologic Rehab, Inc. found at http://www.floridahealthfinder.gov/facilitylocator/FacilityProfilePage.aspx?id=28343, last visited on April 4, 2013.

[18] See 408, Part II, and ch. 400, Part V, F. S., and ch. 59A-17, F.A.C.

[19] Id. n. 4.

According to a news report from Bloomberg, dated January 24, 2012, clients at the Florida Institute for Neurologic Rehabilitation in Wauchula, Florida, were abused, neglected and confined. The news report was based on information from 20 current and former clients and their family members, criminal charging documents, civil complaints and advocates for the disabled.[20] The report states that three former employees face criminal charges for abusing clients. News reports state the facility and three affiliated corporations filed Chapter 11 petitions in U.S. Bankruptcy Court in Tampa.[21] As of April 4, 2013, the facility remains licensed.

Background Screening

Previous Legislation

Florida has one of the largest vulnerable populations in the country with over 25 percent of the state's population over the age of 65, and many more children and disabled adults. These vulnerable populations require special care because they are at an increased risk of abuse.

In 2010, the Legislature substantially amended the requirements and procedures for background screening.[22] Major changes made by the 2010 legislation include:

- No person who is required to be screened may begin work until the screening has been completed.
- All Level 1[23] screenings were increased to Level 2[24] screenings.
- By July 1, 2012, all fingerprints submitted to the FDLE must be submitted electronically.
- Certain personnel that were not being screened were required to begin Level 2 screening.
- The addition of serious crimes that disqualify an individual from employment working with vulnerable populations.
- Authorization for agencies to request the retention of fingerprints by FDLE.
- That an exemption for a disqualifying felony may not be granted until at least 3 years after the completion of all sentencing sanctions for that felony.
- That all exemptions from disqualification may be granted only by the agency head.

[20] Bloomberg, *Abuse of Brain Injured Americans Scandalizes U.S.*, (Jan. 7, 2012) *available at* http://www.bloomberg.com/news/2012-07-24/brain-injured-abuse-at-for-profit-center-scandalizes-u-s-.html, last visited on April 4, 2013.

[21] Bloomberg, *Florida Brain-Injury Facility Files for Bankruptcy*, (Jan. 5, 2013) *available at* http://www.bloomberg.com/news/2013-01-05/florida-brain-injury-facility-files-for-bankruptcy.html, last visited on April 4, 2013.

[22] Chapter 2010-114, L.O.F.

[23] Section 435.03, F.S. Level 1 screenings are name-based demographic screenings that must include, but are not limited to, employment history checks and statewide criminal correspondence checks through the FDLE. Level 1 screenings may also include local criminal records checks through local law enforcement agencies. A person undergoing a Level 1 screening must not have been found guilty of any of the listed offenses.

[24] Section 435.04, F.S. A Level 2 screening consists of a fingerprint-based search of the FDLE and the Federal Bureau of Investigation databases for state and national criminal arrest records. Any person undergoing a Level 2 screening must not have been found guilty of any of the listed offenses.

The Care Provider Background Screening Clearinghouse

In 2012, the Legislature passed CS/CS/CS/HB 943, which created the Clearinghouse. The Clearinghouse establishes a single data source for background screening results of persons required to be screened by law[25] for employment in positions that provide services to children, the elderly, and disabled individuals.[26] The Clearinghouse allows the results of criminal history checks to be shared among specified state agencies, thereby reducing duplicative screenings for individuals requiring screening across multiple state agencies. In addition applicants will now have their fingerprints retained for a period of 5 years. The retention of fingerprints will allow the FDLE to report any new arrest/registration information to the specified state agencies. In turn, if during that 5-year period the individual is arrested or added to a registry, a notification will be sent to the employing provider.[27]

The Clearinghouse also collects submitted photographs of applicants who are required to obtain Level 2 background checks. The requirement to submit a photograph was added to law during the 2012 Legislative Session. However, instead of being in the Clearinghouse statute of s. 435.12, F.S., the requirement currently exists in the general Level 2 screening standards of s. 435.04(1)(e), F.S.

Employers of individuals subject to screening by a specified agency[28] are required to register with the Clearinghouse and maintain the employment status of all employees with the Clearinghouse for screenings conducted after the date the state agency begins participation in the Clearinghouse. Initial employment status and any change in status must be reported within 10 business days.[29] Currently, there is no requirement that screenings be initiated through the Clearinghouse.

The Clearinghouse is in the process of being implemented by six designated state agencies and final implementation is required to be completed by October 1, 2013. Currently, the clearinghouse is active and being used by the AHCA and the Department of Health (DOH)[30]

Current Background Screening Law

Florida licensure laws require providers licensed by AHCA to conduct Level 2 criminal background screening for:[31,32]

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[25] Certain persons are required to be screened by specified agencies. "Specified agency" is defined in s. 435.02(5), F.S., and includes the Department of Health, the Department of Children and Family Services, the Division of Vocational Rehabilitation within the Department of Education, the Agency for Health Care Administration, the Department of Elderly Affairs, the Department of Juvenile Justice, and the Agency for Persons with Disabilities.

[26] *Clearinghouse FAQ*, found at: http://ahca.myflorida.com/MCHQ/Central_Services/Background_Screening/docs/ClearinghouseFAQ.pdf, last visited on April 5, 2013.

[27] Supra n. 7

[28] Supra n. 6

[29] Section 435.12(2), F.S.

[30] According to a phone conversation with Taylor Haddock, Unit Manager of the AHCA Background Screening Unit, on April 5, 2013.

[31] Section 408.809, F.S.

- The licensee;
- Administrators and financial officers;
- Staff of health care providers who offer residential and home care services that provide personal care services or have access to client property, funds or living areas; and
- Any person who is a controlling interest if there is reason to suspect they have committed a disqualifying criminal offense.

Current background screening standards in ch. 435, F.S., and s. 408.809, F.S., the general licensing provisions for health care providers licensed by the AHCA, include various disqualifying offenses pertaining, but not limited to, domestic violence, patient brokering, criminal use of personal identification information, fraudulent use of credit cards, forgery, and possession/sale of illegal drugs.

Some offenses that presently would disqualify an applicant from employment are very similar to certain offenses that presently do not disqualify an applicant from employment. For example, s. 408.809(4)(k), F.S., states that felonious fraudulent use of credit cards, as described in s. 817.61, F.S., is a disqualifying offense. However, using an expired or falsified credit card to obtain goods, as described in s. 817.841, F.S., is not a disqualifying offense.

Designated agencies have the authority to grant exemptions from disqualification.[33] The exemptions enable people who have been convicted of a disqualifying criminal offense to present information as to why they should not be excluded from working with vulnerable individuals. This information includes: specifics of the offense, how long ago the offense occurred, work history, and rehabilitation. Current law states that an applicant who applies for an exemption for a felony offense must have had 3 years elapse since completion of any sentence or have been lawfully released from confinement, supervision, or sanction for the disqualifying felony.[34] The 3-year waiting period would reset with even the smallest related sanction, such as an unpaid balance of a fine. The requirement is similar for disqualifying misdemeanors, except that there is no specific time frame mandated after being lawfully released from confinement, supervision, or sanction.[35,36]

The DHSMV has the authority to maintain a record of driver license photographs, signature, and other data required for identification and retrieval.[37] The DHSMV also has the authority to share those photographs, through interagency agreements, with specific state agencies.[38]

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[32] For a full list of all employees subject to background screening see, *Who is Required to be Screened,* found at: http://ahca.myflorida.com/MCHQ/Central_Services/Background_Screening/docs/BGS_WhoRequiredToBeScreened.pdf, last visited on April 5, 2013.
[33] Section 435.07, F.S.
[34] *Id.*
[35] The term "sanction" does not currently have a formal definition in ch. 435, F.S. Numerous state agencies are bound by chapter 435, F.S., and the interpretation of the term "sanction" varies widely among the agencies.
[36] SB 1112 Bill Analysis and Economic Impact Statement, Agency for Health Care Administration, at page 4, Mar. 13, 2013 (on file with the Senate Health Policy Committee).
[37] Section 322.142(4), F.S.
[38] Section 322.142(4), F.S., provides that the Department of Highway Safety and Motor Vehicles may provide reproductions of the file or digital record to the Department of Business and Professional Regulation, the Department of State, the Department of Revenue, the Department of Children and Families, the Department of Financial Services, or to district medical examiners.

Assisted Living Facilities

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.[39] A personal service is direct physical assistance with, or supervision of, the activities of daily living and the self-administration of medication.[40] Activities of daily living include ambulation, bathing, dressing, eating, grooming, toileting, and other similar tasks.[41]

An ALF is required to provide care and services appropriate to the needs of the residents accepted for admission to the facility.[42] The owner or facility administrator determines whether an individual is appropriate for admission to the facility based on a number of criteria.[43] 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 health care provider, the resident must be discharged in accordance with the Resident Bill of Rights.[44]

There are currently 3,036 licensed ALFs in Florida with 85,413 beds.[45] An ALF must have a standard license issued by the Agency for Health Care Administration (AHCA), pursuant to part I of ch. 429, F.S., and part II of ch. 408, F.S. 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,[46] limited mental health services,[47] and extended congregate care services.[48] There are 1,073 facilities having limited nursing services specialty licenses (LNS licenses), 279 having extended congregate care licenses (ECC licenses), and 1,084 having limited mental health specialty licenses (LMH licenses).[49]

Limited Nursing Services Specialty License

A LNS specialty license enables an ALF to provide, directly or through contract, a select number of nursing services in addition to the personal services that are authorized under the standard license. The nursing services are limited to acts specified in administrative rules, may only be provided as authorized by a health care provider's order, and must be conducted and supervised in accordance with ch. 464, F.S., relating to nursing, and the prevailing standard of practice in the nursing community.

