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 Policy and Steering Committee on Ways and Means

BILL:	CS/CS/SB 2434
INTRODUCER:	Policy and Steering Committee on Ways and Means; Health Regulation Committee and Senator Gardiner
SUBJECT:	Reduction and Simplification of Health Care Provider Regulation
DATE:	April 20, 2010 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Wilson	HR	**Fav/CS**
2.	Hansen	Coburn	WPSC	**Fav/CS**
3.				
4.				
5.				
6.				

I. Summary:

This bill repeals obsolete and redundant provisions, defines and corrects references to the Joint Commission, updates references to a variety of organizations and state agencies to reflect current titles or responsibilities related to facilities regulated by the Agency for Health Care Administration (AHCA), and streamlines reporting by licensed facilities and state agencies.

The bill makes the following substantive changes:

- Authorizes the Department of Health (DOH) to accept funds from local governments and spend those funds for licensable products approved by the U.S. Department of Health and Human Services in response to a public health emergency;
- Revises provisions affecting nursing homes as follows:
  - Limits the DOH food service inspections in nursing homes to twice per year, absent complaints, and the State Fire Marshal inspections to once per year, absent complaints;
  - Revises the timeframe for a nursing home to provide a resident accounting of personal property held by the facility;
  - Expands the authorized staffing of a geriatric outpatient clinic in a nursing home to include a licensed practical nurse under the direct supervision of a registered nurse, advanced registered nurse practitioner, or physician;
  - Authorizes a $1,000 fine per day if a nursing home fails to impose a moratorium on new admissions when the facility has not complied with the minimum-staffing requirements;
  - Eliminates the requirement for a newly hired nursing home surveyor to observe a facility's operations as a part of basic training;

  - Relieves the annual assessment related to Medicaid overpayments for leased nursing homes if the bond fund exceeds $25 million;
  - Requires the AHCA to adopt rules for minimum staffing requirements for nursing homes that serve persons under 21 years of age; and
  - Eliminates the monthly reporting of any notice of claims or liability claims filed against the facility;
- Revises provisions affecting assisted living facilities (ALFs) as follows:
  - Repeals the limited nursing services (LNS) specialty license and authorizes LNS to be provided by appropriately licensed persons in an ALF with a standard license;
  - Increases the per-bed fee for a standard-licensed ALF by $8.50 biennially for beds that are not designated for recipients of optional state supplementation payments (OSS), to offset the loss of revenue that is currently generated from the fees associated with the LNS specialty license. The maximum amount that an ALF is required to pay for the standard license fee is increased;
  - Requires additional monitoring, either onsite or by a desk review, for an ALF that has been cited with a class I or class II deficiency. The bill repeals the requirement for additional monitoring inspections of an ALF licensed with an extended congregate care (ECC) specialty license;
  - Requires all ALFs to report electronically to the AHCA, at least semiannually, certain aggregated data related to the residents and staff of the facility;
  - Modifies the AHCA's consultation responsibilities; and
  - Eliminates the monthly reporting of any notice of claims or liability claims filed against the facility;
- Expands the definition of a portable equipment provider within the requirements for a health care clinic license to include a portable *health service* or equipment provider;
- Provides additional exemptions for licensure and regulation as a health care clinic for the following:
  - Pediatric cardiology or perinatology clinic facilities;
  - Certain corporate entities with $250 million or more in annual sales of health care services provided by licensed health care practitioners; and
  - Certain publicly traded entities;
- Enhances the general licensing provisions of part II of ch. 408, F.S., to:
  - Provide that the license renewal notice that the AHCA sends is a *courtesy* notice;
  - Authorize the AHCA to impose an administrative fine, not to exceed $500 per violation, for violations that do not qualify within the classification scheme of class I – class IV violations;
  - Authorize the AHCA to extend the license expiration date for up to 30 days and impose other conditions during that extension period in order to accomplish the safe and orderly discharge of clients or residents; and
  - Prohibit activities related to altering, defacing, or falsifying a license certificate;
- Authorizes the AHCA to impose an administrative fine for class IV violations that are uncorrected or repeated by a licensed intermediate care facility for developmentally disabled persons;
- Requires a Medicaid claim for a prescription drug billed as a 340B prescribed medication to meet certain requirements;

- Eliminates the requirement for prescription drugs that were purchased at public health prices and held by a contract provider or subcontractor to be stored separately from other prescription drug inventory;
- Requires a community blood center to disclose certain information on its website; exempts certain blood establishments from licensure as a prescription drug manufacturer and registering products; and enables certain community blood centers to obtain a permit to lawfully engage in the wholesale distribution of certain prescription drugs;
- Eliminates the requirement for a pedigree paper for prescription drugs that are distributed in certain medical convenience kits; and
- Includes licensed orthotists and prosthetists in the definition of a health care provider under ch. 766, F.S., related to medical malpractice.

Adoption of this legislation is anticipated to have an insignificant fiscal impact on state agencies. Some types of facilities (such as certain ALFs) may experience a fee increase; and some types of facilities (such as a community blood centers) may experience a fee decrease. Please see the fiscal impact statement in section V of this analysis for details.

This bill amends the following sections of the Florida Statutes: 154.11, 318.21, 381.00315, 381.0072, 381.06014, 394.4787, 394.741, 395.002, 395.003, 395.0193, 395.1023, 395.1041, 395.1055, 395.10972, 395.2050, 395.3036, 395.3038, 395.602, 400.021, 400.0239, 400.0255, 400.063, 400.071, 400.0712, 400.111, 400.1183, 400.141, 400.142, 400.162, 400.179, 400.19, 400.23, 400.275, 400.484, 400.606, 400.607, 400.915, 400.925, 400.931, 400.932, 400.967, 400.9905, 400.991, 400.9935, 408.034, 408.036, 408.043, 408.05, 408.061, 408.07, 408.10, 408.804, 408.806, 408.810, 408.813, 408.815, 409.91196, 409.912, 429.07, 429.11, 429.14, 429.17, 429.19, 429.255, 429.35, 429.41, 429.53, 429.54, 429.71, 429.915, 430.80, 440.13, 483.201, 483.294, 499.003, 499.005, 499.01, 499.01212, 627.645, 627.668, 627.669, 627.736, 633.081, 641.495, 651.118, 766.1015, and 766.202.

The bill repeals the following sections of the Florida Statutes: 112.0455(10)(e), 383.325, 395.1046, 395.3037, 400.147(10), 400.148, 400.195, 408.802(11), 409.221(4)(k), 429.12(2), 429.23(5), 429.28(3), and 429.911(2)(a).

II. Present Situation:

Health Care Licensing

The AHCA regulates over 41,000 health care providers under several regulatory programs based upon individual licensing statutes and the general licensing provisions in part II of ch. 408, F.S. The health care providers include:

- Laboratories authorized to perform testing under the Drug-Free Workplace Act, as provided under ss. 112.0455 and 440.102, F.S.;
- Birth centers, as provided under ch. 383, F.S.;
- Abortion clinics, as provided under ch. 390, F.S.;
- Crisis stabilization units, as provided under parts I and IV of ch. 394, F.S.;
- Short-term residential treatment facilities, as provided under parts I and IV of ch. 394, F.S.;
- Residential treatment facilities, as provided under part IV of ch. 394, F.S.;

- Residential treatment centers for children and adolescents, as provided under part IV of ch. 394, F.S.;
- Hospitals, as provided under part I of ch. 395, F.S.;
- Ambulatory surgical centers, as provided under part I of ch. 395, F.S.;
- Mobile surgical facilities, as provided under part I of ch. 395, F.S.;
- Health care risk managers, as provided under part I of ch. 395, F.S.;
- Nursing homes, as provided under part II of ch. 400, F.S.;
- Assisted living facilities, as provided under part I of ch. 429, F.S.;
- Home health agencies, as provided under part III of ch. 400, F.S.;
- Nurse registries, as provided under part III of ch. 400, F.S.;
- Companion services or homemaker services providers, as provided under part III of ch. 400, F.S.;
- Adult day care centers, as provided under part III of ch. 429, F.S.;
- Hospices, as provided under part IV of ch. 400, F.S.;
- Adult family-care homes, as provided under part II of ch. 429, F.S.;
- Homes for special services, as provided under part V of ch. 400, F.S.;
- Transitional living facilities, as provided under part V of ch. 400, F.S.;
- Prescribed pediatric extended care centers, as provided under part VI of ch. 400, F.S.;
- Home medical equipment providers, as provided under part VII of ch. 400, F.S.;
- Intermediate care facilities for persons with developmental disabilities, as provided under part VIII of ch. 400, F.S.;
- Health care services pools, as provided under part IX of ch. 400, F.S.;
- Health care clinics, as provided under part X of ch. 400, F.S.;
- Clinical laboratories, as provided under part I of ch. 483, F.S.;
- Multiphasic health testing centers, as provided under part II of ch. 483, F.S.; and
- Organ, tissue, and eye procurement organizations, as provided under part V of ch. 765, F.S.

