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 Health Regulation Committee

BILL:	CS/SB 760
INTRODUCER:	Health Regulation Committee and Senator Gaetz
SUBJECT:	Health Care
DATE:	April 8, 2010
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Wilson	HR	**Fav/CS**
2.			HA	
3.			RC	
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:

This committee substitute 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 committee substitute makes the following substantive changes:

- Expands the authorized staffing of a geriatric outpatient clinic in a nursing home to include a nurse practitioner or a licensed practical nurse under the direct supervision of a registered nurse;
- Imposes 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;
- Eliminates the monthly reporting by nursing homes and assisted living facilities 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 service or equipment provider;
- Prohibits activities related to altering, defacing, or falsifying a license certificate;
- 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, and authorize the AHCA to extend the license expiration date for up to 60 days and impose other conditions during that extension period in order to accomplish the safe and orderly discharge of clients or residents;
- Phases out the Medicaid adult day health care waiver program;
- Repeals the limited nursing services (LNS) specialty license and authorizes LNS to be provided by appropriately licensed persons in an assisted living facility (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 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 licensure fees 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 with respect to assisted living facilities;
- Revises the definition of an adult family-care home to address a glitch in the law by authorizing up to two people to own or rent the home;
- Requires a community blood center to disclose certain information on its website; and
- Enables certain community blood centers to obtain a permit to lawfully engage in the wholesale distribution of certain prescription drugs.

This bill amends the following sections of the Florida Statutes: 154.11, 318.21, 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, 400.19, 400.23, 400.275, 400.484, 400.606, 400.607, 400.915, 400.925, 400.931, 400.932, 400.933, 400.953, 400.967, 400.9905, 400.991, 400.9935, 408.034, 408.036, 408.043, 408.05, 408.061, 408.10, 408.804, 408.806, 408.810, 408.813, 408.815, 409.906, 429.07, 429.11, 429.14, 429.17, 429.19, 429.255, 429.35, 429.41, 429.53, 429.54, 429.65, 429.71, 429.915, 430.80, 440.13, 483.201, 483.294, 499.003, 499.005, 499.01, 627.645, 627.668, 627.669, 627.736, 641.495, and 766.1015.

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), 409.912(15)(e),(f), and (g), 429.12(2), 429.23(5), 429.28(3), 429.901(5), 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 with 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]

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.

---

[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 5, 2010).

[2] See: <http://www.fdhc.state.fl.us/MCHQ/Long_Term_Care/FDAU/docs/LiabilityClaims/NH_Chart.pdf> (Last visited on April 5, 2010).

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 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.

---

[3] Source: The AHCA 2010 Bill Analysis & Economic Impact Statement for SPB 7018, on file with the Senate Health Regulation Committee.

[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.

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 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 are 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

[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 5, 2010).

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 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.

The CARES Program

The AHCA is required to submit a report to the Legislature annually regarding the operations of the Comprehensive Assessment and Review for Long-Term Care Services (CARES) program.[13] The CARES program, which is housed in the Department of Elderly Affairs (DOEA), is Florida's federally mandated pre-admission screening program for nursing facility applicants seeking Medicaid funding for their care. The purpose of the CARES program is to ensure that Medicaid payment for nursing facility care is made only for individuals whose conditions require such care and to ensure that long-term care services are provided in the setting most appropriate to the needs of the person and in the most economical manner possible. In addition to pre-admission screening, the CARES program provides assessments for individuals in need of home and community-based services.

The annual report describes:

- The rate of diversion to community alternative programs,
- The CARES program staffing needs to achieve additional diversions,
- Reasons that diversions did not occur when the individuals desired the less restrictive setting and could have been served in that setting,
- Barriers to appropriate placement, and
- Statutory changes needed to ensure services are provided in the least restrictive setting.

The DOEA is required to track individuals over time who are assessed under the CARES program and diverted from nursing home placement. The DOEA is to report annually: demographic information on those individuals who have been diverted, a summary of community services provided to individuals for one year after diversion, a summary of inpatient hospital admissions for these individuals who have been diverted, and a summary of the length of time between diversion and subsequent entry into a nursing home or death.

[13] s. 409.912(15)(e), F.S.

Blood Establishments[14]

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[15] 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:[16] 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 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[17] routinely pay donors.

Community blood centers in Florida are licensed as clinical laboratories by the AHCA, unless otherwise exempt.[18] 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[19] and radiation services.[20]

---

[14] 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).

[15] s. 381.06014, F.S.

[16] 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).

[17] Blood derivatives are classified as prescription drugs.

[18] Rule 59A-7.019, F.A.C., and part I of ch. 483, F.S., related to Health Testing Services.

[19] Rule ch. 64E-16, F.A.C., Biomedical Waste, and s. 381.0098, F.S.