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[39] Section 429.02(5), F.S. An ALF does not include an adult family-care home or a non-transient public lodging establishment.
[40] Section 429.02(16), F.S.
[41] Section 429.02(1), F.S.
[42] For specific minimum standards see Rule 58A-5.0182, F.A.C.
[43] Section 429.26, F.S., and Rule 58A-5.0181, F.A.C.
[44] Section 429.28, F.S.
[45] Agency for Health Care Administration, information provided to Senate Children, Families, and Elder Affairs Committee February 4, 2013.
[46] Section 429.07(3)(c), F.S.
[47] Section 429.075, F.S.
[48] Section 429.07(3)(b), F.S.
[49] Agency for Health Care Administration, information provided to Senate Children, Families, and Elder Affairs Committee February 4, 2013.

Extended Congregate Care Specialty License

The primary purpose of ECC services is to allow residents to remain in a familiar setting as they become more impaired with physical or mental limitations. An ECC specialty license enables a facility to provide, directly or through contract, services performed by licensed nurses and supportive services[50] to persons who otherwise would be disqualified from continued residence in an ALF.[51] A facility licensed to provide ECC services may also admit an individual who exceeds the admission criteria for a facility with a standard license, if the individual is determined appropriate for admission to the ECC facility. A licensed facility must adopt its own requirements within guidelines for continued residency set forth by rule. However, a facility with an ECC license still may not serve residents who require 24-hour nursing supervision.[52]

Limited Mental Health Specialty License

An ALF that serves three or more mental health residents must obtain an LMH specialty license.[53] A mental health resident is an individual who receives social security disability income (SSDI) due to a mental disorder or supplemental security income (SSI) due to a mental disorder, and receives optional state supplementation (OSS).[54] The DCF must ensure that a mental health resident is assessed and determined able to live in an ALF with an LMH license.[55]

The administrator in a LMH facility must consult with a mental health resident and the resident's case manager to develop and help execute a community living support plan for the resident detailing the specific needs and services the resident requires.[56] The LMH licensee must also execute a cooperative agreement with the mental health care services provider. The cooperative agreement specifies, among other things, directions for the ALF accessing emergency and after-hours care for the mental health resident.

[50] Supportive services include social service needs, counseling, emotional support, networking, assistance with securing social and leisure services, shopping service, escort service, companionship, family support, information and referral, assistance in developing and implementing self-directed activities, and volunteer services. *See* Rule 58A-5.030(8)(a), F.A.C.

[51] An ECC program may provide additional services, such as the following: total help with bathing, dressing, grooming, and toileting; nursing assessments conducted more frequently than monthly; measuring and recording basic vital functions and weight; dietary management; assisting with self-administered medications or administering medications and treatments pursuant to a health care provider's order; supervising residents with dementia and cognitive impairments; health education, counseling, and implementing health-promoting programs; rehabilitative services; and escort services related to health-related appointments. Section 429.07(3)(b), F.S., and Rule 58A-5.030, F.A.C.

[52] Section 429.07(3)(b), F.S.

[53] Section 429.075, F.S.

[54] Section 429.02(15), F.S. Optional State Supplementation is a cash assistance program. Its purpose is to supplement a person's income to help pay for costs in an assisted living facility, mental health residential treatment facility, or adult family care home, but it is not a Medicaid program. Department of Elder Affairs, *Florida Affordable Assisted Living: Optional State Supplementation (OSS)*, http://elderaffairs.state.fl.us/faal/operator/statesupp.html (Last visited March 22, 2013).

[55] Section 394.4574, F.S., requires a mental health resident to be assessed by a psychiatrist, clinical psychologist, clinical social worker, psychiatric nurse, or an individual who is supervised by one of these professionals to determine whether it is appropriate for the person to reside in an ALF.

[56] Rule 58A-5.029(2)(c)3., F.A.C.

Department of Elder Affairs Rules

In addition to ch. 429, F.S., ALFs are also subject to regulation under Rule 58A-5, of the Florida Administrative Code (F.A.C.). These rules are adopted by the Department of Elder Affairs (DOEA) in consultation with the AHCA, the DCF, and the Department of Health (DOH).[57] In June 2012, the DOEA initiated a process of negotiated rulemaking to revise many of its rules regarding ALFs. After multiple meetings, a committee that consisted of agency staff, consumer advocates, and industry representatives voted on numerous changes to Rule 58A-5, F.A.C. On November 28, 2012, the DOEA issued a proposed rule and held three public hearings on the proposed rule. The public comment period for the proposed rule ended on December 21, 2012, and the DOEA has not yet issued a final rule.[58]

ALF Staff Training

Administrators and Managers

Administrators and other ALF staff must meet minimum training and education requirements established by the DOEA by rule.[59] This training and education is intended to assist facilities to appropriately respond to the needs of residents, maintain resident care and facility standards, and meet licensure requirements.[60]

The current ALF core training requirements established by the DOEA consist of a minimum of 26 hours of training and passing a competency test. Administrators and managers must successfully complete the core training requirements within 3 months after becoming a facility administrator or manager. The minimum passing score for the competency test is 75 percent.[61]

Administrators and managers must participate in 12 hours of continuing education in topics related to assisted living every 2 years. A newly hired administrator or manager, who has successfully completed the ALF core training and continuing education requirements, is not required to retake the core training. An administrator or manager, who has successfully completed the core training but has not maintained the continuing education requirements, must retake the ALF core training and retake the competency test.[62]

Staff with Direct Care Responsibilities

Facility administrators or managers are required to provide or arrange for 6 hours of in-service training for facility staff who provide direct care to residents which covers various topics as

[57] Section 429.41(1), F.S.
[58] The DOEA rule, documents, and dates for the negotiated rulemaking can be found at: Department of Elderly Affairs, *Assisted Living Facility (ALF) Negotiated Rulemaking*, http://elderaffairs.state.fl.us/doea/alf_rulemaking.php (Last visited March 22, 2013).
[59] Rule 58A-5.0191, F.A.C. Many of the training requirements in rule may be subject to change due to the recent the DOEA negotiated rulemaking process.
[60] Section 429.52(1), F.S.
[61] Administrators who have attended core training prior to July 1, 1997, and managers who attended the core training program prior to April 20, 1998, are not required to take the competency test. Administrators licensed as nursing home administrators in accordance with part II of chapter 468, F.S., are exempt from this requirement.
[62] Rule 58A-5.0191, F.A.C.

mandated in rule.[63] Staff training requirements must generally be met within 30 days after staff begin employment at the facility. However, staff must have at least 1 hour of infection control training before providing direct care to residents. Also, nurses, certified nursing assistants, and home health aides who are on staff with an ALF are exempt from many of the training requirements. In addition to the standard 6 hours of in-service training, staff must complete 1 hour of elopement training and 1 hour of training on do not resuscitate orders. The staff may be required to complete training on special topics such as self administration of medication and Alzheimer's disease, if applicable.

ECC Specific Training

The administrator and ECC supervisor, if different from the administrator, must complete 4 hours of initial training in extended congregate care prior to the facility receiving its ECC license or within 3 months after beginning employment in the facility as an administrator or ECC supervisor. The administrator and ECC supervisor must also complete a minimum of 4 hours of continuing education every 2 years in topics relating to the physical, psychological, or social needs of frail elderly and disabled persons, or persons with Alzheimer's disease or related disorders.[64]

All direct care staff providing care to residents in an ECC program must complete at least 2 hours of in-service training, provided by the facility administrator or ECC supervisor, within 6 months after beginning employment in the facility. The training must address ECC concepts and requirements, including statutory and rule requirements and the delivery of personal care and supportive services in an ECC facility.[65]

LMH Specific Training

Administrators, managers, and staff, who have direct contact with mental health residents in a licensed LMH facility must receive a minimum of 6 hours of specialized training in working with individuals having mental health diagnoses and a minimum of 3 hours of continuing education dealing with mental health diagnoses or mental health treatment every 2 years.[66]

Inspections and Surveys

The AHCA is required to conduct a survey, investigation, or monitoring visit of an ALF:

- Prior to the issuance of a license.
- Prior to biennial renewal of a license.
- When there is a change of ownership.
- To monitor facilities licensed to provide LNS or ECC services, or facilities cited in the previous year for a class I or class II, or four or more uncorrected class III, violations.67
- Upon receipt of an oral or written complaint of practices that threaten the health, safety, or welfare of residents.

[63] See note 24.
[64] Rule 58A-5.0191(7)(b), F.A.C.
[65] Rule 58A-5.0191(7)(c), F.A.C.
[66] Section 429.075, F.S. and Rule 58A-5.0191(8), F.A.C.
[67] *See below* information under subheading "Violations and Penalties" for a description of each class of violation.

- If the AHCA has reason to believe a facility is violating a provision of part III of ch. 429, F.S., relating to adult day care centers, or an administrative rule.
- To determine if cited deficiencies have been corrected.
- To determine if a facility is operating without a license.[68]

Abbreviated Surveys

An applicant for licensure renewal is eligible for an abbreviated biennial survey by the AHCA if the applicant does not have any:

- Class I or class II violations or uncorrected class III violations.
- Confirmed long-term care ombudsman council complaints reported to the AHCA by the council.
- Confirmed licensing complaints within the two licensing periods immediately preceding the current renewal date.[69]

An abbreviated survey allows for a quicker and less intrusive survey by narrowing the range of items the agency must inspect.[70] The AHCA must expand an abbreviated survey or conduct a full survey if violations that threaten or potentially threaten the health, safety, or security of residents are identified during an abbreviated survey.[71]

Monitoring Visits

Facilities with LNS or ECC licenses are subject to monitoring visits by the AHCA in which the agency inspects the facility for compliance with the requirements of the specialty license type. A LNS licensee is subject to monitoring inspections at least twice a year. At least one registered nurse must be included in the inspection team to monitor residents receiving LNS and to determine if the facility is complying with applicable regulatory requirements.[72] An ECC licensee is subject to quarterly monitoring inspections. At least one registered nurse must be included in the inspection team. The 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.[73]

Violations and Penalties

Part II of ch. 408, F.S., provides general licensure standards for all facilities regulated by the AHCA. Under s. 408.813, F.S., ALFs may be subject to administrative fines imposed by the AHCA for certain types of violations. Violations are categorized into four classes according to the nature of the violation and the gravity of its probable effect on residents, as follows.