The general licensing provisions contain standards for licensure application requirements, ownership disclosure, staff background screening, inspections, and administrative sanctions. Each provider type has an authorizing statute (as listed above) that includes unique provisions for licensure beyond the general licensing provisions. If a conflict exists between the general licensing provisions and the authorizing statute, s. 408.832, F.S., provides that the general licensing provisions prevail.

There are several references in the authorizing statutes that conflict or duplicate regulations in the general licensing provisions, including references to the classification of deficiencies, penalties for an intentional or negligent act by a provider, provisional licenses, proof of financial ability to operate, inspection requirements, and plans of corrections from providers.

Nursing Homes

Nursing homes provide long-term and sub-acute care to persons in need of 24-hour nursing services or significant supportive services. Nursing home residents are generally frail, physically and psychosocially compromised, heavily dependent upon others for basic care and sustenance, and in some cases near the end of their lives. When residents live in an environment where they are totally dependent on others, they are especially vulnerable to abuse, neglect, and exploitation.

The quality of care and quality of life for residents of nursing homes have been a concern for decades. Nursing home regulation has evolved over the past 20 years at the state and federal levels. In February 2001, the Committee on Health, Aging and Long-Term Care in the Florida Senate published Interim Project Report 2001-025, *Long-Term Care Affordability and Availability*.[1] This report lays out the historical landscape and challenges of long-term care in Florida as it existed in the early part of this decade. Generally, the nursing home system in Florida was near crisis with increasing litigation and adverse judgments, spiraling liability insurance premiums or the inability to obtain liability coverage from regulated carriers, financial instability of nursing homes, and concerns regarding the quality of care that patients were receiving and prospective care based on increasingly more complex resident needs.
Chapter 2001-45, Laws of Florida (L.O.F.), stemming in part from the Interim Project Report 2001-025, represented a significant overhaul of the long-term care system in Florida. Among other things, this law established a monthly reporting requirement of liability claims filed against nursing homes. This data, as well as other data related to nursing homes was included in a Semi-annual Report on Nursing Homes that the AHCA was required to submit to the Governor and Legislature. This statutory reporting obligation in s. 400.195, F.S., expired on June 30, 2005. Cumulative data is reported on the AHCA's website that reflects trending information on the number of claims filed statewide monthly and quarterly.[2]

Food Services
The DOH regulates all food hygiene standards in nursing homes licensed by the AHCA using rule chapter 64E-11, F.A.C. These rules are based on the most recent U.S. Food and Drug Administration (FDA) Federal Food Code at the time of adoption. Nursing home kitchens are issued a sanitation certificate annually to operate their food service kitchens. Routine inspections are conducted quarterly to ensure that the health of residents is protected and the establishments are in compliance with the food safety, sanitation, and health standards. This complies with the FDA's inspection frequency standards, which recommend that nursing home food operations be inspected four times per year.

Assisted Living Facilities
An assisted living facility (ALF) provides housing, meals, personal care services, and supportive services to older persons and disabled adults who are unable to live independently. ALFs are intended to be an alternative to more restrictive, institutional settings for individuals who need housing and supportive services, but who do not need 24-hour nursing supervision. Generally, an ALF provides supervision, assistance with personal care services, such as bathing, dressing, eating, and assistance with or administration of medications.

As of December 2009, there were 2,830 ALFs licensed with a standard license by the AHCA in this state, for a total of 80,539 beds.[3] In addition to a standard license, an ALF may have

[1] The Florida Senate Interim Project Report 2001-025, *Long-Term Care Affordability and Availability*, may be found at <http://www.flsenate.gov/data/Publications/2001/Senate/reports/interim_reports/pdf/2001-025hc.pdf> (Last visited on April 8, 2010).
[2] See: <http://www.fdhc.state.fl.us/MCHQ/Long_Term_Care/FDAU/docs/LiabilityClaims/NH_Chart.pdf> (Last visited on April 8, 2010).
[3] Source: The AHCA 2010 Bill Analysis & Economic Impact Statement for SPB 7018, on file with the Senate Health Regulation Committee.

specialty licenses that authorize an ALF to provide LNS, limited mental health services,[4] and ECC services. As of September 2009, there were 475 ALFs licensed with a standard license only, for a total of 32,356 beds.[5]

LNS Specialty License

An LNS 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. As of December 2009, there were 977 ALFs licensed with an LNS specialty license.[6]

The nursing services authorized to be provided with this license are limited to acts specified in administrative rules,[7] 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. A nursing assessment, that describes the type, amount, duration, scope, and outcomes or services that are rendered and the general status of the resident's health, is required to be conducted at least monthly on each resident who receives a limited nursing service.

An LNS licensee is subject to monitoring inspections by the AHCA or its agents 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.[8]

The biennial fee for an LNS license is $296 per license with an additional fee of $10 per resident based on the total licensed resident capacity of the facility.[9] Ostensibly, this fee covers the additional monitoring inspections currently required of facilities with an LNS license.

Licensure Fees

The biennial licensure fees for the ALF standard license and specialty licenses are found in s. 429.07(4), F.S. This section refers to the general health care licensure provisions in part II of

[4] An ALF that serves three or more mental health residents must obtain a limited mental health specialty license. 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 OSS.

[5] Source: The AHCA in an email to committee professional staff dated September 23, 2009.

[6] Ibid, 6. The AHCA does not track the number of LNS beds.

[7] Rule 58A-5.031, F.A.C. The additional nursing services that might be performed pursuant to the LNS license include: conducting passive range of motion exercises; applying ice caps or collars; applying heat, including dry heat, hot water bottle, heating pad, aquathermia, moist heat, hot compresses, sitz bath and hot soaks; cutting the toenails of diabetic residents or residents with a documented circulatory problem if the written approval of the resident's health care provider has been obtained; performing ear and eye irrigations; conducting a urine dipstick test; replacing an established self-maintained indwelling urinary catheter, or performing an intermittent urinary catheterization; performing digital stool removal therapies; applying and changing routine dressings that do not require packing or irrigation, but are for abrasions, skin tears and closed surgical wounds; caring for stage 2 pressure sores, (care for stage 3 or 4 pressure sores are not permitted); caring for casts, braces and splints, (care for head braces, such as a halo, is not permitted); assisting, applying, caring for, and monitoring the application of anti-embolism stockings or hosiery; administering and regulating portable oxygen; applying, caring for, and monitoring a transcutaneous electric nerve stimulator (TENS); performing catheter, colostomy, and ileostomy care and maintenance; conducting nursing assessments; and, for hospice patients, providing any nursing service permitted within the scope of the nurse's license, including 24-hour nursing supervision.

[8] s. 429.07(3)(c), F.S.