[20] 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

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,"[21] 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).[22] 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.[23]

The Florida Drug and Cosmetic Act (the Act),[24] as well as federal law,[25] 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,[26] however, some of the 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.[27]

---

the community blood center must register the machine.

[21] 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).

[22] 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.

[23] Ch. 499, F.S., related to Drugs, Devices, and Cosmetics.

[24] s. 499.005(21), F.S.

[25] 21 U.S.C. 353(c)(3)(A)(ii)(l) (Section 503(c)(3)(A)(ii)(l) of the FD&C Act).

[26] A health care entity is defined as a closed pharmacy or any person, organization, or business entity that provides 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.

[27] 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.

In November 2008, the FDA's rule to address this dilemma in federal law became effective.[28] 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, 5, 13, 18, 31, 32, 34, 56, 63, 64, 67, 71, 73, 80, and 81. 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 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 32 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;

[28] 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).

- 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. 409.912(15)(e),(f), and (g), F.S., related to the CARES program. Paragraphs (e) and (f) repeal the annual reporting requirements for the AHCA concerning the operation of the CARES program and the DOEA's longitudinal study of individuals who are diverted from nursing home placement. Paragraph (g) repeals an obsolete reporting requirement that expired in 2005;
- 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 65 of this bill;
- s. 429.901(5), F.S., to eliminate the definition of a term that is no longer used due to the repeal of s. 429.911, F.S., in section 81 of this bill (see the comment under Technical Deficiencies); 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, 6, 19, 41, 49, 53, 83, 84, 90, 91, 92, 93, 94, and 95. 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 adult 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. 381.06014, 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 85 of the bill.

Section 7. Amends s. 394.4787, F.S., to correct a cross-reference concerning licensure of a specialty psychiatric hospital.

Section 8. 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 9. Amends s. 395.003, F.S., to remove obsolete language concerning emergency departments located off-site from a licensed hospital.

Section 10. 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 11. 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 12. 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 14. 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 15. 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 16. Amends s. 395.2050, F.S., to update the reference to the current name of the Centers for Medicare and Medicaid Services.

Section 17. 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 20. 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.

Section 21. 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 an advanced registered nurse practitioner or a licensed practical nurse under the direct supervision of a registered nurse. Currently the definition of a geriatric outpatient clinic provides that it be staffed by a registered nurse or a physician assistant.

Section 22. Amends s. 400.0239, F.S., to delete an obsolete reference to the Medicaid "Up or Out" Quality of Care Contract Management Program.

Section 23. 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 24. 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 25. 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 27 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 26. 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 27. 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 28. 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 29. Amends s. 400.141, F.S., to eliminate 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.

This section requires the AHCA to fine a nursing facility $1,000, as a class II violation, if it fails to impose a moratorium on new admissions when the facility has not complied with the minimum-staffing requirements. Section 400.121(2), F.S., authorizes this fine to be imposed per day, not to exceed $5,000. In other instances, a class II deficiency is subject to a civil penalty of $2,500 for an isolated deficiency, $5,000 for a patterned deficiency, and $7,500 for a widespread deficiency and is intended for ongoing non-compliance issues.

The bill 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 59 of this bill.

Section 30. 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 33. 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 35. 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.

Section 36. 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 37. 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 38. 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 39. 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 40. 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 42. 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 43. Amends s. 400.932, F.S., to clarify the grounds for administrative action by the AHCA against a home medical equipment provider.

Section 44. Amends s. 400.933, F.S., to authorize the AHCA to accept a licensed home medical equipment provider's survey or inspection of an accrediting organization, provided the accreditation is not *conditional* or provisional, in lieu of conducting its own survey or inspection.

Section 45. Amends s. 400.953, F.S., to require the affidavit submitted by the general manager of a home medical equipment provider concerning background screening of the provider's personnel to be submitted in accordance with s. 408.809(6), F.S., which requires the document to be submitted at the time of license renewal.

Section 46. 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.

Section 47. Amends s. 400.9905, F.S., to revise the definitions related to the health care clinic act to include "service" within the term "portable service or equipment provider." This change includes an entity that contracts with or employs a person to provide portable health care service or equipment to multiple locations, which bills third-party payors for those services, and which otherwise, meets the definition of a clinic. Pediatric cardiology and perinatology[29] clinic facilities that are a publicly traded corporation or that are wholly owned by a publicly traded corporation are exempted from the definition of and regulation as a health care clinic.

Section 48. 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 50. 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 51. 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.

[29] Perinatology is a subspecialty of obstetrics concerned with the care of the mother and fetus at higher-than-normal risk for complications See: <http://www.medterms.com/script/main/art.asp?articlekey=7902>, (Last visited on April 5, 2010).

Section 52. 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 54. Amends s. 408.061, F.S., to remove an inappropriate reference to an administrative rule that describes data reporting.

Section 55. Amends s. 408.10, F.S., to authorize the AHCA to provide staffing for the toll-free telephone number dedicated to handling consumer complaints.