[68] *See* s. 429.34, F.S., and Rule 58A-5.033, F.A.C.
[69] Rule 58A-5.033(2), F.A.C.
[70] Rule 58A-5.033(2)(b).
[71] *Id.*
[72] Section 429.07(3)(c), F.S.
[73] Section 429.07(3)(b), F.S.

- Class I violations are those conditions that the AHCA determines present an imminent danger to residents or a substantial probability of death or serious physical or emotional harm. Examples include resident death due to medical neglect, risk of resident death due to inability to exit in an emergency, and the suicide of a mental health resident in an ALF licensed for limited mental health. The AHCA must fine a facility between $5,000 and $10,000 for each violation.
- Class II violations are those conditions that the AHCA determines directly threaten the physical or emotional health, safety, or security of the clients. Examples include no qualified staff in the facility, the failure to call 911 in a timely manner for resident in a semi-comatose state, and rodents in a food storage area. The AHCA must fine a facility between $1,000 and $5,000 for each violation.
- Class III violations are those conditions that the AHCA determines indirectly or potentially threaten the physical or emotional health, safety, or security of clients. Examples include missing or incomplete resident assessments, erroneous documentation of medication administration, and failure to correct unsatisfactory DOH Food Service inspection findings in a timely manner. The AHCA must fine a facility between $500 and $1,000 for each violation, but no fine may be imposed if the facility corrects the violation.
- Class IV violations are those conditions that do not have the potential of negatively affecting clients. Examples include failure to file an adverse incident report, incorrect phone numbers posted for advocacy resources, and failure to post current menus. The AHCA can only fine a facility (between $100 and $200 for each violation) if the problem is not corrected. [74,75]

In addition to financial penalties, AHCA can take other actions against a facility. The AHCA may deny, revoke, and suspend any license for any of the actions listed in s. 429.14(1)(a)-(k), F.S. The AHCA is required to deny or revoke the license of an ALF that has 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.[76] The AHCA may also impose an immediate moratorium or emergency suspension on any provider if it determines that any condition that presents a threat to the health, safety, or welfare of a client.[77] The AHCA is required to publicly post notification of a license suspension, revocation, or denial of a license renewal, at the facility.[78] Finally, Florida's Criminal Code, under ch. 825, F.S., provides criminal penalties for the abuse, neglect, and exploitation of elderly persons[79] and disabled adults.[80]

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[74] When fixing the amount of the fine, the AHCA must consider the following factors: the gravity of the violation and the extent to which any laws or rules were violated, actions taken to correct the violations, any previous violations, the financial benefit of committing or continuing the violation, and the licensed capacity of the facility. Section 429.19(3), F.S.

[75] Section 429.19(2), F.S.

[76] Section 429.14(4), F.S.

[77] Section 408.814, F.S.

[78] Section 429.14(7), F.S.

[79] "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. Section 825.101(5), F.S. It does not constitute a defense to a prosecution for any violation of this chapter that the accused did not know the age of the victim. Section 825.104, F.S.

[80] "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. Section 825.101(4), F.S.

Central Abuse Hotline

The DCF is required under s. 415.103, F.S., to establish and maintain a central abuse hotline to receive reports, in writing or through a single statewide toll-free telephone number, of known or suspected abuse, neglect, or exploitation of a vulnerable adult[81] at any hour of the day or night, any day of the week.[82] Persons listed in s. 415.1034, F.S., who know, or have reasonable cause to suspect, that a vulnerable adult has been or is being abused, neglected, or exploited are required to immediately report such knowledge or suspicion to the central abuse hotline.[83]

Florida's Long-term Care Ombudsman Program

The Federal Older Americans Act (OAA) requires each state to create a Long-Term Care Ombudsman Program to be eligible to receive funding associated with programs under the OAA.[84] In Florida, the program is a statewide, volunteer-based system of district councils that protect, defend, and advocate on behalf of long-term care facility residents, including residents of nursing homes, ALFs, and adult family-care homes. The ombudsman program is administratively housed in the DOEA and is headed by the State Long-Term Care Ombudsman, who is appointed by the Secretary of Elderly Affairs.[85] The ombudsman program is required to establish a statewide toll-free telephone number for receiving complaints concerning matters adversely affecting the health, safety, welfare, or rights of residents of ALFs, nursing homes, and adult family care homes. Every resident or representative of a resident must receive, upon admission to a long-term care facility, information regarding the program and the statewide toll-free telephone number for receiving complaints.[86] The names or identities of the complainants or residents involved in a complaint, including any problem identified by an ombudsman council as a result of an investigation, are confidential and exempt from Florida's public records laws, unless the complainant or resident, or the legal representative of the complainant or resident, consents to the disclosure, or the disclosure is required by court order.[87] In addition to investigating and resolving complaints, ombudsmen conduct unannounced visits to assess the quality of care in facilities, referred to as administrative assessments.

The *Miami Herald* Articles and the Governor's Assisted Living Workgroup

Beginning on April 30, 2011, the *Miami Herald* published a four-part series, titled "Neglected to Death," which detailed abuses occurring in ALFs and the state regulatory responses to such cases. The paper spent a year examining thousands of state inspections, police reports, court

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[81] "Vulnerable adult" means a person 18 years of age or older whose ability to perform the normal activities of daily living or to provide for his or her own care or protection is impaired due to a mental, emotional, sensory, long-term physical, or developmental disability or dysfunction, or brain damage, or the infirmities of aging. Section 415.102(27), F.S.

[82] The central abuse hotline is operated by the DCF to accept reports for investigation when there is a reasonable cause to suspect that a vulnerable adult has been or is being abused, neglected, or exploited; determine whether the allegations require an immediate, 24-hour, or next-working-day response priority; when appropriate, refer calls that do not allege the abuse, neglect, or exploitation of a vulnerable adult to other organizations that might better resolve the reporter's concerns; immediately identify and locate prior reports of abuse, neglect, or exploitation through the central abuse hotline;
Section 415.103(1), F.S.

[83] Section 415.1034, F.S.

[84] 42 U.S.C. 3058. *See also* s. 400.0061(1), F.S.

[85] Section 400.0063, F.S.

[86] Section 400.0078, F.S.

[87] Section 400.0077(1)(b), F.S.

cases, autopsy files, e-mails, and death certificates and conducting dozens of interviews with operators and residents throughout Florida. The series detailed examples of abuses, neglect, and even death that took place in facilities.[88] The series also criticized the state's regulatory and law enforcement agencies' responses to the problems. The paper concluded that the state's agencies, and in particular the AHCA, failed to enforce existing laws designed to protect Florida's citizens who reside in ALFs.[89]

Soon after the *Miami Herald* series, Governor Rick Scott vetoed HB 4045,[90] which reduced requirements relating to ALFs. The Governor then directed the AHCA to form a task force for the purpose of examining current assisted living regulations and oversight.[91] The task force referred to as the Assisted Living Workgroup, held meetings and produced two reports, one in August of 2011 and one in October of 2012. In addition to public testimony and presentations, the Assisted Living Workgroup focused on assisted living regulation, consumer information and choice, and long term care services and access.[92] The workgroup made numerous recommendations in its two reports.[93]

Forensic Toxicology Laboratory Monthly Statistical Report

Florida law requires licensed forensic toxicology laboratories to submit monthly statistical reports to the AHCA.[94] These reports include information including a lab's name, license number, address, the total number of specimens received for testing, the total number of specimens received but not tested, and the total number of confirmed positive reports for various listed drugs. A laboratory that fails to submit the monthly report is subject to administrative action under Rule 59A-24.006(12)(a), F.A.C.