[9] s. 429.07(4)(c), F.S., as adjusted per s. 408.805(2), F.S.

ch. 408, F.S. Section 408.805, F.S., provides for licensure fees to be adjusted annually by not more than the change in the Consumer Price Index (CPI) based on the 12 months immediately preceding the increase. The following chart reflects the licensure fees contained in s. 429.07(4), F.S., and the adjusted licensure fees based on the CPI that are currently in effect.[10]

Fee Description	Per s. 429.07(4), F.S.	CPI adjusted (current fee)
Standard ALF Application Fee	$300	$356
Standard ALF Per-Bed Fee (non-OSS)	$ 50	$ 59
Total Licensure fee for Standard ALF	$10,000	$13,087
ECC Application Fee	$400	$501
ECC Per-Bed Fee (licensed capacity)	$ 10	$ 10
LNS Application Fee	$250	$296
LNS Per-Bed Fee (licensed capacity)	$ 10	$ 10

Senate Interim Project Report 2010-118
During the 2009-2010 interim, professional staff of the Senate Committee on Health Regulation reviewed the licensure structure for ALFs. The recommendations in the resulting report are to repeal the LNS specialty license and authorize a standard-licensed ALF to provide the nursing services currently authorized under the LNS license; require an additional inspection fee, adjusted for inflation, for a facility that indicates that it intends to provide LNS; require each ALF to periodically report electronically information, as determined by rule, related to resident population, characteristics, and attributes; authorize the AHCA to determine the number of additional monitoring inspections required for an ALF that provides LNS based on the type of nursing services provided and the number of residents who received LNS as reported by the ALF; and repeal the requirement for the AHCA to inspect *all* the ECC licensees quarterly, instead targeting monitoring inspections for those facilities with residents receiving ECC services.

Liability Claims Reporting
Chapter 2001-45, L.O.F.,[11] also established a monthly reporting requirement of liability claims filed against assisted living facilities. Cumulative data is reported on the AHCA's website that reflects trending information on the number of claims filed statewide monthly and quarterly.[12]

Adult Family-Care Homes
An adult family-care home is a full-time family-type living arrangement, in a private home, under which a person who owns or rents the home provides room, board, and personal care, on a 24-hour basis, for no more than five disabled adults or frail elders who are not relatives. The adult family-care home provider must live in the home. Adult family-care homes are licensed and regulated under part II of ch. 429, F.S., part II of ch. 408, F.S., and Chapter 58A-14, F.A.C., unless the person who owns or rents the home provides room, board, and personal services for

[10] Found on the AHCA website at: <http://ahca.myflorida.com/MCHQ/LONG_TERM_CARE/Assisted_living/alf/ALF_fee_increase.pdf>, (Last visited on April 5, 2010).
[11] s. 36, ch. 2001-45, L.O.F., creating s. 400.423, F.S.
[12] See: <http://www.fdhc.state.fl.us/MCHQ/Long_Term_Care/FDAU/docs/LiabilityClaims/ALF_Chart.pdf> (Last visited on April 8, 2010).

not more than two adults who do not receive optional state supplementation, or for only his or her relatives. A frail elder is a functionally impaired person who is 60 years of age or older and who has physical or mental limitations that restrict the person's ability to perform the normal activities of daily living and impede the person's capacity to live independently.

Consumer Directed Care Program

The Consumer Directed Care Program (CDC) was implemented as a Medicaid 1115 Research and Demonstration waiver. As part of the new program, the AHCA was required to produce an annual report to the Legislature. In March 2008, the CDC program was approved to be under the 1915(j) self-directed option as a Medicaid state plan amendment instead of an 1115 Research and Demonstration waiver. The 1915(j) state plan amendment requires annual and 3-year comprehensive reporting to the federal Centers for Medicare and Medicaid Services (CMS). The report to the CMS communicates the current status of the CDC program, data on CDC enrollment, demographics, consumer satisfaction and cost effectiveness. The CMS requires this report to be available for public review.

Blood Establishments[13]

A blood establishment is defined in s. 381.06014, F.S., to mean any person, entity, or organization, operating within Florida, which examines an individual for the purpose of blood donation or which collects, processes, stores, tests, or distributes blood or blood components collected from the human body for the purpose of transfusion, for any other medical purpose, or for the production of any biological product.

The state of Florida does not issue a specific license as a blood establishment. Florida law[14] requires a blood establishment operating in Florida to operate in a manner consistent with the provisions of federal law in Title 21 Code of Federal Regulations (C.F.R.) parts 211 and 600-640, relating to the manufacture and regulation of blood and blood components. If the blood establishment does not operate accordingly and is operating in a manner that constitutes a danger to the health or well-being of blood donors or recipients, the AHCA or any state attorney may bring an action for an injunction to restrain such operations or enjoin the future operation of the establishment.

Federal law classifies blood establishments as follows:[15] community (non-hospital) blood bank ("community blood center"), hospital blood bank, plasmapheresis center, product testing laboratory, hospital transfusion service, component preparation facility, collection facility, distribution center, broker/warehouse, and other. Community blood centers are primarily engaged in collecting blood and blood components from voluntary donors to make a safe and adequate supply of these products available to hospitals and other health care providers in the

[13] During the 2009-2010 interim, professional staff of the Senate Committee on Health Regulation reviewed the regulation of blood banks (a.k.a. community blood centers). For additional information refer to Interim Report 2010-119 available at: <http://www.flsenate.gov/data/Publications/2010/Senate/reports/interim_reports/pdf/2010-119hr.pdf> (Last visited on April 8, 2010).

[14] s. 381.06014, F.S.

[15] A description of these classifications may be found at: <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/EstablishmentRegistration/BloodEstablishmentRegistration/ucm055484.htm> (Last visited on April 8, 2010).

community for transfusion. Blood establishments that focus on the collection of plasma that is not intended for transfusion, but is intended to be sold for the manufacture of blood derivatives[16] routinely pay donors.

Community blood centers in Florida are licensed as clinical laboratories by the AHCA, unless otherwise exempt.[17] As a part of the clinical laboratory license, the facility is inspected at least every two years. The AHCA may accept surveys or inspections conducted by a private accrediting organization in lieu of conducting its own inspection. The clinical laboratory personnel are required to maintain professional licensure by the Department of Health (DOH). Community blood centers must also have appropriate licenses issued by the DOH and must comply with laws related to biomedical waste[18] and radiation services.[19]

Currently, there are six not-for-profit corporations and one for-profit corporation that operate community blood centers in Florida. Several hospital-owned blood centers operate in this state as well, primarily collecting for their own use. At least one community blood center that does not have a fixed location in Florida, collects blood and blood components using a mobile blood-collection vehicle from volunteer donors and distributes blood and blood components to health care providers in Florida.

Human blood and blood products are characterized as both "biologics,"[20] for purposes of regulation under the federal Public Health Service Act, as amended, and also as "drugs," subject to regulation under applicable provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act).[21] Some of the community blood centers are licensed by the DOH as a prescription drug wholesaler since they purchase and distribute prescription drugs, such as blood, blood components, blood derivatives, and other prescription drugs used in the collection, processing, and therapeutic activities conducted by the community blood centers.[22]

The Florida Drug and Cosmetic Act (the Act),[23] as well as federal law,[24] prohibits the sale, purchase or trade (wholesale distribution) of a prescription drug that was purchased by… a health care entity. A community blood center is a health care entity,[25] however, some of the