Section 57. Amends s. 408.804, F.S., related to the general licensing provisions. Effective October 1, 2010, 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 58. 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 59. 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 60. 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 61. Amends s. 408.815, F.S., related to general licensing provisions, to authorize the AHCA to extend the license expiration date for up to 60 days and to impose other conditions during that 60-day extension in order to accomplish the safe and orderly discharge of clients. The authority to extend is at the discretion of the AHCA and does not create any right or entitlement to an extension of a license expiration date.

Section 62. Amends s. 409.906, F.S., related to optional Medicaid services, to phase out the adult day health care waiver program from July 1, 2010 through December 31, 2010. Enrollees as of July 1, 2010 will transition to other home and community-based services.

Section 65. 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 $18,500.

The bill eliminates the requirement for the 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 66. Amends s. 429.11, F.S., to remove language related to provisional licenses within the authorizing statutes for assisted living facilities since provisional licenses are authorized in the general licensing provisions in part II of ch. 408, F.S.

Section 68. Amends s. 429.14, F.S., to authorize the AHCA to provide information concerning assisted living facilities that have had their license denied, suspended, or revoked to the Department of Business and Professional Regulation electronically or through the AHCA's website.

Section 69. 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 assisted living facility since this is authorized in the general licensing provisions in part II of ch. 408, F.S.

Section 70. Amends s. 429.19, F.S., to clarify that a monitoring fee may be assessed in addition to an administrative fine.

Section 72. 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 74. Amends s. 429.35, F.S., to authorize the AHCA to provide the results of an inspection of an assisted living facility to the local ombudsman council and others electronically or through the AHCA's website.

Section 75. Amends s. 429.41, F.S., to conform provisions related to rulemaking for ALFs to changes made in this bill.

Section 76. Amends s. 429.53, F.S., related to consultation by the agency pertaining to assisted living facilities. 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 77. Amends s. 429.54, F.S., to require licensed ALFs to report electronically to the AHCA semiannually, or more frequently if required by rule, 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;
- Funding sources of the residents; and
- Professional personnel providing resident services.

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

Section 78. Amends s. 429.65, F.S., to revise the definition of "adult family-care home." The bill authorizes up to two people to own or rent the home and requires these people to reside in the home. The bill also revises the definition of "provider" to mean one or two individuals.

Section 79. 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 82. 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 85. 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 86. 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 87. 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 89 of the committee substitute related to the restricted prescription drug distributor permit for a blood establishment.

Section 88. 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 89 of the committee substitute related to the restricted prescription drug distributor permit for a blood establishment.

Section 89. 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[30] 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 96. Provides an effective date of July 1, 2010, except as otherwise expressly provided in this act. Section 57 provides an effective date of October 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.

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

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 revenue 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 $5,413 to accommodate the increased per-bed licensure fee increase.

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.

C. Government Sector Impact:

Same as comment for the private sector impact. Currently the AHCA contracts for operation of the call center that is used for facility, managed care, and Medicaid fraud complaints, and providing Medicaid information at an annual cost of $1,050,482. Section 55 of this bill authorizes this service to be handled by AHCA staff. The AHCA projects that 10 FTEs are required to provide this service. By providing this service in-house beginning in January 2011, the AHCA estimates a cost savings of $354,274 in the first year and $394,273 thereafter. In addition, 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 58 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.

VI. Technical Deficiencies:

Section 80 of this committee substitute deletes the definition of a term that is used in s. 429.911, F.S. Now that only one paragraph within s. 429.911, F.S., is repealed in section 81, this

definition should not be repealed. An amendment is needed to delete section 80 from the committee substitute.

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 by Health Regulation on April 7, 2010:
This committee substitute originated from a shell bill and:

- 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 AHCA;
- Streamlines reporting by licensed facilities and state agencies;
- Expands the authorized staffing of a geriatric outpatient clinic in a nursing home to include a nurse practitioner or a licensed practical nurse under the direct supervision of a registered nurse;
- Imposes 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;
- Eliminates the monthly reporting by nursing homes and assisted living facilities 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 service or equipment provider;
- Prohibits activities related to altering, defacing, or falsifying a license certificate;
- 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, and authorize the AHCA to extend the license expiration date for up to 60 days and impose other conditions during that extension period in order to accomplish the safe and orderly discharge of clients or residents;
- Phases out the Medicaid adult day health care waiver program;
- Repeals the limited nursing services (LNS) specialty license and authorizes LNS to be provided by appropriately licensed persons in an assisted living facility (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 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 licensure fees 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 with respect to assisted living facilities;
- Revises the definition of an adult family-care home to address a glitch in the law by authorizing up to two people to own or rent the home;
- Requires a community blood center to disclose certain information on its website; and
- Enables certain community blood centers to obtain a permit to lawfully engage in the wholesale distribution of certain prescription drugs.

B. Amendments:

None.