The Florida Hospital Sanford-Burnham Translational Research Institute for Metabolism and Diabetes (Institute)

The Institute focuses on translational research and has established advanced technology resources and formed clinical and pharmaceutical research partnerships to drive discoveries

[88] Rob Barry, Michael Sallah and Carol Marbin Miller, *Neglected to Death, Parts 1-3*, THE MIAMI HERALD, April 30, 2011 *available at* http://www.miamiherald.com/2011/04/30/2194842/once-pride-of-florida-now-scenes.html and http://www.miamiherald.com/2011/05/03/2199747/key-medical-logs-doctored-missing.html (see left side of article to access weblinks to the three-part series).
[89] *Id.*
[90] HB 4045 (2011) repealed a requirement for the annual dissemination of a list of ALFs that had been sanctioned or fined, a requirement for an ALF to report monthly any liability claims filed against it, a requirement to disseminate the results of the inspection of each ALF, provisions concerning rule promulgation for ALFs by the DOEA, provisions concerning the collection of information regarding the cost of care in ALFs, and the authority for local governments or organizations to contribute to the cost of care of local facility residents.
[91] The task force is now referred to as the "Assisted Living Workgroup." Membership details of the task force are available at Florida Agency for Health Care Administration, *Assisted Living Workgroup Members*, http://ahca.myflorida.com/SCHS/CommiteesCouncils/ALWG/wgmembers.shtml, (Last visited Mar. 22, 2013).
[92] Agency For Health Care Administration, Assisted Living Workgroup, *Final Report And Recommendations*, http://ahca.myflorida.com/SCHS/ALWG2011/alwg2011.shtml (Last visited Mar. 22, 2013).
[93] *Id.*
[95] About the Diabetes and Obesity Center, found at: http://www.sanfordburnham.org/research/diabetes/Pages/doc.aspx, last visited on Mar. 4, 2013.

toward patient application.[95] The Institute was designated as a resource for research in the prevention and treatment of diabetes in Florida's 2012 General Appropriations Act[96] but has not been permanently designated as such in the Florida Statutes. According to Sanford-Burnham and Florida Hospital, such a designation will provide a competitive advantage for the Institute over research facilities in other states when applying for federal grants.[97]

Complaint Investigation for Access to Emergency Services and Care

Section 395.1046, F.S., requires the AHCA to investigate any complaint against a hospital for violation of provisions relating to access to emergency services and care which the AHCA deems to be legally sufficient. Under this section, the AHCA must prepare an investigative report with findings and recommendations concerning the existence of probable cause; the complaint and all information obtained by the AHCA during the investigation are exempt from public records laws for specified periods of time. The section does not define the terms "legally sufficient" or "probable cause." Presently, the AHCA is also granted authority under s. 408.811, F.S., to investigate all complaints against a hospital.

State Preemption

There is currently no statutory provision that expressly preempts the regulation pharmacies or pain-management clinics to the state of Florida. Some counties and municipalities have created ordinances for the regulation of these clinics based upon the powers and duties conveyed upon these entities in Florida Statutes.[98]

Prescription Drug Repackaging

The Department of Business and Professional Regulation's (DBPR) Division of Drugs, Devices and Cosmetics regulates and permits prescription drug repackaging in the state of Florida. The term repackaging when applied to prescription drugs includes repacking or otherwise changing the container, wrapper, or labeling to further the distribution of the drug, device, or cosmetic.[99] Some examples of repackaging include:

- Altering a packaging component that is or may be in direct contact with the drug, device, or cosmetic, e.g. repackaging from bottles of 1,000 to bottles of 100.
- Altering a manufacturer's package for sale under a label different from the manufacturer, e.g. a kit that contains an injectable vaccine from manufacturer A; a syringe from manufacturer B; alcohol from manufacturer C; and sterile gauze from manufacturer D, packaged together and marketed as an immunization kit under a label of manufacturer Z.

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[95] About the Diabetes and Obesity Center, found at: http://www.sanfordburnham.org/research/diabetes/Pages/doc.aspx, last visited on Mar. 4, 2013.
[96] 2012-118, L.O.F.
[97] According to telephone conversations with Elizabeth Gianini, representing Sanford-Burnham, and Amy Christian, representing Florida Hospital, on Mar. 4, 2013.
[98] DOH bill analysis on SB 1192, dated Mar. 1, 2013, on file with the Senate Health Policy Committee.
[99] Prescription Drug Repackager, found at: http://www.myfloridalicense.com/dbpr/ddc/PrescriptionDrugRepackager.html, last visited on Mar. 14, 2013.

- Altering a package of multiple units, which the manufacturer intended to be distributed as one unit, for sale or transfer to a person engaged in the further distribution of the product.[100]

Prescription drug repackagers located in Florida[101] must be permitted by the DBPR. In order to obtain a permit an applicant must have an FDA establishment registration number, pass an on-site inspection (unless the applicant holds a Prescription Drug Manufacturer permit), and pay a fee of $1,500 for a two-year permit and a one-time $150 pre-permit inspection fee.[102] Prescription drug repackagers must comply with all the requirements of, and rules and regulations promulgated under, part I of ch. 499, F.S., that apply to wholesale distributors as well as all appropriate state and federal good manufacturing procedures.[103]

III. Effect of Proposed Changes:

Sections 2, 9, 23, 29, 32, 49, 56, 57, 69, 74, and 80 through 85 amend ss. 154.11, 394.741, 397.403, 400.925, 400.9935, 402.7306, 409.966, 409.967, 430.80, 440.13, 627.645, 627.668, 627.669, 627.736, 641.495, and 766.1015, F.S., to update those sections with the most current names for CARF International and the Joint Commission; add the American Osteopathic Association/Healthcare Facilities Accreditation Program to those organizations specifically recognized as accrediting organizations (except for s. 409.967, F.S.); and to make other technical revisions.

Section 1 amends s. 112.0455, F.S., to delete language requiring drug-testing laboratories to submit a monthly report with statistical information regarding the testing of employees and job applicants to the AHCA and detailing what information must be included in the report.

Section 3 amends s. 322.142, F.S., to allow the DHSMV to share with the AHCA, pursuant to an interagency agreement, a data file that includes the digital image and signature of a driver licensee for the purpose of verifying photographs in the CPBSC.

Section 4 amends s. 381.745, F.S., to conform to changes made by the bill.

Section 5 amends s. 381.75, F.S., to eliminate a reference to the responsibility of the DOH to develop rules with the AHCA for the regulation of transitional living facilities. Provisions in this section are moved and revised in the newly-created ss. 400.997-400.9984, F.S.

Section 6 amends s. 381.78, F.S., to strike specific language on the composition and duties of the Advisory Council on Brain and Spinal Cord Injuries. These duties are duplicative of the regulation by AHCA under the bill and, as a result, are removed.

Section 7 creates s. 385.2035, F.S., to designate the Florida Hospital Sanford-Burnham Translational Research Institute for Metabolism and Diabetes as a resource for research in the prevention and treatment of diabetes.

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[100] Supra, n. 14
[101] s. 499.01(b), F.S.
[102] Supra, n. 14
[103] s. 499.01(b)(1) and (2), F.S.

Section 8 amends s. 394.4574, F.S., to specify that Medicaid prepaid behavioral health plans are responsible for enrolled state supported mental health residents and that managing entities under contract with the DCF are responsible for such residents who are not enrolled with a Medicaid prepaid behavioral health plan. Section 394.4574, F.S., requires a mental health resident's community living support plan be completed and provided to the administrator of the facility when the facility admits a mental health resident and be updated when there is a significant change to the resident's behavioral health status. The resident's case manager must keep a 2-year record of any face-to-face interaction with the resident. Finally, this section charges the entity responsible for a mental health resident to ensure that there is adequate and consistent monitoring of the community living support plan. The entity must also report to the appropriate regulatory oversight organization any concerns about a regulated provider acting in a manner with the potential to cause harm to the resident.

Section 10 amends s. 395.0161, F.S., to allow hospitals, ambulatory surgical centers, and mobile surgical facilities to pay inspection fees at times other than the time of inspection.

Section 11 repeals s. 395.1046, F.S., which grants the AHCA duplicative authority to investigate complaints related to access to emergency services and care which it finds to be legally sufficient. This section also details the AHCA's duties when investigating such complaints and details what information, under what circumstances, and for how long information related to the complaint and investigation is exempt from public records.

Section 12 amends s. 395.3038, F.S., to update those sections with the most current names for CARF International and the Joint Commission; add the American Osteopathic Association/Healthcare Facilities Accreditation Program to those organizations specifically recognized as accrediting organizations; and delete obsolete language regarding the AHCA's list of primary and comprehensive stroke centers.

Section 13 repeals s. 395.40. F.S., establishing findings and legislative intent regarding trauma care.

Section 14 amends s. 395.4001, F.S., to revise the definition of:

- "Level II trauma center" to include a Level II trauma center designated pursuant to s. 395.4025(14), F.S.; and
- "Trauma center" to include Level II trauma centers that are designated pursuant to s. 395.4025(14), F.S..

Section 15 amends s. 395.401, F.S., to strike the requirement to have the number and location of needed trauma centers based on local needs in local and regional trauma plans.

Section 16 amends s. 395.4015, F.S., to require regional trauma plans to recognize trauma service areas that reflect well established patient flow patterns.

Section 17 amends s. 395.402, F.S., to repeal provisions requiring the DOH to conduct an assessment of Florida's trauma system, to update the assignment of counties into trauma service

areas, and to annually review those assignments. Provisions establishing minimum and maximum numbers of trauma centers are also repealed.

Section 18 amends s. 395.4025, F.S., to require the DOH to designate hospitals that are located in areas with limited access to trauma center services as Level II trauma centers if they hold a certificate of trauma center verification from the American College of Surgeons. This section also defines areas with limited access to trauma center services by the following criteria:

- The hospital is located in a area with a population greater than 600,000 persons but with a population density less than 300 persons per square mile;
- The hospital is located in a county with no designated or provisional trauma center; and
- The hospital is located at least 15 miles, or 20 minutes, travel time by ground transport from the nearest trauma center.

Current Level I, Level II and pediatric trauma centers retain their designations unless they are unable to comply with the adopted standards for such centers and provisionally approved trauma centers are allowed to complete their applications.

Section 19 amends s. 395.405, F.S., to remove s. 395.402, F.S., from a list of statutory sections for which the DOH is directed to adopt and enforce rules.

Section 20 amends s. 395.701, F.S., to exempt all state-operated hospitals, rather than only hospitals run by the DOC, from the annual assessments on net operating revenues for inpatient and outpatient services, required by s. 395.701, F.S., which fund public medical assistance.

Section 21 repeals s. 395.7015, F.S., which levies the PMATF assessment on health care entities. The PMATF was found to be unconstitutional by Florida 1st District Court of Appeal in 2003 but the language remains in the Florida Statutes.[104]

Section 22 amends s. 395.7016, F.S., to conform to changes made by the bill.