[16] Blood derivatives are classified as prescription drugs.
[17] Rule 59A-7.019, F.A.C., and part I of ch. 483, F.S., related to Health Testing Services.
[18] Rule ch. 64E-16, F.A.C., Biomedical Waste, and s. 381.0098, F.S.
[19] Rule ch. 64E-5, F.A.C., Control of Radiation Hazards. If a blood center irradiates blood products using radioactive materials, the location in which this occurs must be licensed. If a blood center irradiates blood products using a machine, then the community blood center must register the machine.
[20] The term "biologics" or "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product,… applicable to the prevention, treatment, or cure of a disease or condition of human beings.
See: <http://www.law.cornell.edu/uscode/42/usc_sec_42_00000262----000-.html> (Last visited on April 8, 2010).
[21] The FDA "CPG 230.120 – Human Blood and Blood Products as Drugs" "Inspections, Compliance, Enforcement, and Criminal Investigations" available at:
< http://www.fda.gov/ICECI/ComplianceManuals/CompliancePrograMManual/ucm073863.htm> (Last visited on April 8, 2010). Blood and blood components intended for further manufacture into products that meet the device definition are biological devices.
[22] Ch. 499, F.S., related to Drugs, Devices, and Cosmetics.
[23] s. 499.005(21), F.S.
[24] 21 U.S.C. 353(c)(3)(A)(ii)(l) (Section 503(c)(3)(A)(ii)(l) of the FD&C Act).
[25] A health care entity is defined as a closed pharmacy or any person, organization, or business entity that provides

community blood centers in this state are licensed as prescription drug wholesalers in order to purchase and distribute certain prescription drugs that are needed by community blood centers and hospitals to deliver health care services that are traditionally performed by, or in cooperation with, community blood centers. For example, some community blood centers offer hospitals the full range of blood-related products, such as albumin (to replace fluid), Rh Immune Globulin (to prevent incompatible maternal-fetal blood admixture), and erthropoietin (to stimulate the production of red blood cells), as well as trained personnel and expertise in handling those products. The Act and licensure of community blood centers under the Act are at odds with providing critical health care services by community blood centers.[26]

In November 2008, the FDA's rule to address this dilemma in federal law became effective.[27] That rule provides for exceptions to authorize a registered blood establishment that qualifies as a health care entity to sell, purchase, or trade certain prescription drugs that would otherwise be prohibited. The DOH suggested that the authorizations in the federal rule should be included in the Act, but could be more narrowly crafted to limit the sale, purchase, or trade of these prescription drugs *to a health care entity* to avoid unintended consequences or the opportunity for community blood centers to compete in the marketplace as a prescription drug wholesaler.

The DOH recently noted that blood establishments have not been permitted under the Act as a prescription drug manufacturer and have not registered the prescription drugs that they manufacture (the blood and blood components) with the DOH, notwithstanding the fact that blood establishments are considered manufacturers of prescription drugs under federal law. The distribution of the prescription drugs that blood establishments manufacture have been exempted from the definition of wholesale distribution under s. 499.003(53)(d), F.S., for years. This situation applies to the community blood centers as well as other types of blood establishments, such as the establishments that collect plasma from paid donors.

III. Effect of Proposed Changes:

Sections 1, 7, 15, 20, 33, 34, 38, 59, 65, 70, 74, 76, and 82. Repeal the following sections of the Florida Statutes:

- s. 112.0455(10)(e), F.S., to remove an obsolete provision concerning drug testing within the Drug-Free Workplace Act. The Division of Statutory Revision requested clarification of this provision;
- s. 383.325, F.S., related to public access to governmental inspection reports for birth centers, since this is required in the general licensing provisions in part II of ch. 408, F.S.;
- s. 395.1046, F.S., related to the AHCA's investigation procedures for complaints against a hospital for violations of the access to emergency services and care provisions under s. 395.1041, F.S. Complaint procedures exist in the general licensing provisions in part II of

diagnostic, medical, surgical, or dental treatment or care, or chronic or rehabilitative care, but does not include any wholesale distributor or retail pharmacy licensed under state law to deal in prescription drugs. See s. 499.003(23), F.S. The federal definition, found at 21 C.F.R. § 203.3(q), is similar.

[26] The DOH indicated in an email to Florida Senate Health Regulation Committee staff, dated November 12, 2009, that at the present time, they are not aware of any serious abuses or action by the licensed community blood centers that may pose a public health threat.

[27] The final rule in Vol. 73, No. 197 of the Federal Register on page 59496, published on October 9, 2008, is available at: <http://edocket.access.gpo.gov/2008/pdf/E8-24050.pdf> (Last visited on April 8, 2010).

ch. 408, F.S. The federal process for emergency access complaints dictates that access to emergency services and care complaints be handled similarly to routine complaints;

- s. 395.3037, F.S., related to definitions of Department and Agency as they pertain to stroke centers. These terms are already defined in s. 395.002, F.S., which provides definitions for all of ch. 395, F.S.;
- s. 400.147(10), F.S., related to the requirement for a licensed nursing home to report to the AHCA monthly any notice of claims against the facility for violation of a resident's rights or negligence. This information has been required to be submitted since 2001. It was included in the AHCA's Semi-Annual Report on Nursing Homes, which is repealed in section 31 of this bill. Currently this information is reported on the AHCA's website;
- s. 400.148, F.S., related to the obsolete Medicaid "Up-or-Out" Quality of Care Contract Management Program;
- s. 400.195, F.S., related to an obsolete requirement for the AHCA to report on lawsuits against and deficiencies in nursing homes. The statutory reporting requirement was for the period June 30, 2001 through June 30, 2005;
- s. 408.802(11), F.S., related to the general licensure provisions, to delete reference to private review agents. The regulation of private review agents was repealed by the Legislature in 2009;
- s. 409.221(4)(k), F.S., related to the CDC program, to eliminate the requirement for the AHCA, the DOEA, the DOH, the Department of Children and Family Services, and the Agency for Persons with Disabilities to review and assess the implementation of this program on an ongoing basis. The requirement for the AHCA to submit an annual written report to the Legislature on these reviews and recommendations to improve the program is also repealed;
- s. 429.12(2), F.S., related to change of ownership for assisted living facilities, since this is addressed under the general licensing provisions in part II of ch. 408, F.S.;
- s. 429.23(5), F.S., to repeal the requirement for an assisted living facility to report monthly to the AHCA any liability claim filed against it, which is currently reported on the AHCA's website;
- s. 429.28(3), F.S., to eliminate duplicative provisions related to inspections and monitoring facilities that have been cited with violations. The provision requiring the AHCA to determine whether an ALF licensee is adequately protecting residents' rights in its biennial survey is transferred to s. 429.07, in section 68 of this bill; and
- s. 429.911(2)(a), F.S., related to adult day care center licensure, to remove a duplicative provision that now exists in the general licensing provisions in part II of ch. 408, F.S.

Sections 2, 9, 21, 45, 51, 55, 84, 85, 92, 93, 94, 95, 97, and 99. Amend the following sections of the Florida Statutes to update the name of certain accrediting organizations, including the Joint Commission:

- s. 154.11, F.S., related to facilities owned and operated by the board of trustees of each public health trust;
- s. 394.741, F.S., related to providers of behavioral health care services;
- s. 395.3038, F.S., related to stroke centers;
- s. 400.925, F.S., related to home medical equipment providers;
- s. 400.9935, F.S., related to health care clinics;
- s. 408.05, F.S., related to health care quality measures that are reported by the AHCA;

- s. 430.80, F.S., related to the teaching nursing home pilot project;
- s. 440.13, F.S., related to workers' compensation;
- s. 627.645, F.S., related to health insurance;
- s. 627.668, F.S., related to insurance coverage for mental and nervous disorders;
- s. 627.669, F.S., related to insurance for substance abuse impaired persons;
- s. 627.736, F.S., related to personal injury protection automobile insurance;
- s. 641.495, F.S., related to health maintenance organizations and prepaid health clinics; and
- s. 766.1015, F.S., related to boards or other groups established for quality improvement purposes.

Section 3. Amends s. 318.21, F.S., to redirect funding intended to serve Medicaid recipients with complex spinal cord injuries from the AHCA to the Brain and Spinal Cord Injury Rehabilitation Trust Fund within the DOH.

Section 4. Amends s. 381.00315, F.S., to authorize the DOH to accept funds from local governments and spend those funds for licensable products that have been approved by the U.S. Department of Health and Human Services in response to a public health emergency.

