

## HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** CS/CS/HB 119 Health Care

**SPONSOR(S):** Health & Human Services Committee; Health & Human Services Quality Subcommittee; Hudson

**TIED BILLS:** **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health & Human Services Quality Subcommittee	10 Y, 4 N, As CS	Guzzo	Calamas
2) Appropriations Committee	17 Y, 5 N	Hicks	Leznoff
3) Health & Human Services Committee	16 Y, 0 N, As CS	Guzzo	Gormley

### SUMMARY ANALYSIS

The bill amends the Health Care Licensing Procedures Act (Act) and the various authorizing statutes of entities regulated by the Agency for Health Care Administration (AHCA) to reduce, streamline, and clarify regulations for those providers.

- The bill eliminates the Limited Nursing Services specialty license type for assisted living facilities (ALFs) to allow a licensed nurse to provide such services in a standard licensed ALF. The bill replaces the requirement to monitor specialty license facilities with a requirement to monitor all ALFs based upon citation of serious violations. The bill modifies AHCA consultation duties related to ALFs and requires the adoption of rules for data submission by ALFs related to the numbers of residents receiving mental health or nursing services, resident funding sources, and staffing.
- The bill limits the frequency of fire safety inspections by the State Fire Marshal for nursing homes and expands the ability of nursing homes to provide respite services and provides criteria for the provision of such services.
- The bill amends the Health Care Clinic Act to provide additional exemptions.
- The bill amends various licensure provisions, including those related to bankruptcy notifications, licensure renewal notices, billing complaints, accrediting organizations, licensure application document submissions, staffing in geriatric outpatient clinics, medical records, property statements, AHCA inspection staff, litigation notices, and health care clinic licensure exemptions.
- The bill repeals obsolete or duplicative provisions in licensing and related statutes, including expired reports and regulations and provisions that exist in other sections of law. The bill resolves conflicts among and between provisions in the Act and various authorizing statutes for individual provider types. The bill also makes various revisions to update terminology and conforms current law to prior legislative changes.
- The bill requires prescribed drugs billed as 340B prescribed medication to meet the requirements of the Deficit Reduction Act of 2005 and the federal 340B program; contain a national drug code and be billed at the actual acquisition cost or payment will be denied.
- The bill adds orthotic, pedorthic and prosthetic licensees to the list of "health care providers" for purposes of medical malpractice lawsuits.
- The bill requires hospital housekeeping and sanitation staff to wear masks and gloves while cleaning patient rooms and disinfect environmental surfaces in patient rooms in accordance with the time restrictions on the label of the disinfectant used.
- The bill provides additional time extensions for trauma center applicants.
- The bill revises self-referral exceptions for nurse registries, home health agencies, and group practices.

The bill has a positive fiscal impact on state government and the private sector. (See Fiscal Comments.)

The bill has an effective date of July 1, 2011.

This document does not reflect the intent or official position of the bill sponsor or House of Representatives.

STORAGE NAME: h0119f.HHSC

DATE: 4/24/2011

## FULL ANALYSIS

### I. SUBSTANTIVE ANALYSIS

#### A. EFFECT OF PROPOSED CHANGES:

##### **Background**

The Agency for Health Care Administration (AHCA) regulates over 41,000 health care providers under various regulatory programs. Regulated providers include:

- Laboratories authorized to perform testing under the Drug-Free Workplace Act (ss. 112.0455, 440.102, F.S.).
- Birth centers (Ch. 383, F.S.).
- Abortion clinics (Ch. 390, F.S.).
- Crisis stabilization units (Pts. I and IV of Ch. 394, F.S.).
- Short-term residential treatment facilities (Pt. I and IV of Ch. 394, F.S.).
- Residential treatment facilities (Pt. IV of Ch. 394, F.S.).
- Residential treatment centers for children and adolescents (Pt. IV of Ch. 394, F.S.).
- Hospitals (Part I of Ch. 395, F.S.).
- Ambulatory surgical centers (Pt. I of Ch. 395, F.S.).
- Mobile surgical facilities (Pt. I of Ch. 395, F.S.).
- Health care risk managers (Pt. I of Ch. 395, F.S.).
- Nursing homes (Pt. II of Ch. 400, F.S.).
- Assisted living facilities (Pt. I of Ch. 429, F.S.).
- Home health agencies (Pt. III of Ch. 400, F.S.).
- Nurse registries (Pt. III of Ch. 400, F.S.).
- Companion services or homemaker services providers (Pt. III of Ch. 400, F.S.).
- Adult day care centers (Pt. III of Ch. 429, F.S.).
- Hospices (Pt. IV of Ch. 400, F.S.).
- Adult family-care homes (Pt. II of Ch. 429, F.S.).
- Homes for special services (Pt. V of Ch. 400, F.S.).
- Transitional living facilities (Pt. V of Ch. 400, F.S.).
- Prescribed pediatric extended care centers (Pt. VI of Ch. 400, F.S.).
- Home medical equipment providers (Pt. VII of Ch. 400, F.S.).
- Intermediate care facilities for persons with developmental disabilities (Pt. VIII of Ch. 400, F.S.).
- Health care services pools (Pt. IX of Ch. 400, F.S.).
- Health care clinics (Pt. X of Ch. 400, F.S.).
- Clinical laboratories (Pt. I of Ch. 483, F.S.).
- Multi-phasic health testing centers (Pt. II of Ch. 483, F.S.).
- Organ, tissue, and eye procurement organizations (Pt. V of Ch. 765, F.S.).

##### **Health Care Licensing Procedures Act**

Providers are regulated under the Health Care Licensing Procedures Act (Act) in part II of chapter 408, F.S. The Act provides uniform licensing procedures and standards applicable to most AHCA-regulated entities. The Act contains basic licensing standards for 29 provider types in areas such as licensure application requirements, ownership disclosure, staff background screening, inspections, administrative sanctions, license renewal notices, and bankruptcy and eviction notices.

In addition to the Act, each provider type has an authorizing statute which includes unique provisions for licensure beyond the uniform criteria. Pursuant to s. 408.832, F.S., in the case of conflict between the Act and an individual authorizing statute, the Act prevails. There are several references in authorizing statutes that conflict with or duplicate provisions in the Act, 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. Chapter 2009-223, L.O.F., made changes to part II of chapter 408, F.S., which supersede components of the specific licensing statutes.

This bill repeals obsolete or duplicative provisions in licensing and related statutes, including expired reports and regulations and provisions that exist in other sections of law like the Act. The bill also makes changes to the Act to reduce, streamline, or clarify regulations for all providers regulated by AHCA.

The bill changes individual licensing statutes to reflect updates to the uniform standards in the Act. The bill makes corresponding changes to provider licensing statutes to reflect the changes made to the Act to eliminate conflicts and obsolete language.