Section 24 amends s. 400.0074, F.S., to require the Long-Term Care Ombudsman Program's administrative assessments of ALFs be comprehensive in nature. This section also requires ombudsmen to conduct an exit interview with the facility to discuss issues and concerns from the visit in areas affecting the rights, health, safety, and welfare of residents, and recommend improvements.

Section 25 amends s. 400.0078, F.S., to require that ALFs provide information to new residents that retaliatory action cannot be taken against a resident for presenting grievances or for exercising any other resident right.

Section 26 amends s. 400.462, F.S., to amend the definition of "nurse registry" to clarify that a nurse registry may be considered a "home health agency," as defined in s. 400.462(12), F.S., for

[104] A full summary of the case law finding the PMATF unconstitutional is on file with the Senate Health Policy Committee.

the purposes of the delivery of services under s. 627.94071(5), F.S. This clarifies an ambiguity between the two chapters that has hindered payment for delivered services.

Section 27 amends s. 400.464, F.S., to exempt the delivery of home dialysis services provided directly, or through a sub-contractor, by a end-stage renal disease provider certified under 42 C.F.R. part 405, subpart U, from the licensure requirements for home health agencies.

Section 28 repeals s. 400.805, F.S., regulating transitional living facilities. Transitional living facilities are regulated by provisions created in this bill in ss. 400.9970 – 400.9984, F.S.

Section 30 amends s. 400.93, F.S., to conform to the provisions regulating transitional living facilities in this bill.

Section 31 amends s. 400.9905, F.S., to amend the definition of "clinic" to exclude pediatric cardiology and perinatology clinical facilities, and anesthesia clinical facilities not otherwise exempt under s. 400.9905(a) and (k), F.S., and entities that are owned by a corporation that has $250 million or more in total annual sales of health care services where one or more of the persons responsible for the operations of the entity is a health care practitioner who is responsible for supervising the business activities of the entity and is responsible for the entity's compliance with state law.

Section 33 designates s. 400.9970 through 400.9984, F.S., as part XI of chapter 400, Florida Statutes, entitled "Transitional Living Facilities."

Section 34 creates s. 400.9970, F.S., to state the intent behind the regulation of transitional living facilities. The bill specifies that such facilities shall be licensed by the AHCA to ensure the quality of care for clients, provide the least restrictive placement, and assist clients to achieve a higher level of functioning. The goal of the transitional living program is to enable the clients to return to the community. The bill also states that it is the policy of the state that the use of restraints and seclusion on clients is justified only as an emergency safety measure and that the intent of the legislature is to achieve a reduction of the use of restraints in seclusion in programs and facilities that serve persons with brain and spinal cord injuries.

Section 35 creates s. 400.9971, F.S., to define terms including, but not limited to:

- "Chemical restraint," meaning a pharmacologic drug which physically limits, restricts, or deprives an individual of movement or mobility, is used for the client protection or safety, and is not required for the treatment of medical conditions or symptoms;
- "Physical restraint," meaning any manual method or physical or mechanical device, material, or equipment attached or adjacent to the individual's body so the client cannot easily remove the restraint and restricts freedom of movement or normal access to one's body; and
- "Seclusion" meaning the physical segregation of a person in any fashion or the involuntary isolation of a person in a room or area from which the person is prevented from leaving. The prevention may be by physical barrier or by a staff member who is acting in a manner, or who is physically situated, so as to prevent the person from leaving the room or area. For purposes of this chapter, the term does not mean isolation due to a person's medical condition or symptoms; and

- "Transitional living facility," the definition of which is moved from s. 381.475, F.S., and clarified so that a currently-licensed health care provider that treats brain and spinal cord injuries within the scope of its license need not be licensed as a transitional living facility.

Section 36 creates s. 400.9972, F.S., to provide for licensure requirements and application fees for transitional living facilities. The bill codifies the current license fee of $4,588 and the per bed fee of $90.[105] The bill requires certain information from the applicant, including:

- The facility's location;
- Proof that local zoning requirements have been met;
- Proof of liability insurance;
- Documentation of a satisfactory fire safety inspection; and
- Documentation of satisfactory sanitation inspection by the county health department.

The bill also requires facilities to be accredited by an accrediting organization specializing in rehabilitation facilities which may be used by the AHCA in lieu of a licensure inspection.

Section 37 creates s. 400.9973, F.S., to set standards transitional living facilities must meet for client admission, transfer, and discharge from the facility. The facility is required to have admission, transfer, and discharge policies and procedures in writing.

Admission Criteria
Clients may only be admitted to the facility:

- Upon prescription by a licensed physician and they must remain under the care of the physician for the duration of their stay in the facility;
- If they have a brain and spinal cord injury[106] with evidence of the significant involvement of two of the listed impairments; and
- Upon submission of documentation indicating the person is free of apparent signs and symptoms of communicable disease.

Clients may be admitted for an evaluation period of up to 90 days if their medical condition and diagnosis does not positively identify a cause of their disability.

Clients may not be admitted to the facility if:
- Their primary diagnosis is a mental illness or an intellectual or developmental disability;
- They present significant risk of infection to other clients or personnel;
- They are a danger to themselves or others as determined by a physician or mental health practitioner;
- They require mental health treatment;
- They require nursing supervision on a 24-hour basis; or
- They are bedridden.

[105] Section 400.805(2)(b), F.S., authorizes a license fee of $4,000 and a per bed fee of $75.50. Pursuant to s. 408.805(2), F.S., AHCA can increase the fees each year by up to the increase in the consumer price index for that year. The current fee is $4,588 and $90 per bed and bill uses these amounts.

[106] as defined in s. 381.745(2), F.S.

Client Plans and Evaluation

At or before admission, the facility must develop a "discharge plan" that states the intended placement after the client has received rehabilitative services. The goal of the placement is to return the client to independent living in the community. Discharge plans must be updated at least monthly.

The medical or nursing director must complete an initial evaluation of the client within 72 hours of admission and develop and implement an "initial" comprehensive treatment plan within 4 days of admission. The bill contains requirements for the treatment plans.

A facility must discharge the client as soon as practicable when the specialized services of the facility are no longer required, the client is not making measurable progress, or the facility is no longer the most appropriate treatment option. Facilities must provide at least 30 days notice to clients before involuntarily transferring or discharging them unless the client voluntarily terminates their residency.

Section 38 creates s. 400.9974, F.S., to provide the requirements for clients' comprehensive treatment plans and services. The facility must develop a comprehensive treatment plan for each client within 33 days of admission. An interdisciplinary team, including the client, as appropriate, must develop the plan. Each plan must be updated at least monthly and include the following:

- Physician's orders, diagnosis, medical history, physical exams and rehab needs;
- A nursing evaluation with physician orders for immediate care completed at admission;
- A comprehensive assessment of the client's functional status and the services needed to become independent and return to the community; and
- Steps necessary for the client to achieve transition to the community.

The facility must have qualified staff to carry out and monitor rehabilitation services in accordance with the stated goals of the treatment plan.

Section 39 creates s. 400.9975, F.S., to provide for certain rights of each client. Specifically, the facility must ensure that each client:

- Lives in a safe environment;
- Is treated with respect, recognition of personal dignity, and privacy;
- Retains use of his or her own clothes and personal property;
- Has unrestricted private communications, which includes mail, telephone, and visitors;
- Has the opportunity to participate in community services and activities;
- Has the opportunity to manage his or her own financial affairs, unless the client or the client's representative authorizes the administrator of the facility to provide safekeeping for funds;
- Has reasonable opportunity for regular exercise and to be outdoors several times a week;
- Has the opportunity to exercise their civil and religious liberties;
- Has adequate access to appropriate health care services;

- Has the ability to present grievances and recommend changes in policies, procedures, and services;
- Promotes participation of client's representative in the process of treatment for the client;
- Answers communications from a client's family and friends promptly;
- Is able to have visits by individuals with a relationship to the client at any reasonable hour without prior notice;
- Is allowed leave from the facility to visit or to take trips or vacations; and
- That the client's representative is promptly notified of any significant incidents or changes in condition.

The bill requires the administrator to post a written notice of provider responsibilities in a prominent place in the facility that includes the statewide toll-free telephone number for reporting complaints to the AHCA and the statewide toll-free number of Disability Rights of Florida. The facility must ensure the client has access to a telephone to call the AHCA, the central abuse hotline, Disabilities Rights of Florida, or the local advocacy council. The facility cannot take retaliatory action against a client for filing a complaint or grievance. These are similar to protections provided to residents of nursing homes and assisted living facilities.

Section 40 creates s. 400.9976, F.S., to require the facility to record the client's medication administration, including self-administration, and each dose of medication. The medication must be administered in compliance with the physician's orders. The interdisciplinary team that develops the client's treatment plan must determine whether a client is capable of self-administration of medications. Drug administration errors and adverse drug reaction must be recorded and reported immediately to the physician.

Section 41 creates s. 400.9977, F.S., to state that the facility is responsible for developing and implementing policies and procedures for screening and training employees, protection of clients, and for the prevention, identification, investigation, and reporting of abuse, neglect, mistreatment, and exploitation. This includes the facility identifying clients whose history renders the client a risk for abusing other clients.