Section 5. Amends s. 381.0072, F.S., to limit the DOH food services inspections in nursing homes to twice per year, absent complaints, and requires the inspection to occur at least 60 days after a recertification visit by the AHCA.

Section 6. Amends s. 381.06014, F.S., to define a volunteer donor as a person who does not receive remuneration, other than an incentive, for a blood donation intended for transfusion and the product container of the donation from the person qualifies for labeling with the statement "volunteer donor" under federal regulations.

The committee substitute requires a blood establishment that collects blood or blood components from volunteer donors to disclose information on its Internet website concerning its activities. A hospital that collects blood or blood components from volunteer donors for its own use is not required to disclose this information. The disclosures may be cumulative for all blood establishments (branches) within the business entity. The information required to be disclosed includes:

- A description of the activities of the blood establishment related to collecting, processing, and distributing volunteer blood donations. This information is to be presented in a manner that is appropriate for the donating public;
- The number of units by component (whole blood, red blood cells, leukoreduced red blood cells, fresh frozen plasma or equivalent, recovered plasma, platelets, and cryoprecipitated AHF) that the blood establishment:
  - Produced (such as units that passed quality control and are available for use),
  - Obtained from other sources,
  - Distributed to health care providers that are located outside the state. However, if the blood center collects donations in a county outside Florida and distributes to health care providers in that county, then the distributions made to that county must be excluded. This distribution information must be aggregated by health care providers that are located

within the United States and its territories or outside the United States and its territories, and
    - Distributed to entities that are health care providers. This information must be aggregated by purchasers that are located within the United States and its territories or outside the United States and its territories.

  This information must be on the establishment's website by March 1 of each year reflecting data from the preceding calendar year;
- The blood establishment's policies pertaining to conflicts of interest, related-party transactions, and determining executive compensation. If any changes are made to any of these policies, the revised document must be on the blood establishment's website by the following March 1; and
- Either the most recent three years of a not-for-profit blood establishment's Form 990 that have been reported to the Internal Revenue Services, which must be posted within 30 calendar days after filing, or an audited or reviewed balance sheet, income statement, and statement of changes in cash flow, along with the expression of opinion on these statements from a certified public accountant, which must be posted within 120 days following the end of the fiscal year for a for-profit blood establishment and which must remain on the website for 36 months.

The clinical laboratory license of a blood establishment that fails to disclose this information is subject to an administrative fine as provided in section 86 of the bill.

Section 8. Amends s. 394.4787, F.S., to correct a cross-reference concerning licensure of a specialty psychiatric hospital.

Section 10. Amends s. 395.002, F.S., to redefine the term "accrediting organizations" as it relates to hospitals and other licensed facilities to delete the list of four organizations that are identified in statute. The term is redefined to mean nationally recognized or approved accrediting organizations whose standards incorporate comparable licensure requirements as determined by the AHCA. In addition, the following obsolete definitions are repealed: "initial denial determination," "private review agent," "utilization review," and "utilization review plan."

Section 11 Amends s. 395.003, F.S., to remove obsolete language concerning emergency departments located off-site from a licensed hospital.

Section 12. Amends s. 395.0193, F.S., related to peer review of physicians within hospitals and licensed facilities, to correct references to the Division of Medical Quality Assurance of the DOH.

Section 13. Amends s. 395.1023, F.S., related to reporting actual or suspected cases of child abuse, abandonment, or neglect by hospitals and licensed facilities, to clarify that references to the Department mean the Department of Children and Family Services.

Section 14. Amends s. 395.1041, F.S., to remove obsolete language pertaining to services within a hospital's service capability. The Division of Statutory Revision requested clarification of this provision.

Section 16. Amends s. 395.1055, F.S., to require that the AHCA's rulemaking concerning licensed facility beds conform to standards specified by the AHCA, the Florida Building Code, and the Florida Fire Prevention Code.

Section 17. Amends s. 395.10972, F.S., to update the reference to the current name of the Florida Society for Healthcare Risk Management and Patient Safety.

Section 18. Amends s. 395.2050, F.S., to update the reference to the current name of the Centers for Medicare and Medicaid Services.

Section 19. Amends s. 395.3036, F.S., to correct a cross-reference concerning the confidentiality of records and meetings of corporations that lease public health care facilities. The Division of Statutory Revision requested clarification of this provision.

Section 22. Amends s. 395.602, F.S., to eliminate one of the conditions that qualifies a hospital as a rural hospital. This condition is a hospital in a constitutional charter county with a population of over 1 million persons that has imposed a local option health service tax, in an area that was directly impacted by a catastrophic event on August 24, 1992, for which the Governor of Florida declared a state of emergency, has 120 beds or less that serves an agricultural community with an emergency room utilization of no less than 20,000 visits, and a Medicaid inpatient utilization rate greater than 15 percent. No hospitals meet this condition.

Section 23. Amends s. 400.021, F.S., to expand the definition of a geriatric outpatient clinic in a nursing home, to add that it may be staffed by a licensed practical nurse under the direct supervision of a registered nurse, advanced registered nurse practitioner, or physician. Currently the definition of a geriatric outpatient clinic provides that it be staffed by a registered nurse or a physician assistant.

Section 24. Amends s. 400.0239, F.S., to delete an obsolete reference to the Medicaid "Up or Out" Quality of Care Contract Management Program.

Section 25. Amends s. 400.0255, F.S., to correct an obsolete cross-reference to an administrative rule concerning fair hearings requested by nursing home residents. This correction was requested by the Joint Administrative Procedures Committee.

Section 26. Amends s. 400.063, F.S., to eliminate a cross-reference in the procedures for resident protection and relocation accounts, since the section of law that is referenced was repealed. The Division of Statutory Revision requested clarification of this provision.

Section 27. Amends s. 400.071, F.S., to repeal disclosure of certain information related to the closure of other licensed facilities in which the nursing home licensure applicant held a controlling interest. Section 29 of this bill amends s. 400.111, F.S., to require certain disclosures to replace these requirements. This section also repeals the requirement for a nursing home licensure applicant to identify the number of beds and number of Medicare and Medicaid certified beds since this is required in the general licensing provisions in s. 408.806(1)(d), F.S.

Section 28. Amends s. 400.0712, F.S., to repeal the authority for a nursing home to request an inactive license for a portion of its beds and to provide a cross-reference to the general licensure provisions in part II of ch. 408, F.S.

Section 29. Amends. s. 400.111, F.S., to require disclosure of certain information concerning other licenses that a controlling interest has held when requested by the AHCA instead of a mandatory submission for all nursing home licensure applications.

Section 30. Amends s. 400.1183, F.S., to repeal the requirement for a nursing home to report to the AHCA upon relicensure information concerning grievances received by the facility.

Section 31. Amends s. 400.141, F.S., to authorize a nursing home with a standard licensure status or one that has been awarded a Gold Seal, to provide respite care for a maximum of 14 days per stay pursuant to an abbreviated plan of care. The abbreviated plan of care must, at a minimum, include nutritional requirements, medication orders, physician orders, nursing assessments, and dietary preferences. A contract must be executed for each person admitted under the respite care program that specifies the services to be provided and the charges for those services. This contract may be used for subsequent admissions for that person within one year after the date of execution. A respite resident may receive a total of 60 days of respite care within a 12-month period. A prospective respite resident must provide medical information from one of the specified practitioners along with an order for respite care. Provisions are made for the respite resident to use his or her personal medications and the nursing home must arrange for transportation to certain health care services to ensure continuity of care and services while the resident is receiving the respite care. A person admitted to the nursing home under the respite care program is exempt from requirements related to discharge planning and is covered by certain residents' rights.

A nursing home is required to maintain complete clinical records on each resident that must be readily accessible and systematically organized.

The committee substitute eliminates the requirement for a licensed nursing facility to disclose, within 30 days after the nursing home executes an agreement with a company to manage the nursing home, certain information related to the closure of other licensed facilities in which the management company held a controlling interest.