### Certificates of Need

A certificate of need (CON) is a written statement issued by AHCA providing evidence of community need for a new, converted, expanded, or otherwise significantly modified health care facility, health service, or hospice.<sup>1</sup> Section 408.037, F.S., requires the applicants for CON to be audited. According to AHCA, the applicant is frequently a sub-entity of a larger corporation and usually has no operations yet.<sup>2</sup> Therefore, the applicant has to go through the expense of getting a separate audit on the sub-entity company to meet the filing requirement.<sup>3</sup>

The bill modifies s. 408.037, F.S., to allow audited financial statements of an applicant's parent corporation in exchange for the audited financial statements of an applicant when such statements do not exist.

### License Renewal Notices

Section 408.806, F.S., requires AHCA to notify licensees by mail or electronically when it is time to renew their licenses. AHCA mails renewal notices to over 30,000 providers every two years. While the statute does not specify the manner of mailing notices, AHCA sends them by certified mail to verify receipt by the providers. The cost of certified mail is approximately \$56,000 annually. According to AHCA, some certified mail is returned, as providers do not pick it up or the post office is unable to obtain necessary signatures for delivery. AHCA has also encountered situations in which licensees did not timely renew their licenses and claimed that their lack of receipt of a renewal reminder was a reason for that failure.

The bill clarifies that renewal notices are courtesy reminders only and do not excuse the licensees from the requirement to file timely licensure applications. The revised language gives AHCA clear flexibility to use or not use certified mail to send courtesy renewal reminders.

### Classification and Fines for Violations

Section 408.813, F.S., includes criteria for the classification of deficiencies for all providers licensed by AHCA. Some authorizing statutes also contain criteria for the classification of deficiencies, some of which do not match the provisions contained in the Act. The provisions in the Act legally supersede conflicting provisions in the authorizing statutes. However, the dual provisions may be confusing, and some conflicts still exist. Additionally, authorizing statutes are inconsistent related to fines for unclassified deficiencies such as failure to maintain insurance or exceeding licensed bed capacity.

The bill modifies the classification of licensure violations related to nursing homes, home health agencies, intermediate care facilities for the developmentally disabled, and adult family care homes to refer to the scope and severity in s. 408.813, F.S. Fine amounts for violations are unchanged. For

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<sup>1</sup> S. 408.032(2), F.S.

<sup>2</sup> AHCA email dated March 8, 2011 on file with Subcommittee staff.

<sup>3</sup> Id.

intermediate care facilities for the developmentally disabled, the amount of fines for Class I, II, and III violations are unchanged, but a new Class IV is added for consistency with s. 408.813, F.S., with a fine not to exceed \$500. The addition of the Class IV violation creates a lower category for minor violations by those facilities. This resolves conflicting or confusing differences between the Act and the authorizing statutes, and resolves inconsistencies between these three authorizing statutes.

In addition, the bill establishes uniform sanction authority for unclassified deficiencies of up to \$500 per violation. Examples of unclassified deficiencies include failure to maintain insurance and other administrative requirements, exceeding licensed capacity, or violating a moratorium. Without fine authority, AHCA would be required to initiate revocation action for violations against those providers that do not have general fine authority. These violations may not warrant such a severe sanction.

### Licensure Denial and Revocation

An action by AHCA to deny or revoke a license is subject to challenge under the Administrative Procedures Act (chapter 120, F.S.) If a licensee challenges the agency action, s. 408.815(2), F.S., allows the license to continue to exist and the provider to continue to operate during the pendency of the case. Once a final order is issued on the denial or revocation, if the original licensure expiration date has passed, there is no valid license and the provider must cease operations immediately. According to AHCA, this can be problematic for residents or clients who must immediately be moved to another facility or find another health care provider.

Section 408.815(4), F.S., gives AHCA authority to deny an application for a license or license renewal if the applicant or a person having a controlling interest in an applicant has been:

- Convicted of a felony;
- Terminated from the Florida Medicaid program; or
- Terminated from the federal Medicare program.

The bill amends s. 408.815, F.S., to authorize AHCA to extend a license expiration date up to 30 days beyond the final order date in the event of a licensure denial or revocation to allow for the orderly transfer of residents or patients.

The bill also allows AHCA to consider certain mitigating circumstances for applications subject to denial. The mitigating circumstances include but are not limited to:

- Completion or lawful release from confinement, supervision, or sanction, including any terms of probation, and full restitution;
- Execution of a compliance plan with AHCA;
- Compliance with any integrity agreement or compliance plan with any other government agency;
- Determination by any state Medicaid program or the Medicare program that the controlling interest is currently allowed to participate in the state Medicaid program or the Medicare program;
- Continuation of licensure by the controlling interest;
- Overall impact on public health, safety or welfare; or
- Determination that license denial is not commensurate with the prior action taken by the state Medicaid program or the Medicare program.

### Billing Complaint Authority

The Act provides authority to review billing complaints across all programs and gives the impression that AHCA can take licensure action regarding billing practices. Section 408.10(2), F.S., requires AHCA to investigate consumer complaints regarding billing practices and determine if the facility has engaged in billing practices which are unreasonable and unfair to the consumer. However, the Act does not provide specific standards for billing practices which AHCA can use to cite violations and

discipline a provider's license. Nor does the Act define what activities would be unreasonable and unfair. Several providers' authorizing statutes do include billing standards, including nursing homes and assisted living facilities.<sup>4</sup> However, other authorizing statutes are silent on billing standards, including hospitals, labs, crisis stabilization units and residential treatment facilities.

For calendar year 2010, AHCA received 473 complaints that alleged billing-related issues. Of those, 74 were for providers that have billing standards in their licensure statutes. The remaining 399 were related to billing issues for which no regulatory authority existed for billing matters. When the agency receives a billing complaint regarding one of the providers which does not have statutory billing standards, it is the agency's policy to review the complaint and encourage the parties to work together to resolve the problem. However, the provider is not cited or disciplined due to lack of authority.

The bill repeals AHCA's independent authority related to billing complaints in the Act. However, a review for regulatory compliance will continue to be conducted when a complaint is received for one of the providers over which AHCA has well-defined statutory billing authority. This review could possibly result in citations and discipline.

### License Display

Section 408.804, F.S., makes it unlawful to provide or offer services that require licensure without first obtaining a license. This section of law also makes licenses valid only for entities and locations for which they are issued. Licensees are required to display licenses in a conspicuous place readily visible to the clients. The Act does not currently address falsification or ill-usage of license documents.

The bill makes it a second degree misdemeanor to knowingly alter, deface, or falsify a license and is punishable by up to 60 days in jail and a fine of up to \$500. The bill makes it an administrative violation for a licensee to display an altered, defaced, or falsified license. Such violations are subject to licensure revocation and a fine of up to \$1,000 per day.