The facility must implement procedures to:

- Screen potential employees for a history of abuse, neglect, or mistreatment of clients;
- Train employees through orientation and on-going sessions on abuse prohibition practices;
- Have sufficient numbers of staff to meet the needs of the clients and assure staff has knowledge of each individual client's care needs;
- Provide adequate supervision to identify inappropriate behaviors, such as rough handling or ignoring clients while giving care
- Provide clients, families, and staff information on how and to whom they may report concerns, incidents and grievances without fear of retribution;
- Identify, correct, and intervene in situations where abuse, neglect, mistreatment, or exploitation is likely to occur, including conditions in the physical environment that make abuse and/or neglect more likely to occur, such as secluded areas;
- Identify events, such as suspicious bruising of clients, that may constitute abuse to determine the direction of the investigation;

- Investigate different types of incidents and identify staff members responsible for the initial reporting, and reporting of results to the proper authorities;
- Protect clients from harm during an investigation;
- Analyze the occurrences of abuse, exploitation, mistreatment, or neglect and determine what changes are needed to policies and procedures to prevent further occurrences; and
- Report all alleged violations and all substantiated incidents as required under chs. 39 and 415, F.S., to the appropriate licensing authorities.

Section 42 creates s. 400.9978, F.S., to require each facility to provide a therapeutic milieu that supports a culture of individual empowerment and responsibility with the health and safety of the client as the primary concern at all times. To require that physical and chemical restraints be ordered for clients before they are used by the facility. The bill also requires that the order must be documented by the client's physician and the client or client's representative must be informed of the facility's physical and chemical restraint policy at the time of the client's admission.

Chemical restraint is limited to the dosage of medications prescribed by the client's physician. Clients receiving medications that can serve as a restraint must be evaluated by their physician at least monthly to assess:

- Continued use of medication;
- Level of the medication in client's blood; and
- Adjustments in the prescription.

A physician may order medications, limited to a 24-hour period, for emergency treatment when a client exhibits symptoms indicating an immediate risk of injury or death to self or others.

The facility must ensure clients are free from unnecessary drugs and physical restraints. Physical restraints and seclusion may only be used in accordance with the facility's written policies and state law. All interventions to manage dangerous client behaviors must be administered with sufficient safeguards and supervision. Also, The facility must also notify the parent or guardian of a client within 24 hours each time restraint or seclusion is used.

The AHCA may adopt rules relating to the use of restraints, seclusion, and emergency treatment orders for psychotropic medications.

Section 43 creates s. 400.9979, F.S., to require all facility personnel to complete a Level 2 background screening.[107] The facility must maintain personnel records which contain the staff's background screening, job description, training requirements, compliance documentation, and a copy of all licenses or certification held by staff who perform services for which licensure or certification is required. The record must also include a copy of all job performance evaluations. In addition, the bill requires the facility to:

- Implement infection control policies and procedures.

[107] As required in s 408.809(1)(e), F.S., and pursuant to ch. 435, F.S.

- Maintain liability insurance, as defined by s. 624.605, F.S., at all times.
- Designate one person as administrator who is responsible for the overall management of the facility.
- Designate in writing a person responsible for the facility when the administrator is absent for 24 hours.
- Obtain approval of the comprehensive emergency management plan from the local emergency management agency.
- Maintain written records in a form and system in accordance with standard medical and business practices and be available for submission to the AHCA upon request. The records must include:
  - A daily census record;
  - A report of all accident or unusual incidents involving clients or a staff member that caused or had the potential to cause injury or harm to any person or property within the facility;
  - Agreements with third party providers;
  - Agreements with consultants employed by the facility; and
  - Documentation of each consultant's visits and required written, dated reports.

Section 44 creates s. 400.9980, F.S., to allow clients the option of using their own personal belongings and choosing a roommate whenever possible. The admission of a client to a facility and his or her presence therein shall not confer on a licensee, administrator, employee, or representative any authority to manage, use, or dispose of any property of the client. The licensee, administrator, employee, or representative may not act as the client's guardian or trustee for any of the client's property.

The licensee, administrator, employee, or representative may act as a competent client's payee for social security or other benefits or be granted power of attorney for a client if the licensee has filed a surety bond with the AHCA in an amount equal to twice the average monthly income of the client.

The bill states the facility, upon consent from the client, shall provide for the safekeeping in the facility of personal effects not in excess of $1,000 and funds of the client not in excess of $500 in cash, and shall keep complete and accurate records of all funds and personal effects received.

The bill provides that any funds or other property belonging to or due to a client, or expendable for his or her account, which are received by the licensee, shall be trust funds which shall be kept separate from the funds and property of the licensee, and other clients, or shall be specifically credited to the client. At least once every month, unless upon order of a court of competent jurisdiction, the facility shall furnish the client and the client's representative a complete and verified statement of all funds and other property, detailing the amount and items received, together with their sources and disposition.

The bill mandates that any person who intentionally withholds the personal property of the a client or who borrows from any client's personal funds commits a crime punishable as a misdemeanor of the first degree. Also, any licensee, administrator, or staff, or representative thereof, who is granted power of attorney for any client of the facility and who misuses or misappropriates funds obtained through this power commits a felony of the third degree.

In the event of the death of a client, the facility shall return all refunds, funds, and property held in trust to the client's personal representative. If the client has no spouse or adult next of kin or such person cannot be located, funds due the client shall be placed in an interest-bearing account, and all property held in trust by the licensee shall be safeguarded until such time as the funds and property are disbursed pursuant to the Florida Probate Code.

The bill allows the AHCA, by rule, to clarify terms and specify procedures and documentation necessary to administer the provisions relating to the proper management of clients' funds and personal property and the execution of surety bonds.

Section 45 creates s. 400.9981, F.S., to authorize the AHCA to publish and enforce rules to include criteria to ensure reasonable and consistent quality of care and client safety. The AHCA may adopt and enforce rules related to:

- Physical plant of transitional living facilities.
- Qualifications of all personnel having responsibility for any part of the client's care and services.
- Requirements for personnel procedures and reporting procedures.
- Services provided to clients.
- The preparation and annual update of a comprehensive emergency management plan.

Section 46 creates s. 400.9982, F.S., which establishes penalties for violations. Current law requires the AHCA to determine if violations in health care related facilities are isolated, patterned or widespread by the AHCA.[108] The penalties in the bill take into account the frequency of the problems within the facility. Section 408.813, F.S., also separates violations into classes, 1 through 4, based on severity. Class 1 violations put clients in imminent danger, Class 2 violations directly threaten the safety of clients, Class 3 violations indirectly threaten the safety of clients, and Class 4 violations are primarily for paperwork violations that would not harm clients. The classifications must be included on the written notice of the violation provided to the facility.

The fines for violations are to be levied at the following amounts:

Class of Violation/Correction	Isolated	Patterned	Widespread
1 - regardless of correction	$5,000	$7,500	$10,000
2 - regardless of correction	$1,000	$2,500	$5,000
3 – if uncorrected	$500	$750	$1,000
	Range		
4 – if uncorrected	$100		$200

Section 47 creates s. 400.9983, F.S., to establish the right for the AHCA to use receivership proceedings established in s. 429.22, F.S. That section allows the AHCA to petition a court for the appointment of a receiver when the following conditions exist:

[108] s. 408.813(2), F.S.

- The facility is closing or has informed the AHCA that it intends to close.
- The AHCA determines the conditions exist in the facility that presents danger to the health, safety, or welfare of the clients of the facility.
- The facility cannot meet its financial obligations for providing food, shelter, care, and utilities.

Section 429.22, F.S., states that petitions for receivership shall take priority over other court business. A hearing shall be conducted within 5 days of the petition filing and the AHCA notifies the facility administrator or owner of the petition and sets the date of the hearing. The court may grant the petition only upon finding that the health, safety, or welfare of the client is threatened if certain conditions exist.

A receiver is appointed from a list of persons qualified to act as receiver developed by the AHCA and must make provisions for the continued health, safety, and welfare of all clients for the facility and perform all duties set out by the court. The receiver must operate the facility to assure the safety and adequate health care for the clients. The receiver may use all resources and consumable goods in the provision of care services to the client and correct or eliminate any deficiency in the structure or furnishings of the facility which endangers the safety of clients and staff. The receiver may hire or contract staff to carry out the duties of the receiver. The receiver must also honor all leases and mortgages, and has the power to direct and manage and to discharge employees of the facility.

Section 48 creates s. 400.9984, F.S., to require the AHCA, the DOH, the Agency for Persons with Disabilities, and the DCF to develop electronic systems to ensure relevant data pertaining to the regulation of transitional living facilities and clients is communicated timely among all agencies for the protection of clients. This system must include a brain and spinal cord injury registry and a client abuse registry. A database containing information on facilities will assist the various state agencies that are involved in regulating the facilities and the treatment of their clients.

Section 50 amends s. 408.061, F.S., to exempt state-operated hospitals from filing the FHURS report which the AHCA uses to gauge the amount required for the annual assessments on net operating revenues for inpatient and outpatient services. State-operated hospitals are made exempt from that assessment by the bill.

Section 51 amends s. 408.20, F.S., to exempt state operated hospitals, rather than only hospitals run by the Department of Children and Families, the DOH, and the DOC, from an assessment used to fund the data collection and analysis activities of the AHCA.

Section 52 amends s. 408.802, F.S., to conform to changes made to the regulation of transitional living facilities in this bill.

Section 53 amends s. 408.809, F.S., to add to the list of crimes which disqualify an applicant subject to a background check from employment with a health care entity. The added crimes include:

- Attempts, solicitation, and conspiracy to commit an offense listed in s. 408.809(4), F.S.;[109]
- Felonies involving the use of false, counterfeit, or expired credit cards;[110]
- Fraudulently obtaining goods or services from a health care provider;[111]
- Crimes related to racketeering and the collection of illegal debts;[112] and
- Violating the provisions in the Florida Money Laundering Act.[113]

Section 54 amends s. 408.820, F.S., to make conforming changes.

Section 55 amends s. 409.9122, F.S., to extend the requirements for Medicaid recipients with HIV/AIDS to be referred to certain specialty plans beyond the sunset date of October 1, 2014.