The committee substitute requires the AHCA to fine a nursing facility $1,000 if it fails to impose a moratorium on new admissions when the facility has not complied with the minimum-staffing requirements.

The committee substitute repeals the requirement for a licensed nursing home to report to the AHCA information concerning filing for bankruptcy, divestiture of assets, or corporate reorganization. A similar provision is amended into the general licensing provisions in s. 408.810, F.S., in Section 62 of this bill.

Section 32. Amends s. 400.142, F.S., to eliminate the requirement for the AHCA to adopt rules related to nursing facility staff implementing an order to withhold or withdraw cardiopulmonary

resuscitation inasmuch as statutory provisions exist in s. 401.45, F.S., for emergency medical responders.

Section 35. Amends s. 400.162, F.S., to require a nursing home to provide a resident accounting of personal property held by the facility annually or within 7 days after a request for a statement, rather than quarterly.

Section 36. Amends s. 400.179, F.S., to require the AHCA to assess the cumulative fees collected minus authorized deductions under the leased nursing home bond provisions for Medicaid overpayments annually by March 31. If the net amount exceeds $25 million, leased nursing homes do not have to make the annual bond payment.

Section 37. Amends s. 400.19, F.S., to authorize the AHCA to certify correction of a class III or class IV deficiency related to resident rights or resident care based on written documentation from the facility.

Section 39. Amends s. 400.23, F.S., to update the reference to the current name of the Division of Children's Medical Services Network of the DOH. The Division of Statutory Revision requested clarification of this provision.

In addition, the committee substitute requires the AHCA to adopt rules for minimum staffing requirements for nursing homes that serve persons under 21 years of age. These rules are to be adopted in collaboration with the DOH Division of Children's Medical Services Network and must require, at a minimum, 3.9 hours of direct care per resident per day for residents requiring skilled care and 5 hours of direct care per resident per day for residents who are fragile.

Section 40. Amends s. 400.275, F.S., to eliminate the requirement for the AHCA to assign each newly hired nursing home surveyor to observe a facility's operations as a part of basic training. The AHCA nursing home staff must be qualified under the federal requirements for the Surveyor Minimum Qualifications Test.

Section 41. Amends s. 400.484, F.S., related to violations by home health agencies, to cross-reference the definitions of the classes of violations in the general licensing provisions in part II of ch. 408, F.S., thereby eliminating redundant definitions for deficiencies in this section.

Section 42. Amends s. 400.606, F.S., to eliminate the requirement for an applicant for a hospice license to submit the projected annual operating cost of the hospice. Under the general licensing provisions, in part II of ch. 408, F.S., an applicant for licensure must submit information pertaining to the applicant's financial ability to operate.

Section 43. Amends s. 400.607, F.S., to clarify the grounds for administrative action by the AHCA against a hospice and eliminate duplicative provisions found in the general licensing provisions in part II of ch. 408, F.S.

Section 44. Amends s. 400.915, F.S., to correct an obsolete cross-reference to an administrative rule concerning the construction or renovation of a prescribed pediatric extended care center. This correction was requested by the Joint Administrative Procedures Committee.

Section 46. Amends s. 400.931, F.S., to repeal the option for an applicant for a home medical equipment provider license to submit a $50,000 surety bond in lieu of proof of financial ability to operate.

Section 47. Amends s. 400.932, F.S., to clarify the grounds for administrative action by the AHCA against a home medical equipment provider.

Section 48. Amends s. 400.967, F.S., related to violations by intermediate care facilities for developmentally disabled persons, to cross-reference the definitions of the classes of violations in the general licensing provisions in part II of ch. 408, F.S., thereby eliminating redundant definitions for deficiencies in this section. In addition, the committee substitute requires the AHCA to impose an administrative fine not to exceed $500 for each occurrence and each day that an uncorrected or repeated class IV violation exists.

Section 49. Amends s. 400.9905, F.S., to revise the definitions related to the health care clinic act. This includes an entity that contracts with or employs a person to provide portable *health care services or* equipment to multiple locations, which bills third-party payors for those services, and that otherwise, meets the definition of a clinic.

The committee substitute also exempts the following entities from the definition and regulation as a health care clinic:

- A pediatric cardiology or perinatology clinic facility that is a publicly traded corporation or that is wholly owned by a publicly traded corporation;
- Entities that are owned by a corporation that has $250 million or more in total annual sales of health care services provided by licensed health care practitioners if at least one of the owners is a Florida-licensed health care practitioner who is responsible for supervising the business activities and legally responsible for compliance with state law for purposes of this section of law; and
- Entities that are owned or controlled, directly or indirectly, by a publicly traded entity with $100 million or more in total annual revenues derived from providing health care services by licensed health care practitioners who are employed with or contracted by the entity.

Section 50. Amends s. 400.991, F.S., to repeal the option for an applicant for a health care clinic license to submit a $500,000 surety bond in lieu of proof of financial ability to operate. Another cross-reference is added to reflect an existing provision concerning proof of financial ability to operate for an applicant for a health care clinic license.

Section 52. Amends s. 408.034, F.S., to correct a reference to the AHCA's authority to issue licenses to intermediate care facilities for developmentally disabled persons under part VIII of ch. 400, F.S., without the facility first obtaining a certificate of need as required by s. 408.036(1)(a), F.S.

Section 53. Amends s. 408.036, F.S., to eliminate a cross-reference to an exception to the certificate-of-need requirements for a hospice. No exceptions are currently provided in s. 408.043, F.S.

Section 54. Amends s. 408.043, F.S., to remove the term "primarily" to clarify that a certificate of need is required to establish or expand an inpatient hospice facility unless the facility is licensed as a health care facility, such as a hospital or skilled nursing facility.

Section 56. Amends s. 408.061, F.S., to remove an inappropriate reference to an administrative rule that describes data reporting.

Section 57. Amends s. 408.07, F.S., to conform the definition of a rural hospital to the provisions related to licensure of rural hospitals in s. 395.602, F.S., as amended in section 22 of this committee substitute.

Section 58. Amends s. 408.10, F.S., to eliminate the requirement for the AHCA to investigate consumer complaints related to health care facilities' billing practices and publish related reports.

Section 60. Amends s. 408.804, F.S., related to the general licensing provisions. The act of, or causing another to alter, deface, or falsify a license certificate is a misdemeanor of the second degree. A licensee or provider who displays an altered, defaced, or falsified license certificate is subject to an administrative fine of $1,000 for each day of illegal display and a license or application for a license is subject to revocation or denial.

Section 61. Amends s. 408.806, F.S., related to general licensing provisions, to require the AHCA to send a courtesy notice to the licensee 90 days before renewal. However, the AHCA's failure to do so or the licensee's failure to receive the notice does not excuse the licensee's responsibility to timely submit the renewal application and fee. Submission of the renewal application, application fee, and any applicable late fees is required to renew the license.

Section 62. Amends s. 408.810, F.S., related to general licensing provisions, to require an applicant to submit to the AHCA proof that the applicant has notified a mortgagor or landlord, if applicable, of the applicant's intent to provide services on the property that require licensure by the AHCA and instructed the mortgagor or landlord to notify the AHCA if the mortgagor or landlord initiates action against the applicant.

A controlling interest shall notify the agency within 10 days after initiation of a court action, such as bankruptcy proceedings, foreclosure, or eviction proceedings in which the controlling interest is a petitioner or defendant.

Section 63. Amends s. 408.813, F.S., related to general licensing provisions, to authorize the AHCA to impose an administrative fine, not to exceed $500 per violation, for violations that do not qualify within the classification scheme of class I – class IV violations. Unclassified violations might include: violating any term or condition of a license; violating any provision of the general licensing provisions, authorizing statutes, or applicable rules; exceeding licensed capacity without authorization; providing services beyond the scope of the license; or violating a moratorium.