## **Hospital Licensure**

### Accreditation Organizations

Currently, Florida law allows AHCA to consider and use hospital accreditation by certain accrediting organizations for various purposes, including accepting accreditation surveys in lieu of AHCA surveys, requiring accreditation for designation as certain specialty hospitals, and setting standards for quality improvement programs. Section 395.002, F.S., defines "accrediting organizations" as the Joint Commission on Accreditation of Healthcare Organizations, the American Osteopathic Association, the Commission on Accreditation of Rehabilitation Facilities, and the Accreditation Association for Ambulatory Health Care, Inc.

The bill broadens the definition of "accrediting organizations" for hospitals and ambulatory surgery centers to include any nationally recognized accrediting organization whose standards incorporate comparable licensure requirements as determined by AHCA. This gives AHCA and providers greater flexibility to accept new or improving accrediting organizations and reconsider existing organizations based on current statutory and rule-based standards.

### Complaint Investigation Procedures

Complaint investigation procedures for hospitals exist in the hospital authorizing statutes as well as in the Act. Section 395.1046, F.S., provides special procedures for hospital complaints regarding emergency access issues. AHCA may investigate emergency access complaints even if the complaint is withdrawn. When the investigation is complete, AHCA shall prepare an investigative report that makes a probable cause determination. AHCA reports that the federal process for emergency access

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<sup>4</sup> S. 400.23, F.S., (Nursing Homes) and s. 429.19, F.S., (Assisted Living Facilities).

complaints dictates that these complaints should not be handled any differently from other types of complaints.

The bill repeals s. 395.1046, F.S., which eliminates the special procedures for investigating hospital emergency access complaints and would allow AHCA to employ existing hospital complaint investigation procedures used for all other types of complaints.

### Infection Control

Section 395.1055(1), F.S., requires AHCA to adopt rules requiring hospitals to meet certain minimum standards of patient care and safety. The rules must include:

- Infection control, housekeeping, sanitary conditions, and medical record procedures that will adequately protect patients; and
- Conforming of licensed facility beds to minimum space, equipment, and furnishings standards as specified by DOH.

AHCA Rule 59A-3.250, F.A.C., was promulgated in 1995 to comply with the provisions of s. 395.1055, F.S.

Hospitals use chemical disinfectants to control infection in their facilities. The Environmental Protection Agency (EPA) has been testing hospital sterilants, disinfectants, and tuberculocides since 1991 to ensure that products meet stringent efficacy standards.<sup>5</sup> If disinfectants meet these standards, they are given a registration number that appears on the product label, along with other required statements.<sup>6</sup> One of the label requirements is the recommended contact time for the disinfectant to be effective. The labels of most registered disinfectants specify a contact time of 10 minutes. However, EPA will approve a shortened contact time if a product manufacturer submits confirmatory efficacy data.<sup>7</sup>

The bill amends s. 395.1055(1)(b), F.S., to require AHCA to adopt rules requiring hospital sanitation and housekeeping staff to:

- Wear gloves and masks while cleaning patient rooms; and
- Disinfect environmental surfaces in patient rooms in accordance with the time instructions on the label of the disinfectant used by the hospital.

The bill allows AHCA to impose an administrative fine for each day that a violation of these provisions occurs.

The bill also amends s. 395.1055(1)(e), F.S., providing that licensed facility beds conform to minimum space, equipment, and furnishings standards as specified by AHCA, the Florida Building Code, and the Florida Fire Prevention Code, instead of DOH.

### Licensure Inspection

Section 395.0161(3), F.S., requires hospital license applicants to pay a fee at the time of inspection. The fee cannot be less than \$8 per bed, and cannot be more than \$12 per bed, with a minimum fee of \$400 per facility.

The bill removes the requirement for the fees to be paid at the time of inspection, allowing for a single collection of fees when the license is renewed, rather than separate billing after each inspection.

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<sup>5</sup> See, Antimicrobial Testing Program, U.S. Environmental Protection Agency, available at <http://www.epa.gov/oppad001/antimicrobial-testing-program.html> (last viewed April 21, 2011).

<sup>6</sup> *Id.*

<sup>7</sup> *Id.*

## Trauma Centers

Section 395.4025, F.S., contains licensure requirements for a hospital seeking designation as a trauma center. A Trauma center is a hospital that has been verified by DOH to be in compliance with the requirements of s. 395.4025, F.S., and has been approved by DOH to operate as a Level I, Level II or pediatric trauma center.<sup>8</sup>

There are 19 trauma service areas throughout the state. Within each service area and based on the state trauma system plan, the local or regional trauma services system plan, and recommendations of the local or regional trauma agency, DOH establishes the approximate number of trauma centers needed to ensure reasonable access to trauma services.<sup>9</sup> There can be no more than 44 trauma centers in the state.<sup>10</sup>

Section 395.4025(2)(a), F.S., requires DOH to notify each acute care general hospital and each local and regional trauma agency in the state that it is accepting letters of intent from hospitals that are interested in becoming trauma centers. Section 395.4025(2)(b), F.S., requires DOH to send an application package, by October 15, to all hospitals that submitted a letter of intent during the calendar year. Applications are due to DOH by the following April. The applicants must meet all the statutory requirements at the time of application submission.

Section 395.4025(2)(d), F.S., gives DOH authority to grant trauma center applicants up to an additional 18 months if they are unable to meet all the necessary requirements, and the number of applicants in the service area in which they are located is equal to or less than the service area allocation.

The bill amends s. 395.4025(2)(d), F.S., to allow hospital applicants that have been granted the 18 month extension the ability to receive two additional six-month extensions if:

- Construction related to a critical element is delayed as a result of governmental action or inaction with respect to regulations or permitting; and
- The applicant has made a good faith effort to comply with the applicable regulations or obtain the required permits.

## **Nursing Home Licensure**

### Nursing Home License Application

An application for nursing home licensure must include the following:

- A signed affidavit disclosing financial or ownership interest of a nursing home controlling interest in the last five years in any health or residential facility which has closed, filed bankruptcy, has a receiver appointed or an injunction placed against it, or been denied, suspended, or revoked by a regulatory agency. This information is also required in s. 400.111, F.S.
- A plan for quality assurance and risk management. This plan is also reviewed during onsite inspections by AHCA.
- The total number of beds including those certified for Medicare and Medicaid. This information is also required by s. 408.806(1)(d), F.S.

The bill eliminates routine submission of documents at licensure by amending ss. 400.071, 400.111, and 400.1183, 400.141, F.S., to substitute the requirement for nursing homes to routinely submit certain documents at the time of licensure with the ability for AHCA to request the documents, if needed.

### Nursing Home Geriatric Outpatient Clinics

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<sup>8</sup> S. 395.4001(14), F.S.