Section 57 amends s. 409.967, F.S., is amended to require Medicaid managed care plans to permit enrollees who were taking medications on the plan's formulary and the medication was subsequently removed or changed, to continue on their current prescription medication if a provider submits a written request demonstrating that the drug is medically necessary and the enrollee meets clinical criteria to receive the drug.

Section 58 amends s. 429.07, F.S., to make changes to improve the regulation of facilities with ECC and LNS specialty licenses. These changes include:

- Requiring that an ALF be licensed for 2 or more years before being issued a ECC license that is not provisional.
- Creating a provisional ECC license for ALFs that have been licensed for less than 2 years. The provisional license lasts for a period of 6 months. The facility must inform the AHCA when it has admitted one or more residents requiring ECC services. After the facility admits one or more ECC residents, the AHCA must inspect the facility for compliance with the requirements of the ECC license. If the licensee demonstrates compliance, the AHCA must grant the facility an ECC license that is not provisional. If the licensee fails to demonstrate compliance with the requirements of an ECC license, the licensee must immediately suspend ECC services and the provisional ECC license expires.
- Reducing monitoring visits for facilities with ECC licenses from quarterly to twice a year, and for facilities with LNS licenses from twice a year to once a year.
- Clarifying under what circumstances the AHCA may waive one of the required monitoring visits for facilities with ECC licenses and also allowing the AHCA to waive the required monitoring visit for facilities with an LNS license under the same conditions.
- Clarifying under what circumstances the AHCA may deny or revoke a facility's ECC license.

Section 59 amends s. 429.075, F.S., to change the requirement that facilities with three or more state supported mentally ill residents obtain a LMH license. Under the bill facilities with one or more state supported mentally ill residents must obtain a LMH license. This will expand the protections and services to all state supported mentally ill residents in ALFs.

[109] As detailed in s. 777.04, F.S.
[110] As detailed in s. 817.481, F.S. The crime is a felony if the value of the goods or services obtained in violation of s. 817.481, F.S., is $300 or more.
[111] As detailed in s. 817.50, F.S.
[112] As detailed in s. 895.03, F.S.
[113] As detailed in s. 896.101, F.S.

Section 60 amends s. 429.14, F.S., to strengthen the administrative penalties available to the AHCA by:

- Allowing the AHCA to revoke, rather than just deny, a license for a facility with a controlling interest that has, or had, a 25 percent or greater financial or ownership interest in a second facility that closed due to financial inability to operate or that was the subject of other specified administrative sanctions.
- Adding additional criteria under which the AHCA must deny or revoke a facility's license.
- Requiring the AHCA to impose an immediate moratorium on a facility that fails to provide the AHCA with access to the facility, prohibits a regulatory inspection, denies access to records, or prohibits the confidential interview of facility staff or residents.
- Exempting a facility from the 45-day notice requirement in s. 429.28(k), F.S., if that facility is required to relocate all or some of its residents due to action by the AHCA.

Section 61 amends s. 429.178, F.S., to make technical changes and to conform this section to other parts of the bill.

Section 62 amends s. 429.19, F.S., to reduce the discretion of the AHCA when imposing fines to make such penalties more predictable. Specifically, the bill:

- Fixes the dollar amount for fines at $7,500 for class I violations, $3,000 for class II violations, $750 for class III violations, and $150 for class IV violations for facilities licensed for fewer than 100 beds at the time of the violation. This is the midpoint of the current ranges for fines in current law.
- Multiplies fine amounts by 1.5 for facilities licensed for 100 or more beds, so that the fine is $11,250 for class I violations, $4,500 for class II violations, $1,125 for class IV violations, and $225 for class IV violations.
- Allows the AHCA to impose a fine on a facility for a class I violation, even if the facility corrects the violation before the AHCA conducts an investigation. Facilities may still challenge such fines through an administrative hearing pursuant to ch. 120, F.S.
- Doubles the fines for facilities with repeat class I and class II violations.
- Imposes a fine on facilities with repeat class III and class IV violations, regardless of correction. Current law prohibiting the AHCA from assessing fines for corrected class III and IV violations continues for the first survey finding such violations.
- Doubles the fines for class III or class IV violations if a facility is cited for two or more such violations, stemming from the same regulation, during the AHCA's last two licensure inspections.
- Fines a facility $500 for failure to comply with background screening requirements. This fine will take the place of fines based on the class of the violation.

Section 63 amends s. 429.26, F.S., to allow residents who require assistance with portable oxygen, colostomy care, and anti-embolism stockings or hosiery to be admitted to an assisted living facility if the facility has a nurse on staff or under contract to perform those services.

Section 64 amends s. 429.28, F.S., to require the notice of a resident's rights, obligations, and prohibitions specify that complaints to the ombudsman program, as well as the names and

identities of the complainant and any residents involved, are confidential. The notice must also contain information that retaliatory action cannot be taken against a resident for presenting grievances or for exercising any other resident right. This section also creates a fine of $2,500 which is imposed if a facility cannot show good cause in state court for terminating the residency of an individual. Section 429.28, F.S., is updated to reflect the most recent name of Disability Rights Florida.

Section 65 amends s. 429.34, F.S., to require certain state officials, such as Medicaid Fraud investigators, staff from the Attorney General's Office, and state or local fire marshals report to the DCF central abuse hotline any knowledge or reasonable suspicion that a vulnerable adult has been or is being abused, neglected, or exploited. The bill provides that a facility with one or more class I violations, two or more class II violations cited within 60 days, or two or more unrelated class II violations cited during one survey is subject to an additional inspection within 6 months. The licensee must pay a fee to the AHCA to cover the cost of the additional inspection.

Section 66 amends s. 429.52, F.S., to require that, effective October 1, 2013, a facility provide a 2 hour pre-service orientation for new facility employees who have not previously completed core training. The pre-service orientation must cover topics that help the employee provide responsible care and respond to the needs of the residents. The employee and the facility's administrator must sign an affidavit that the employee completed the orientation, and the facility must keep the affidavit in the employee's work file.

Section 67 creates a non-statutory provision of Florida law that requires the AHCA to conduct a study of inter-surveyor reliability to determine if different surveyors consistently apply licensure standards. The AHCA must report its findings and make recommendations to the governor, the president of the Senate, and the speaker of the House of Representatives by November 1, 2013.

Section 68 creates a non-statutory provision of Florida law that finds that consumers need additional information in order to select an ALF. To facilitate this, the bill requires the AHCA to propose a rating system for ALFs. The AHCA must submit the proposal to the governor, the president of the Senate, and the speaker of the House of Representatives by November 1, 2013. The AHCA is also required to create a consumer guide website by January 1, 2014. The website must contain information on ALFs and include a monitored comment section.

Section 70 amends s. 435.04, F.S., to require vendors who submit fingerprints on behalf of employers to provide the first, middle, and last name, social security number, date of birth, mailing address, sex, and race of an applicant. Attempts, solicitation, and conspiracy to commit any offense listed in s. 435.04(2), F.S.,[114] are added to the list of crimes which disqualify any applicant subject to a Level 2 background check from employment.

Section 71 amends s. 435.07, F.S., to strike the term "sanction" from s. 435.07, F.S., and revise the conditions an agency head must consider when determining whether to grant an exemption to disqualification from employment. Under the bill, the 3-year waiting period for a felony offense applies to nonmonetary conditions imposed by the court and not to the satisfaction of monetary requirements. However, all court-ordered fees, fines, or other monetary requirements relating to

[114] As detailed in s. 777.04, F.S.

a disqualifying felony or misdemeanor must be paid in full as a condition of eligibility for an exemption from disqualification of employment.

Section 72 amends s. 435.12, F.S., to require employers of persons subject to background screening by specified agencies[115] to register and initiate all criminal history checks through the CPBSC before referring an employee or potential employee for electronic fingerprint submission to the FDLE. The registration submitted must include the employee's first, middle, and last name, social security number, date of birth, mailing address, sex, and race. This section now includes the requirement that a photograph be submitted at the time fingerprints are submitted, which is transferred from s. 435.04, F.S.

Section 73 amends s. 440.102, F.S., to delete language requiring drug-testing laboratories to submit a monthly report to conform to other changes made in the bill. The bill also deletes language requiring laboratories that analyze initial drug testing specimens to comply with certain requirements, conforming to changes made to the statutes in 2009.[116]

Section 75 creates s. 465.1902, F.S., to:

- Preempt to the state all regulation of the licensure, activity, and operation of pharmacies and pharmacists as defined in ch. 465, F.S.;
- Restrict local governments or political subdivisions of the state from enacting or enforcing ordinances that imposes a levy, charge, or fee upon, or that otherwise regulate pharmacies and pharmacists as defined in ch. 465, F.S.; and
- Allow local governments and political subdivisions to enact ordinances regarding:
    - Local business taxes adopted pursuant to ch. 205, F.S.; and
    - Land use development regulations adopted pursuant to ch. 163, F.S., which include regulation of any aspect of development, including a subdivision, building construction, sign regulation, and any other regulation concerning the development of land, landscaping, or tree protection, and which do not include restrictions on pain-management services, health care services, or the prescribing of controlled substances.

Section 76 amends s. 499.003, F.S., to exempt the transfer of prescription drugs from a hospital's supplier to a prescription drug repackager from the definition of the term wholesale distribution and to make conforming changes.

Section 77 amends s. 499.01, F.S., to require that any person located outside of the state who repackages and delivers prescription drugs into Florida under the provisions in s. 499.003, F.S., as amended by the bill must obtain a prescription drug repackager permit.

Section 78 amends s. 499.01212, F.S., to require that the pedigree paper for prescription drugs transferred to a repackager pursuant to the provisions in s. 499.003, F.S., as amended by the bill include:

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[115] Supra n. 6

[116] Ch. 2009-127, L.O.F., removed the requirement for initial drug-free workplace testing to be performed by a licensed forensic toxicology laboratory from s. 440.102(5)(d), F.S.