Section 64. Amends s. 408.815, F.S., related to general licensing provisions, to authorize the AHCA to extend the license expiration date for up to 30 days and to impose other conditions during that 30-day extension in order to accomplish the safe and orderly discharge of clients. The

authority to extend is at the discretion of the AHCA after considering the nature and number of clients, the availability and location of acceptable alternative placements, and the ability of the licensee to continue providing care to the clients. This agency authority does not create any right or entitlement to an extension of a license expiration date.

Section 66. Amends s. 409.91196, F.S., related to Medicaid supplemental rebate agreements, to correct a cross-reference resulting from the amendment in section 67 of this bill.

Section 67. Amends s. 409.912, F.S., to require a Medicaid claim for a prescription drug billed as a 340B prescribed medication to meet certain requirements and be billed at the actual acquisition cost.

Section 68. Amends s. 429.07, F.S., to repeal the LNS specialty license and its requirements and the quarterly monitoring requirements related to ALFs that are licensed to provide ECC services. The bill requires an ALF that has been cited within the previous 24 months for a class I or class II violation to be subject to unannounced monitoring. This monitoring may occur through a desk review or onsite, unless a cited violation relates to providing or failing to provide nursing care. In that case, a registered nurse is required to participate in at least two onsite monitoring visits within a 12-month period. The monitoring requirement applies regardless of the status of the enforcement or disciplinary action for the cited violation.

The biennial per-bed licensure fee for a standard license is increased by $8.50 to $67.50 from the current per-bed licensure fee (CPI adjusted) of $59. The other licensure fees in this section are amended to reflect the current CPI adjusted fee, only. The total standard licensure fee is increased from the current fee (CPI adjusted) of $13,087 to $18,000.

The bill eliminates the requirement for the Department of Elderly Affairs (DOEA) to report annually to the Governor and Legislature on the status of and recommendations related to ECC services. A provision requiring the AHCA to determine whether the ALF licensee is adequately protecting residents' rights in its biennial survey is transferred from s. 429.28(3), F.S.

Section 69. Amends s. 429.11, F.S., to remove language related to provisional licenses within the authorizing statutes for the ALFs since provisional licenses are authorized in the general licensing provisions in part II of ch. 408, F.S.

Section 71. Amends s. 429.14, F.S., to authorize the AHCA to provide information concerning any ALFs that have had their license denied, suspended, or revoked to the Department of Business and Professional Regulation electronically or through the AHCA's website. The committee substitute also strikes language that duplicates a provision in the general licensing provisions in part II of ch. 408, F.S.

Section 72. Amends s. 429.17, F.S., to conform provisions related to the ALF licenses to the repeal of the LNS specialty license. This section of law is also amended to remove the requirement for a plan of correction as a part of issuing a conditional license for an ALF since this is authorized in the general licensing provisions in part II of ch. 408, F.S.

Section 73. Amends s. 429.19, F.S., to clarify that a monitoring fee may be assessed against an ALF in addition to an administrative fine.

Section 75. Amends s. 429.255, F.S., to eliminate the authorization for an ALF to use volunteers to provide certain health-related services, including: administering medications, taking residents' vital signs, managing individual pill organizers for residents who self-administer medication, giving prepackaged enemas, observing residents and documenting observations on the resident's record or reporting observations to the resident's physician, and performing all duties within the scope of their license or certification in a facility licensed to provide ECC services.

In addition, this section authorizes contracted personnel or facility staff who are licensed under the nurse practice act to provide LNS to residents in a standard-licensed ALF. The licensee is responsible for maintaining documentation of health-related services provided as required by rule and ensuring that staff are adequately trained to monitor residents who have received these health-related services.

Section 77. Amends s. 429.35, F.S., to authorize the AHCA to provide the results of an inspection of an ALF to the local ombudsman council and others electronically or through the AHCA's website.

Section 78. Amends s. 429.41, F.S., to conform provisions related to rulemaking for ALFs to changes made in this bill.

Section 79. Amends s. 429.53, F.S., related to consultation by the agency pertaining to an ALF. The bill expands the staff who may provide consultation and eliminates the requirement for the AHCA to consult in areas that are beyond its jurisdiction and areas of expertise.

Section 80. Amends s. 429.54, F.S., to require licensed ALFs to report electronically to the AHCA semiannually certain data related to the facility's residents and staffing. This data includes, but is not limited to the:

- Number of residents;
- Number of residents receiving LMH services;
- Number of residents receiving ECC services;
- Number of residents receiving LNS; and
- Professional personnel providing resident services.

The DOEA, in consultation with the AHCA, is required to adopt rules related to these reporting requirements.

Section 81. Amends s. 429.71, F.S., related to violations by adult family-care homes, to cross-reference the definitions of the classes of violations in the general licensing provisions in part II of ch. 408, F.S., thereby eliminating redundant definitions for deficiencies in this section. The provisions within the section related to the plan of correction are removed since it is also addressed in the general licensing provisions.

Section 83. Amends s. 429.915, F.S., to remove the requirement for a plan of correction as a part of issuing a conditional license for an adult day care facility since this is authorized in the general licensing provisions in part II of ch. 408, F.S.

Section 86. Amends s. 483.201, F.S., to add the failure of a blood establishment that collects blood or blood components from volunteer donors to disclose the information required by s. 381.06014, F.S., regarding the blood establishment's activities to the grounds for which disciplinary action may be taken against a blood establishment's clinical laboratory license. If multiple blood establishments are operated by the blood establishment, the fines may be assessed against only one of the clinical laboratory licenses of the business entity. A $1,000 fine may be assessed for each day for which the disclosure is not made, up to a maximum amount of $10,000 for each annual reporting period.

Section 87. Amends s. 483.294, F.S., to correct the inspection frequency for licensed multiphasic health testing centers to biennially, consistent with the general licensing provisions in part II of ch. 408, F.S.

Section 88. Amends s. 499.003, F.S., to revise the definition of a health care entity to authorize a blood establishment that collects blood or blood components from volunteer donors to be a health care entity and engage in the wholesale distribution of prescription drugs in accordance with the requirements contained in section 90 of the committee substitute related to the restricted prescription drug distributor permit for a blood establishment.

The committee substitute also eliminates the requirement for prescription drugs that were purchased at public health prices and held by a contract provider or subcontractor to be stored separately from other prescription drug inventory.

Section 89. Amends s. 499.005, F.S., to remove the prohibition against the wholesale distribution by a blood establishment that collects blood or blood components from volunteer donors if the blood establishment is operating in compliance with the requirements contained in section 90 of the committee substitute related to the restricted prescription drug distributor permit for a blood establishment.

Section 90. Amends s. 499.01, F.S., to exempt a blood establishment that only manufactures blood and blood components from the requirements to be permitted as a prescription drug manufacturer and register the products it manufacturers.

The committee substitute also requires certain blood establishments to obtain a permit as a restricted prescription drug distributor in order to lawfully sell and distribute prescription drugs to another health care entity. The committee substitute provides for certain restrictions on this authorization, including:

- The permit may be issued only to a blood establishment that is located in Florida;
- The permit may be issued to a blood establishment that collects blood and blood components from volunteer donors only or pursuant to an authorized practitioner's order for medical treatment or therapy;

- The distributions may be made only to a health care entity that is licensed as a closed pharmacy or provides health care services at the location where the health care entity receives the prescription drugs;
- The prescription drugs that may be distributed pursuant to the restricted prescription drug distributor permit are limited to:
  - A prescription drug that is indicated for a bleeding disorder, clotting disorder, or anemia;
  - A blood collection container that is approved under s. 505 of the federal FD&C Act related to new drugs;
  - A drug that is a blood derivative, or a recombinant or synthetic form of a blood derivative; or
  - A prescription drug that is essential to services performed or provided by blood establishments and is authorized for distribution by blood establishments under federal law if it is identified in rules adopted by the DOH; and
- The blood establishment may only provide health care services that:
  - Are related to its activities as an FDA-registered blood establishment;
  - Consist of collecting, processing, storing, or administering human hematopoietic stem cells or progenitor cells; or
  - Consist of performing diagnostic testing of specimens if these specimens are tested together with specimens undergoing routine donor testing.