<sup>9</sup> S. 395.4025(1), F.S.

<sup>10</sup> S. 395.402(4)(c), F.S.

Currently, nursing homes may establish a geriatric outpatient clinic as authorized in s. 400.021, F.S., to provide outpatient health care to persons 60 years of age or older. The clinic can be staffed by a registered nurse or a physician's assistant.

Section 400.021(16), F.S., defines "resident care plan" as a written plan developed, maintained, and reviewed not less than quarterly by a registered nurse, which includes a comprehensive assessment of the needs of an individual resident. The resident care plan is required to be signed by the director of nursing or another registered nurse employed by the facility.

The bill expands the health care professionals that may staff a geriatric outpatient clinic in a nursing home to include licensed practical nurses under the direct supervision of a registered nurse, advanced registered nurse practitioner, physician assistant, or physician.

The bill also removes the requirement that the director of nursing or other administrative nurse sign the resident care plan.

### Nursing Home Records

Section 400.141(1)(j), F.S., requires licensees to maintain full patient records. AHCA Rule 59A-4.118, F.A.C., establishes certain requirements regarding the credentials of nursing home records personnel. Specifically, the rule requires nursing homes to employ or contract with a person who is eligible for certification as a registered record administrator or an accredited record technician by the American Health Information Management Association or is a graduate of a school of medical record science that is accredited jointly by the Council on Medical Education of the American Medical Association and the American Health Information Management Association. AHCA Rule 59A-4.118, F.A.C., was promulgated in 1994 and the credentialing organizations referred to in the rule presently do not exist as listed. There is also no authorizing statute that requires nursing homes to contract with a medical records consultant.

The bill amends s. 440.141(1)(j), F.S., to include federal language regarding maintenance of medical records consistent with federal medical records regulations contained in Title 42, Code of Federal Regulations. Specifically, the federal regulations require nursing homes to maintain medical records in accordance with accepted professional standards and practices that are complete, accurately documented, readily accessible, and systematically organized.<sup>11</sup> The addition of these federal standards will require the repeal of AHCA Rule 59A-4.118, F.A.C., related to the credentials of medical records personnel.

Nursing homes are required to maintain records of all grievances, and to report to the agency, upon licensure renewal, various data regarding those grievances. The bill retains the requirement for nursing homes to maintain all grievance records, but removes the requirement that nursing homes report the grievance information at the time of relicensure. The bill requires nursing homes to retain a log to be made available for inspection by AHCA.

### Nursing Home Staffing Ratios - General

Nursing homes must comply with staff-to-resident ratios requirements. Under s. 400.141(1)(o), F.S., nursing homes are required to semiannually submit to AHCA information regarding facility staff-to-resident ratios, staff turnover, and staff stability, including information regarding certified nursing assistants, licensed nurses, the director of nursing, and the facility administrator. The ratio must be reported as an average of the most recent calendar quarter. Staff turnover must be reported for the most recent 12-month period. The formula for determining staff stability is the total number of employees that have been employed for more than 12 months, divided by the total number of employees employed at the end of the most recent calendar quarter, and expressed as a percentage.

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<sup>11</sup> 42 C.F.R. 483.75.



If a nursing home fails to comply with minimum staffing requirements for two consecutive days, the facility must cease new admissions until the staffing ratio has been achieved for six consecutive days. Failure to self-impose this moratorium on admissions results in a Class II deficiency cited by AHCA. All other citations for a Class II deficiency represent current ongoing non-compliance that AHCA determines has compromised a resident's ability to maintain or reach his or her highest practicable physical, mental, and psychosocial well-being. Use of the Class II deficiency for a failure to cease admissions is an inconsistent use of a "Class II" deficiency in comparison to all other violations. No nursing homes were cited for this violation in 2010.

The bill removes the requirements under s. 400.141(1)(o), F.S., for reporting staff-to-resident ratio information semiannually to AHCA.

The bill modifies the penalty for nursing homes that fail to self-impose an admissions moratorium for insufficient staffing to a fine of \$1,000 instead of a Class II deficiency.

### Nursing Home Staffing Requirements

Section 400.23(5), F.S., requires AHCA, in collaboration with the Division of Children's Medical Services within the Department of Health (DOH), to adopt rules for minimum standards of care for persons under 21 years of age who reside in nursing home facilities. In 1997, Rule 59A-4.1295, F.A.C., was adopted to provide these additional standards of care for pediatric nursing homes which consist of the following:

- For residents who require **skilled care**, each nursing home must provide an average of 3.5 hours of nursing care per patient per day. A maximum of 1.5 hours may be provided by a certified nursing assistant (CNA), and no less than 1 hour of care must be provided by a licensed nurse.
- For residents who are **fragile**, each nursing home must provide an average of 5 hours of direct care per patient per day. A maximum of 1.5 hours of care may be provided by a CNA, and no less than 1.7 hours of care must be provided by a licensed nurse.

Section 400.23(3)(a), F.S., establishes general nursing home staffing standards. Until 2001, s. 400.23(3)(a) did not require a minimum number of licensed nurses or certified nursing assistants. When Rule 59A-4.1295, F.A.C., was adopted in 1997, it was in compliance with s. 400.23(3)(a), F.S., because there were no minimum staffing standards required in the statute at that time. However, the minimum staffing requirements in s. 400.23(3)(a), F.S., have changed since the Rule language above was adopted.

In 2001, s. 400.23(3)(a), F.S., was amended to include a minimum staffing standard, which is still in effect today. Currently, s. 400.23(3)(a), F.S., establishes general nursing home staffing standards and requires at least 3.9 hours of licensed nursing and CNA direct care per resident per day. Minimums of 2.7 hours of direct care by a CNA and 1 hour of direct care by a licensed nurse are required. The minimum staffing requirements for pediatric nursing homes in Rule 59A-4.1295, F.A.C., are inconsistent with those required for general nursing homes in s. 400.23(3)(a), F.S. The rule limits CNA care to no more than 1.5 hours per day for both fragile and skilled patients, while the statute allows a minimum of 2.7 hours of CNA care per day.

AHCA has tried several times to amend the pediatric staffing ratios in Rule 59A-4.1295, F.A.C. In their most recent proposal, AHCA attempted to delete the rule requirements for skilled and fragile residents detailed above in an effort to comply with s. 400.23(3)(a), F.S. However, the proposed rule has since been withdrawn. During this process, the Joint Administrative Procedures Committee informed the agency that according to s. 120.52(8)(c), F.S., a rule which "enlarges, modifies or contravenes the specific provisions of law implemented" is an "invalid exercise of delegated legislative authority."<sup>12</sup> AHCA has been unsuccessful as of yet in amending language in the rule to comply with the current version of s. 400.23, F.S.