- A statement that the distributor purchased the prescription drug directly from the manufacturer;
- The manufacturer's national drug code identifier;
- The name and address of the distributor and purchaser of the prescription drug;
- The name of the drug as it appears on the label; and
- The quantity, dosage form, and strength of the drug.

This section also requires the pedigree paper for prescription drugs transferred from a repackager to a hospital or health care entity pursuant to the provisions in s. 499.003, F.S., as amended by this bill include:

- A statement that the distributor purchased the prescription drug directly from the manufacturer;
- The lot numbers of the prescription drugs;
- The name and address of the repackager;
- The repackager's signature;
- The date of receipt; and
- The name and address of the person authorized by law to purchase prescription drugs for the purpose of administering or dispensing the drugs.

Section 79 amends s. 499.041, F.S., to allow the DOH to assess a licensing fee on an out-of-state repackager permitee or applicant.

Section 86 creates s. 893.0552, F.S., to preempt to the state all regulation of the licensure and activity and operation of pain management clinics as defined in ss. 458.3265 and 459.0137, F.S., in the following circumstances:

- The clinic is wholly owned and operated by a physician who performs interventional pain procedures routinely billed using surgical codes, who has never been suspended or revoked for prescribing certain controlled substances, *and who*:
  - has completed a fellowship in pain medicine approved by certain bodies;
  - is board-certified in pain medicine by specified entities; or
  - has a board certification or subcertification in pain management or pain medicine by an approved specialty board.
- The clinic is wholly owned and operated by a physician-multispecialty practice if one or more board-eligible or board-certified medical specialists has one of the qualifications specified above, performs interventional pain procedures of the type routinely billed using surgical codes, and has never been suspended or revoked for prescribing certain controlled substances.
- Allow local governments and political subdivisions to enact ordinances regarding:
  - Local business taxes adopted pursuant to ch. 205, F.S.; and
  - Land use development regulations adopted pursuant to ch. 163, F.S.

A pain-management clinic specified in this section is permissible use in a land use or zoning category that permits hospitals and other health care facilities or clinics as defined in chapter 395 or s. 408.07, F.S.

Upon the request of a local government, a pain-management clinic must annually demonstrate that it qualifies for the preemption outlined in this section.

Section 87 provides an effective date of July 1, 2013.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

The bill requires the AHCA to conduct a new survey of assisted living facilities within six months after finding a class I or two or more class II violations. The AHCA must assess a fee on the facility for the cost of the survey as is the case in other surveys. Facilities with serious violations that require this additional survey will pay this additional fee. According to the AHCA, current fees and fines from ALFs do not cover the cost of regulating such facilities statewide.

B. Private Sector Impact:

Transitional living facilities may incur indeterminate increased costs based on the increased requirements for those facilities under the bill.

Some physicians and health care practices may be negatively impacted from a time management perspective by the additional requirement to consult the PDMP prior to dispensing.

Assisted living facilities will experience more consistent regulation and more predictable penalties under the bill. The bill revises fines used to sanction facilities with violations, but such fines can still be challenged and settled through ch. 120, F.S. Facilities having fewer than 100 beds that commit class I violations will now be assessed a fine of $7,500, while current law allows the fine to be between $5,000 and $10,000. Some facilities will see a reduction in fines, while other will see an increase. The range for fines for class II, III, and IV violations are replaced with an amount equal to the midpoint of the range. Fines for facilities having 100 beds or more will see higher fines. This will help resolve

an inequity in penalties whereby small facilities must pay the same fine amount as larger facilities.

Assisted living facilities that remove residents without cause, as determined by a state court, will be assessed a fine of $2,500. Facilities will also be assessed a fine for class I violations even if they are corrected when the AHCA visits the facility. Facilities violating the background screening requirements will be fined $500. Currently, facilities are cited for a class II or III violation for not screening the background of facility staff, so the fine amount can vary. All fines are subject to challenge through an administrative hearing under ch. 120, F.S. This due process is retained under the bill.

Assisted living facilities will be required to provide new employees that have not already gone through the ALF core training program with a 2 hour pre-service training session before they work with residents. The cost of this training is not expected to be significant and in many cases is already provided.

Assisted living facilities having specialty licenses which meet licensure standards will see fewer monitoring visits from the AHCA. This will positively impact the facilities as they will have less interruption of staff time due to such visits.

Assisted living facilities having any state supported mentally ill residents must meet limited mental health licensure requirements. Facilities with one or two state supported mentally ill residents which do not meet these requirements may see increased costs to comply. Some facilities with one or two such residents however, may already meet the requirements for a limited mental health license.

Assisted living facilities having significant uncorrected violations will be more likely to see their licenses suspended or revoked under the bill. Closing facilities that have significant problems will improve the public's assessment of ALFs and may improve the financial success of those facilities that meet licensure standards.

C. Government Sector Impact:

The AHCA currently regulates the 13 transitional living facilities in the state and is not expected to incur increased costs of regulation under the bill. The AHCA may experience increased costs to develop a database to hold information on facilities that would be shared with other state agencies as required under the bill, but those costs should be absorbed within existing resources.

The DOH will incur non-recurring costs for rulemaking which can be absorbed within existing resources. The DOH may also experience an indeterminate increase in workload implementing the requirements of this bill.

The AHCA and the DOEA may need to revise their rules regulating assisted living facilities. The bill requires the AHCA to study the extent to which surveyors are consistent. The bill requires the AHCA to propose a rating system for assisted living

facilities that would help consumers in selecting a facility. The cost of these requirements would be insignificant.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The CS amends s. 395.4025, F.S., to provide a definition for "areas with limited trauma center services." One of the criteria to meet the definition includes being located in a county with no "designated or provisional" trauma centers. This section is also amended to allow current trauma centers "designated as Level I, Level II, or pediatric trauma centers" to retain their designations unless they are unable to comply with the adopted standards for such centers.

Although the term "designated" is used at times in current law, the DOH "approves" trauma centers, rather than "designates" them. To avoid ambiguity with the new designated trauma centers in areas with limited access to trauma center services, this section should be amended to read "approved or provisional" trauma centers.

VIII. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS/CS by Appropriations on April 18, 2013:

The committee substitute:

- Allows the DHSMV to share the digital image and signature of driver licensees with the AHCA for the purpose of verifying photographs in the CPBSC;
- Revises the regulations for trauma centers;
- Amends the definition of nurse registry to comply with provisions in the insurance code;
- Exempts the delivery of home dialysis services provided by a federally certified end-stage renal disease provider from the licensure requirements for home health agencies;
- Excludes certain health care facilities from the definition of "clinic" under section 400.9905, F.S.;
- Significantly revises regulations for transitional living facilities:
- Adds conspiracy, attempt, and solicitation, to commit listed crimes as well as several other monetary based crimes to the list of offenses which disqualify an applicant subject to a Level 2 background check from employment;
- Authorizes an agency head to grant an exemption to disqualification from employment if 3 years have elapsed since the applicant has completed all nonmonetary conditions for a felony offense and the applicant has paid all monetary costs associated with a disqualifying felony or misdemeanor;
- Extends the requirements for Medicaid recipients with HIV/AIDS to be referred to certain specialty plans beyond the sunset date of October 1, 2014

- Requires Medicaid managed care plans to permit enrollees to continue on their current medication if a provider submits a written request demonstrating that the drug is medically necessary;
- Strengthens the enforcement of current regulations for ALFs.
- Allows nurses to provide assistance with portable oxygen, colostomy care, and anti-embolism stockings in a standard license ALF; and
- Preempts the regulation of pharmacies and pain management clinics to the state under certain circumstances.

CS by Health Policy on March 14, 2013:
The CS substantially amends SB 966 to:
- Add the American Osteopathic Association/Healthcare Facilities Accreditation Program to those organizations specifically recognized as accrediting organizations in ss. 154.11, 394.741, 395.3038, 397.403, 400.925, 400.9935, 402.7306, 409.966, 430.80, 440.13, 627.645, 627.668, 627.669, 627.736, 641.495, and 766.1015, F.S.;
- Delete language requiring drug-testing laboratories to submit a monthly report to the AHCA;
- Allow hospitals, ambulatory surgical centers, and mobile surgical facilities to pay inspection fees at times other than the time of inspection;
- Repeal s. 395.1046, F.S., which grants the AHCA duplicative authority to investigate complaints related to access to emergency services and care;
- Delete obsolete language regarding the AHCA's list of primary and comprehensive stroke centers;
- Exempt all state-operated hospitals, rather than only hospitals run by the DOC, from the annual assessments on net operating revenues for inpatient and outpatient services to fund public medical assistance required by s. 395.701, F.S.;
- Repeal an annual assessment on health care entities that was found to be unconstitutional;
- Exempt state-operated hospitals from filing the FHURS report which the AHCA uses to assess the amount required for the annual assessments on net operating revenues for inpatient and outpatient services required; State-operated hospitals are made exempt from that assessment by section 8 of the bill;
- Exempt state-operated hospitals from an assessment used to fund the data collection and analysis activities of the AHCA; and
- Create the Standardized Credentials Collection and Verification Program for physicians.
- Restricts health care entities from requesting core credentials from physicians.
- Exempt the transfer of prescription drugs from a hospital's supplier to a prescription drug repackager from the definition of the term wholesale distribution and make conforming changes.
- Require any person located outside of the state who repackages and delivers prescription drugs into Florida to obtain a prescription drug repackager permit.
- Require that the pedigree paper for prescription drugs transferred to a repackager and from a repackager contain the specified information.

B. Amendments:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.