In addition, the committee substitute provides that a blood establishment that is permitted as a restricted prescription drug distributor must comply with all the storage, handling, and recordkeeping requirements with which a prescription drug wholesale distributor must comply. This includes providing pedigree papers[28] upon the wholesale distribution of these prescription drugs.

The DOH is authorized to adopt rules related to the distribution, transportation, storage, and recordkeeping of prescription drugs by blood establishments. These rules may include requirements for the use of prescription drugs in mobile blood-collection vehicles.

Section 91. Amends s. 499.01212, F.S., to exempt the wholesale distribution of prescription drugs that are contained within a sealed medical convenience kit that has been assembled in an establishment that is registered with the FDA as a medical device manufacturer and which does not contain controlled substances from the requirement for a pedigree paper.

Section 96. Amends s. 633.081, F.S., to limit inspection of nursing homes by the State Fire Marshal to once per year and upon receiving a complaint that forms the basis of a reasonable cause to believe that a violation may exist or upon identifying a violation in the course of conducting orientation or training activities within a nursing home.

Section 98. Amends s. 651.118, F.S., related to nursing homes in continuing care communities, to conform a cross-reference to changes made in section 31 of this committee substitute.

[28] A pedigree paper contains information required by s. 499.01212, F.S., regarding the sale and distribution of a prescription drug.

Section 100. Amends s. 766.202, F.S., to add licensed orthotists and prosthetists to the definition of a health care provider under ch. 766, F.S., related to medical malpractice.

Section 101. Provides an effective date of July 1, 2010.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Art. I, s. 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

D. Other Constitutional Issues:

Article III, Section 6 of the Florida Constitution requires every law to embrace but one subject and matter properly connected therewith, and the subject must be briefly expressed in the title. The title of this committee substitute was amended to "an act relating to the reduction and simplification of health care provider regulation." This title may be too narrow. For example, the committee substitute includes requirements for billing a 340B prescribed medication in section 67, requirements for blood establishments in sections 6 and 90, an exemption for prescription drug wholesalers in section 91, and the addition of orthotists and prosthetists in a definition related to medical malpractice in section 100.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

This bill authorizes an ALF to provide LNS without obtaining an additional specialty license at a fee of $296 plus $10 per-bed fee based on the total licensed resident capacity of the facility. The per-bed licensure fee for all ALFs is increased $8.50 biennially for non-OSS beds. This increased fee offsets the loss of revenue currently generated from the LNS license and will be used to fund monitoring of any ALF that has been cited with a class I or class II deficiency. The maximum amount that an ALF is required to pay biennially for the licensure fees associated with the standard license is increased by $4,913 to accommodate the increased per-bed licensure fee increase.

Instead of paying $900 annually for a prescription drug wholesale distributor permit, providing a $100,000 bond, and employing a certified designated representative, a community blood center that intends to engage in the wholesale distribution of certain prescription drugs in order to provide healthcare services typically provided by blood establishments will pay a $600 fee biennially for a restricted prescription drug distributor permit.

B. Private Sector Impact:

This bill streamlines regulations for 29 provider types regulated by the AHCA through repeal of obsolete or duplicative provisions in licensing laws and reform of regulations related to inspections, electronic publication of documents and reports, timeframes for reporting licensure changes, and financial information and bonds.

The bill does not require an ALF to provide LNS, but an ALF may choose to do so with appropriate nursing personnel without the requirement to obtain an additional specialty license. All ALFs are required to report electronically, at least semiannually, certain information about the facility's residents and professional staffing. Monitoring inspections will be tied to performance rather than requiring a set number of monitoring inspections for each specialty license.

A community blood center that collects donations of blood and blood components from volunteer donors, except hospitals, will be required to post certain information concerning its activities on its Internet website.

A community blood center that chooses to engage in the wholesale distribution of certain prescription drugs may lawfully do so if it is permitted as a restricted prescription drug distributor and complies with the requirements of that permit.

C. Government Sector Impact:

Same as comment for the private sector impact. The AHCA estimates that $55,700 will be saved in certified mail costs as a result of the courtesy notice for license renewal in section 61 of the bill. The AHCA will be able to target its monitoring resources on facilities that have been cited for certain violations rather than whether a facility has a particular type of specialty license. This should generate efficiencies and focus resources on resident protection activities.

The AHCA and DOH are required to adopt rules, some of which require collaboration with other state agencies.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

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 Steering Committee on Ways and Means on April 20, 2010:

- Adds respiratory care practitioners into the staffing mix for nursing homes serving persons under 21 years of age who require skilled care. This change makes the mix identical to nursing homes serving persons under 21 years of age who are fragile. Residents who are fragile require greater care.

CS by Health Regulation on April 13, 2010:

- Eliminates the limitation on the use of traffic fines for *adult* Medicaid recipients with certain spinal cord injuries;
- Authorizes the DOH to accept funds from local governments and spend those funds for licensable products approved by the U.S. Department of Health and Human Services in response to a public health emergency;
- Limits the DOH food service inspections in nursing homes to twice per year, absent complaints, and requires the inspections to occur at least 60 days after a recertification visit by the AHCA;
- Adds a physician as another practitioner who may supervise a licensed practical nurse in a geriatric outpatient clinic in a nursing home;
- Simplifies regulatory requirements for respite care provided by an expanded group of eligible nursing homes;
- Requires nursing homes to provide a resident accounting of personal property held by the facility annually or within 7 days of a request, rather than quarterly;
- Requires the AHCA to assess the nursing home lease bond fund annually and if the fund has a balance exceeding $25 million, leased nursing homes do not have to make the annual payment;
- Requires the AHCA to adopt rules for minimum staffing requirements for nursing homes that serve persons under 21 years of age;
- Reinstates the exemption from inspection by the AHCA for a home medical equipment provider with a conditional accreditation rating;
- Eliminates the requirement for the background screening attestation for a home medical equipment provider to be submitted upon licensure renewal rather than annually;
- Provides for the AHCA to impose an administrative fine for class IV violations that are uncorrected or repeated by a licensed intermediate care facility for developmentally disabled persons;
- Exempts additional entities from licensure as a health care clinic;
- Eliminates the explicit authority for the AHCA to staff the complaint hot-line and strikes the requirement for the AHCA to investigate consumer complaints related to billing practices;
- Reduces the timeframe for a license extension to provide for the orderly discharge of clients from 60 days to 30 days and provides factors the AHCA must consider in its determination whether to extend the license;

- Eliminates the phase-out of the Medicaid adult day health care waiver program;
- Reinstates the reporting requirements for the CARES program;
- Requires a Medicaid claim for a prescription drug billed as a 340B prescribed medication to meet certain requirements and be billed at the actual acquisition cost;
- Eliminates the requirement for the LNS specialty license, modifies the licensure fees for an ALF, eliminates the annual report by the DOEA concerning ECC, and requires all ALFs to report semiannually certain information related to residents and staffing;
- Eliminates the authorization for an adult family-care home to be owned or rented by two individuals;
- Reinstates the section of law related to administrative action against adult day care homes and repeals only the duplicative provision;
- Eliminates the requirement for prescription drugs that were purchased at public health prices and held by a contract provider or subcontractor to be stored separately from other prescription drug inventory;
- Exempts the distribution of prescription drugs in certain medical convenience kits from the pedigree paper requirements;
- Limits inspections of nursing homes by the State Fire Marshal to once per year and upon receiving a complaint;
- Requires a community blood center to disclose certain information on its website;
- Enables certain community blood centers to obtain a permit to lawfully engage in the wholesale distribution of certain prescription drugs; and
- Adds licensed orthotists and prosthetists to the definition of a health care provider under ch. 766, F.S., related to medical malpractice;

B. Amendments:

None.

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