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<sup>12</sup> Oates, Jowanna. "To Bernard Hudson." 14 September 2010. Joint Administrative Procedures Committee.

The bill requires AHCA and the Children’s Medical Services Network to adopt rules for minimum staffing requirements for nursing homes that serve individuals less than 21 years of age. Further, the bill provides that these rules are to apply in lieu of the standards contained in s. 400.23(3)(a), F.S. The staffing requirements are as follows:

- For individuals under age 21 who require **skilled** care, each nursing home facility must provide a minimum combined average of licensed nurses, respiratory therapists, and certified nursing assistants of 3.9 hours of direct care per resident per day.
- For individuals under age 21 who are **fragile**, each nursing home must include a minimum combined average of licensed nurses, respiratory therapists, and certified nursing assistances of 5.0 hours of direct care per resident per day.

<b>Current General</b> <b>400.23(3)(a)</b>	<b>Current Pediatric Skilled</b> <b>59A-4.1295(8)(a)</b>	<b>HB 119 Pediatric Skilled</b>	<b>Current Pediatric Medically Fragile</b> <b>59A-4.1295(8)(b)</b>	<b>HB 119 Pediatric Medically Fragile</b>
Nurse – 1 hr.	Nurse – 1 hr. minimum	3.9 hrs.	Nurse – 1.7 hrs. minimum	5 hrs.
CNAs – 2.7 hrs. minimum	CNAs – 1.5 hrs. maximum	Can be all CNAs	CNAs – 1.5 hrs. maximum	Can be all CNAs

#### Nursing Home Do Not Resuscitate Orders

Section 400.142, F.S., requires AHCA to develop rules relating to implementation of do not resuscitate orders (DNRs) for nursing home residents. Criteria for DNRs are found in s. 401.45, F.S., which allows for emergency pre-hospital treatment to be provided by any licensee and provides that resuscitation may be withheld from a patient by an emergency medical technician (EMT) or paramedic if evidence of a DNR is presented.<sup>13</sup> Section 401.45, F.S., also provides rule-making authority to DOH to implement this section and requires DOH, in consultation with the Department of Elderly Affairs and AHCA, to develop a standardized DNR identification system with devices that signify, when carried or worn, that the patient has been issued an order not to administer cardiopulmonary resuscitation by a physician.<sup>14</sup>

DOH developed rule 64J-2.018, F.A.C., which became effective October, 1 2008, while AHCA has yet to promulgate any rules relating to the implementation of DNRs. Rule 64J-2.018, F.A.C., provides the following:<sup>15</sup>

- An EMT or paramedic must withhold or withdraw cardiopulmonary resuscitation if presented with an original or completed copy of DH Form 1896 (Florida DNR Form).
- The DNR Order form must be printed on yellow paper and have the words “DO NOT RESUSCITATE ORDER” printed in black.
- A patient identification device is a miniature version of DH Form 1896 and is a voluntary device intended to provide convenient and portable DNR order form.
- The DNR order form and patient identification device must be signed by the patient’s physician.
- An EMT or paramedic must verify the identity of the patient in possession of the DNR order form or patient identification device by means of the patient’s driver license or a witness in the presence of the patient.
- During transport, the EMT must ensure that a copy of the DNR order form or the patient identification device accompanies the live patient.
- A DNR may be revoked at any time by the patient.

<sup>13</sup> Section 401.45, F.S.

<sup>14</sup> Id.

<sup>15</sup> Florida Department of Health Rule 64J-2.018, F.A.C.

The bill removes the requirement for AHCA to promulgate rules related to the implementation of DNRs for nursing home residents. This requirement appears to be duplicative of DOH rulemaking authority in s. 401.45(5), F.S.

#### Nursing Home Inspections and Surveys

AHCA employs surveyors to inspect nursing homes. Pursuant to s. 400.275, F.S., newly hired nursing home surveyors must spend two days in a nursing home as part of basic training in a non-regulatory role. Federal regulations prescribe an extensive training process for nursing home inspection staff. Staff must pass the federal Surveyor Minimum Qualifications Test. Federal regulations prohibit an AHCA staff person who formerly worked in a nursing home from inspecting a nursing home within two years of employment with that home; state law requires a five year lapse.

The bill removes the requirement for new AHCA nursing home inspection staff to spend two days in a nursing home as part of basic training and aligns staff requirements with federal regulations. AHCA nursing home staff must still be fully qualified under federal requirements for the Surveyor Minimum Qualifications Test.

#### Nursing Home Internal Risk Management and Quality Assurance Program

Sections 400.147(10) and 400.0233, F.S., require nursing homes to report civil notices of intent to litigate and civil complaints filed with clerks of courts by a resident or representative of a resident. This information has been used to produce the Semi-Annual Report on Nursing Homes required by s. 400.195, F.S. However, s. 400.195, F.S., was repealed in 2010.

Section 400.147(7), F.S., requires nursing homes to initiate an investigation and notify AHCA within one business day after the risk manager has received an incident report. The notification must be made in writing and be provided electronically, by facsimile device or overnight mail delivery.

The bill eliminates the requirement to report notices of intent to litigate and civil complaints. The bill also eliminates the requirement that nursing homes notify AHCA in writing when they initiate an investigation. However, providers must still initiate their own evaluation within one day. A full report is also still required to be sent to AHCA within 15 calendar days if the incident is determined to be an adverse incident.

#### Nursing Home Respite Care

Section 400.141(1)(f), F.S., allows nursing homes to provide respite care for people needing short-term or temporary nursing home services. Only nursing homes with standard licensure status with no Class I or Class II deficiencies in the past two years or having Gold Seal status may provide respite services. AHCA is authorized to promulgate rules for the provision of respite services.

The bill amends s. 400.141, F.S., to expand the ability of nursing homes to provide respite services not exceeding 60 days per year and individual stays may not exceed 14 days. The bill allows all licensed nursing homes to provide respite services without limitations based on prior deficiencies. The bill provides additional criteria for the provision of respite services. For each patient, the nursing home must:

- Have an abbreviated plan of care for each respite patient, covering nutrition, medication, physician orders, nursing assessments and dietary preferences;
- Have a contract that covers the services to be provided;
- Ensure patient release to the proper person; and
- Assume the duties of the patient's primary caregiver.

The bill provides that respite patients are exempt from discharge planning requirements, allowed to use his or her personal medication with a physician's order, and covered by the resident rights as

delineated in s. 400.022, F.S., except those related to transfer, choice of physician, bed reservation policies, and discharge challenges. The bill requires prospective respite patients to provide certain medical information to the nursing home and entitles the patient to retain his or her personal physician.

### Nursing Home Fire Inspections

The Florida Fire Prevention Code is established in chapter 633, F.S., which also establishes the duties and responsibilities of the Florida Fire Marshal and his agents, who are housed within the Department of Financial Services (DFS). Currently, s. 633.081, F.S., requires the Fire Marshal to inspect nursing homes when DFS has “reasonable cause” to believe that a violation of the Florida Fire Code, any rules promulgated under the Florida Fire Code, or of a fire safety code established by a local authority, exists.

The bill amends s. 633.081, F.S., to limit fire inspections of nursing homes by the State Fire Marshal or his agent to once a year. The Fire Marshal may make additional inspections in response to a complaint giving rise to “reasonable cause” for believing a violation exists. The Fire Marshal may also make additional inspections upon identifying violations when accessing a nursing home facility for orientation or training activities.

### Notice of Bankruptcy and Eviction

Currently, nursing homes are required to notify AHCA of bankruptcy filing pursuant to s. 400.141(1)(r), F.S. However, nursing homes are not required to notify AHCA of eviction, and there is no statutory requirement for other types of facility providers to notify AHCA if served with an eviction notice or of bankruptcy filing. AHCA reports that it has recently been made aware of several eviction and bankruptcy orders affecting regulated facilities.<sup>16</sup>

The bill amends s. 408.810, F.S., to require providers’ controlling interests to notify AHCA within 10 days after a court action to initiate bankruptcy, foreclosure, or eviction proceedings. This applies to any such action to which the controlling interest is a petitioner or defendant. According to AHCA, this new requirement would allow the agency to monitor the facility to ensure patient protection and safe transfer, if necessary.<sup>17</sup>

## **Home Health Agency Licensure**

### Home Health Agency Remuneration

A home health agency is an organization that provides home health services and staffing services.<sup>18</sup> Home health agencies are regulated by AHCA pursuant to part III of chapter 400, F.S. Florida law regulates the business relationships of home health agencies, prohibiting “self-referral” situations, in which home health agencies provide monetary incentives for referrals. Section 400.474(6), F.S., provides AHCA the authority to deny, revoke, or suspend the license of a home health agency and impose a fine of \$5,000 against a home health agency that gives remuneration to:

- Another home health agency with which it has formal or informal patient-referral transactions or arrangements for staffing services;
- A health services pool with which it has formal or informal patient-referral transactions or arrangements for staffing services;
- A physician without a medical director contract, and the home health agency has received a patient referral in the preceding 12 months from that physician;
- A physician, and the home health agency has more than one medical director contract in effect at one time, and the home health agency has received a patient referral in the preceding 12 months from that physician;

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<sup>16</sup> AHCA, *Staff Analysis and Economic Impact, House Bill Number 119* (February 7, 2011).

<sup>17</sup> *Id.*

<sup>18</sup> S. 400.462(12), F.S.

- A member of the physician's office staff, and the home health agency has received a patient referral in the preceding 12 months from that physician; or
- An immediate family member of the physician, and the home health agency has received a patient referral in the preceding 12 months from that physician.

Remuneration is defined as any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind.<sup>19</sup>

The bill amends s. 400.462(27), F.S., revising the definition of "remuneration" to allow home health agencies to distribute items with an individual value of up to \$15 and which include, but are not limited to, plaques, certificates, trophies, or novelties that are intended solely for promotional, recognition, or advertising purposes.

## **Nurse Registry Licensure**

### Nurse Registry Remuneration

A nurse registry is defined as any person that procures, offers, promises, or attempts to secure health-care-related contracts for registered nurses, licensed practical nurses, CNAs, home health aides, companions, or homemakers, who are compensated by fees as independent contractors to provide services to patients, or staffing services to facilities.<sup>20</sup> Nurse registries are regulated by AHCA pursuant to part III of chapter 400, F.S. Florida law regulates the business relationships of nurse registries, prohibiting "self-referral" situations, in which nurse registries provide monetary incentives for referrals.

Section 400.506(15)(a), F.S., allows AHCA to deny, suspend, or revoke the license of a nurse registry and impose a fine of \$5,000 against a nurse registry that:

- Provides services to residents in an ALF for which the nurse registry does not receive fair market value remuneration;
- Provides staffing to an ALF for which the nurse registry does not receive fair market value remuneration;
- Gives remuneration to a case manager, discharge planner, facility-based staff member, or third-party vendor who is involved in the discharge planning process of a hospital or facility licensed under chapter 395, F.S.; or
- Gives remuneration to a physician, member of the physician's staff, or an immediate family member of the physician, and the nurse registry received a patient referral in the last 12 months from that physician.

However, nurse registries can give remuneration in the manner described above if they do not bill the Florida Medicaid program or the federal Medicare program, or share a controlling interest with any entity licensed under part II of chapter 408, F.S.

The bill amend s. 400.506(15)(a), F.S., to broaden the exemption to nurse registry marketing restrictions, by exempting nurse registries that bill the Florida Medicaid program.

## **Hospice Licensure**

Section 408.810(8) F.S., requires any hospice initial or change of ownership applicant show anticipated provider revenue and expenditures, the basis for financing anticipated cash flow requirements and access to contingency financing. Section 400.606(1)(I), F.S., requires that an annual operating budget be submitted, which duplicates the financial information now required in the Act.

The hospice authorizing statutes and federal regulations require that hospices have inpatient beds for pain control, symptom management, and respite care. Inpatient beds may be in a hospital, skilled

<sup>19</sup> S. 400.462(27), F.S.

<sup>20</sup> S. 400.462(21), F.S.

nursing facility or a freestanding inpatient facility operated by a hospice. Section 408.043, F.S., requires that there be a certificate of need for a hospice freestanding facility “primarily engaged in providing inpatient care and related services.” This provision is repeated in the Act.

The bill removes the requirement for hospice licensure applicants to submit a projected annual operating budget. Financial projections are already submitted as part of the proof of financial ability to operate as required in the Act; therefore, this removes duplicative requirements.

The bill amends both the Act and the hospice authorizing statutes related to certificates of need for inpatient hospice facilities. The bill eliminates the modifier “primarily” to provide that any provision of inpatient hospice care, in any facility not already licensed as a health care facility (like a hospital or nursing home), requires a certificate of need. In effect, the bill provides that no exemptions to this requirement exist.

### **Home Medical Equipment Licensure**

Section 400.931(2), F.S., allows a bond be posted as an alternative to submitting proof of financial ability to operate for a home medical equipment provider. Section 408.8065, F.S., requires the submission of financial statements demonstrating the ability to fund start up costs, working capital, and contingency requirements.

The bill deletes the provisions of s. 400.931, F.S., related to the ability to submit a bond as an alternative to submitting proof of financial ability to operate. Due to 2009 legislative changes, financial oversight is now addressed in the Act. In addition, the bill requires out-of-state home medical equipment providers to be accredited to be licensed in Florida.

### **Health Care Clinic Licensure**

Part X of chapter 400, F.S., contains the Health Care Clinic Act. This act was passed in 2003 to reduce fraud and abuse in the personal injury protection (PIP) insurance system. Florida’s Motor Vehicle No-Fault Law<sup>21</sup> requires motor vehicle owners to maintain \$10,000 of PIP insurance. PIP benefits are available for certain express damages sustained in a motor vehicle accident, regardless of fault.

Pursuant to the Health Care Clinic Act, AHCA licenses entities that meet the definition of a “clinic”: “an entity at which health care services are provided to individuals and which tenders charges for reimbursement for such services...”<sup>22</sup> Licensure applications must identify the owners, medical director, and medical providers employed by the clinic. Applicants must provide proof of compliance with applicable rules and financial ability to operate. A level two background screening is required of each applicant for clinic licensure, and certain criminal offenses bar licensure. Each clinic must have a medical director or clinic director who agrees in writing to accept legal responsibility pursuant to s. 400.9935, F.S., for the following activities on behalf of the clinic:

- Ensuring that all practitioners providing health care services or supplies to patients maintain a current, active, and unencumbered Florida license;
- Reviewing patient referral contracts or agreements made by the clinic;
- Ensuring that all health care practitioners at the clinic have active appropriate certification or licensure for the level of care being provided;
- Serving as the clinic records owner;
- Ensuring compliance with the recordkeeping, office surgery, and adverse incident reporting requirements of chapter 456, F.S., the respective practice acts, and rules adopted under the Health Care Clinic Act; and
- Conducting systematic reviews of clinic billings to ensure billings are not fraudulent or unlawful. If an unlawful charge is discovered, immediate corrective action must be taken.

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<sup>21</sup> Sections 627.730-627.7405, F.S., the Florida Motor Vehicle No-Fault Law, were repealed on October 1, 2007 pursuant to s. 19, ch. 2003-411 L.O.F. The No-Fault Law was revived and reenacted effective January 1, 2008 pursuant to ch. 2007-324 L.O.F.

<sup>22</sup> Section 400.9905(4), F.S.

AHCA may deny, revoke, or suspend a health care clinic license and impose administrative fines of up to \$5,000 per violation pursuant to s. 400.995, F.S.

Although all clinics must be licensed, s. 400.9905(4), F.S., contains a listing of entities that are not considered a "clinic" for purposes of licensure, including:

- Entities licensed or registered by the state under one or more specified practice acts and that only provide services within the scope of their license, and entities that own such entities, and entities under common ownership with such entities;
- Entities that are exempt from federal taxation under 26 U.S.C. sec. 501(c)(3) or sec. 501(c)(4);
- Community college and university clinics;
- Entities owned or operated by the federal or state government;
- Clinical facilities affiliated with an accredited medical school which provides certain training;
- Entities that provide only oncology or radiation therapy services by physicians and are owned by publicly-traded corporations;
- Clinical facilities affiliated with an accredited certain college of chiropractic which provides certain training;
- Entities that provide a certain amount of practitioner staffing or anesthesia services to hospitals;
- Orthotic or prosthetic facilities owned by publicly-traded corporations; and

The bill expands an existing exemption from health care clinic licensure for clinics that are wholly owned, directly or indirectly, by a publicly traded corporation to include pediatric cardiology or perinatology clinics. The bill also creates exemptions from licensure for entities:

- Owned by a corporation generating more than \$250 million in annual sales and which have at least one owner who is a health care practitioner;
- Owned directly or indirectly by a publically traded entity with \$100 million or more in total annual revenues derived from providing health care services by employed or contracted licensed health care practitioners; and
- Entities that employ 50 or more licensed health care practitioners where the billing for medical services is under a single tax identification number.

Licensure for health care clinics includes mobile clinics and portable equipment providers. The bill provides that portable service providers, such as mobile ultrasound providers, are subject to health care clinic licensure even though they do not deliver care at the clinic's location.

Section 400.991(4), F.S., allows a bond to be posted as an alternative to submitting proof of financial ability to operate for health care clinics. The bill deletes provisions in s. 400.991(4), F.S., related to the ability to submit a bond as an alternative to submitting proof of financial ability to operate. Due to 2009 legislative changes, financial oversight is now addressed in the Act.

### **Local Health Councils**

Local health councils are established in s. 408.033, F.S., as public or private nonprofit agencies to provide certain health related services to the counties of a district. Funding for local health councils is provided in s. 408.033(2), F.S., which states the cost of local health councils is to be borne by assessments on selected health care facilities subject to facility licensure by AHCA. Currently there is no timetable in statute addressing when fees are to be paid.

The bill requires fees to be collected prospectively at the time of licensure renewal and prorated for the licensure period.

### **Assisted Living Facility Licensure**

Currently, an ALF that wishes to provide certain nursing services must also have a limited nursing services (LNS) license or extended congregate care (ECC) specialty license to provide certain nursing services. These specialty licenses allow facilities to provide a variety of additional services beyond those allowed in a standard licensed ALF.

With a LNS specialty license, a facility may provide nursing assessment; care and application of routine dressings; care of casts, braces and splints; administration and regulation of portable oxygen; catheter, colostomy, and ileostomy care; maintenance and the application of cold or heat treatments; passive range of motion exercises; and ear and eye irrigations.

Facilities with the ECC specialty license may provide additional services, including total help with activities of daily living (bathing, dressing, toileting); dietary management (special diets and nutrition monitoring); administering medication and prescribed treatments; rehabilitative services; and escort to health services. Additionally, licensed nursing staff in an ECC program may provide any nursing service permitted within the scope of their license consistent with residency requirements and the facility's written policies and procedures. A facility is required to pay an additional licensure fee for the LNS and ECC specialty license.

In accordance with current law, LNS facilities must be monitored at least twice a year and ECC facilities must be monitored quarterly. Additional fees required for these programs cover the costs of monitoring visits and the additional oversight during routine inspections and licensure due to the higher acuity of residents and services. As of January 2011, there are a total of 2,919 ALFs with standard licenses with a total of 82,176 beds. Of the 2,919 ALFs in Florida, 1,038 have a LNS specialty license and 285 have an ECC specialty license. Of these 48 have both a LNS and an ECC license.<sup>23</sup>

ALFs are not currently required to submit resident population data to AHCA. However, chapter 2009-223, L.O.F., requires the submission of disaster/emergency information electronically via AHCA's Emergency Status System (ESS) in conjunction with the licensure renewal process. Currently, 42.1 percent (1,197) of ALFs are enrolled in this system.

Section 429.195, F.S., prohibits ALFs from contracting to pay or receive any commission, bonus, kickback, or rebate with any person for resident referrals. These actions are considered patient brokering and are punishable as a third degree felony as provided in s. 817.505, F.S.

Section 429.23, F.S., requires each ALF to submit a monthly report on civil liability claims filed against the facility and provides that the reports are not discoverable on civil or administrative actions. Section 429.35, F.S., requires AHCA to forward the results of biennial licensure surveys to various entities, including a local public library, the local ombudsman council, and the district Adult Services and Mental Health Program Office.

The bill eliminates the LNS specialty license for ALFs and allows a licensed nurse to provide limited nursing services in a standard licensed ALF without additional licensure. The bill repeals the requirement to monitor ECCs, and replaces it with a requirement to monitor based upon citation of serious violations (Class I or Class II) in any ALF. The bill increases ALF licensure fees to compensate for the loss of LNS licensure fees and maintain the licensure program. The bill authorizes a fee of \$71 per private pay bed.

During Fiscal Year 2009-2010, AHCA conducted a total of 667 monitoring visits for LNS and ECC licensure. Under the new monitoring proposed in the bill, AHCA expects to conduct 726 monitoring visits per year, assuming an average monitoring of three times per year. AHCA expects the monitoring based upon citation of violations proposed in the bill to have a neutral effect on the number of visits conducted per year despite the elimination of the LNS license.<sup>24</sup>

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<sup>23</sup>AHCA, *Staff Analysis and Economic Impact, House Bill Number 119* (February 7, 2011).

<sup>24</sup>AHCA email dated February 22, 2011 on file with Subcommittee staff.



The bill modifies AHCA's consultation duties by removing the required provision of a checklist of necessary general, local and state approvals prior to the construction of a facility; and an explanation of benefits and financial assistance options available to a facility resident who is a recipient of supplemental security income.

The bill requires AHCA to adopt rules for data submission by ALFs related to staffing and numbers of residents receiving certain services. The bill requires facilities to electronically submit resident population data to AHCA semi-annually. Licensees will be required to report ALF resident information not currently required and requires the Department of Elder Affairs (DOEA), in consultation with AHCA, to adopt rules. According to AHCA, this resident information will be useful for health planning and regulatory purposes.<sup>25</sup>

The bill amends s. 429.195(3), F.S., providing that the following activities are not prohibited patient brokering by ALFs and are not punishable as third degree felonies:

- Employing or contracting for marketing services;
- Referral services which provide information, consultation, or referrals to consumers; or
- Referrals to an ALF by residents of the ALF.

The bill also eliminates the requirement that ALFs report civil liability claims to AHCA and allows AHCA to provide biennial survey results to the public electronically or via the AHCA website.

### **Drug Free Workplace Act**

Section 112.0455, F.S., contains the Drug Free Workplace Act (Act). The purpose of the Act is to:

- Promote the goal of drug-free workplaces within government through fair and reasonable testing methods for the protection of public employees and employers;
- Encourage employers to provide employees who have drug use problems with an opportunity to participate in an employee assistance program or an alcohol and drug rehabilitation program;
- Provide for confidentiality of testing results.

Section 112.0455(12), F.S., establishes drug testing standards for laboratories licensed under part II of chapter 408. Laboratories are required to submit a monthly report with statistical information regarding the testing of employees and job applicants to AHCA. The reports must include the following information:<sup>26</sup>

- The methods of analyses conducted;
- Drugs tested for;
- The number of positive and negative results for both initial and confirmation tests; and
- Any other information deemed appropriate by AHCA.

Identical language requiring the same report to be submitted to AHCA can be found in s. 440.102(9)(d), F.S., as it relates to the drug free workplace program requirements of the workers' compensation program.

The bill removes the requirement for laboratories to submit a monthly report to AHCA from s. 112.0455, F.S., as well as s. 440.102, F.S. The laboratory reports are not used by AHCA, so the removal of this requirement would reduce regulation that requires unnecessary reporting.<sup>27</sup>

### **Patient Self-Referral Act of 1992**

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<sup>25</sup>AHCA, *Staff Analysis and Economic Impact, House Bill Number 119* (February 7, 2011).

<sup>26</sup> Section 112.0455(12)(d), F.S.

<sup>27</sup> AHCA email dated March 8, 2011 on file with Subcommittee staff.

Section 456.053, F.S., contains the “Patient Self Referral Act of 1992” (Act). The purpose of the act is to prevent conflicts of interest relating to patient referrals by health care providers to a provider of health care services in which the referring provider has an investment interest. Section 456.053(5), F.S., prohibits a health care provider from referring a patient for health care services to an entity in which the provider has a financial interest, with several exceptions. That section defines “referral”, and provides that referral by a provider in a group practice, to another provider in the group practice, does not constitute a “referral”, and so is not prohibited.

The law defines “group practice” as well. A “group practice” is a group of two or more health care providers legally organized as a partnership, professional corporation, or similar association, and meets the following conditions:

- Each health care provider who is a member of the group provides substantially the full range of services, which the health care provider routinely provides, including medical care, consultation, diagnosis, or treatment, through the joint use of office space, facilities, and equipment;
- All of the services of the health care providers who are members of the group are provided through the group and are billed in the name of the group; and
- The overhead expenses of and the income from the practice are distributed in accordance with methods previously determined by members of the group.<sup>28</sup>

The bill amends s. 456.053(3)(h)4., F.S., revising the definition to require group practices that include radiation therapy services to provide a full range of radiation therapy services such that no single type of cancer constitutes 40 percent or more of the group’s cases for radiation therapy services. A “case” means an individual patient’s radiation treatment course, in which the providers within the group who are referring patients for radiation therapy services must not own 50 percent or more of the group practice.

## **Clinical Laboratories**

### Advanced Registered Nurse Practitioners

Part I of chapter 483, F.S., contains licensure requirements for, and regulation of, clinical laboratories operated by practitioners for exclusive use. Section 483.035(1), F.S., requires clinical laboratories licensed by one or more practitioners under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, or chapter 466 to be licensed under, and comply with the provisions of part I of chapter 483. It provides authority for AHCA to adopt rules for staffing, for personnel, including education and training of personnel, for proficiency testing, and for construction standards relating to the licensure and operation of the laboratory based upon the standards contained in the federal Clinical Laboratory Improvement Amendments (CLIAs) of 1988.

Currently, the above list does not include advanced registered nurse practitioners (ARNPs). A laboratory owned or operated by an ARNP is required to have a laboratory director qualified in accordance with part III of chapter 483, F.S., and the Department of Health (DOH) Rule 64B-3, F.A.C. Rule 64B3-5.007, F.A.C., requires any laboratory director to have specialty/subspecialty specific qualifications and be a licensed physician or dentist, or hold a doctoral degree and be licensed by DOH as a clinical laboratory director.

The bill adds ARNPs to the list of exclusive use laboratory providers in s. 483.035(1), F.S., which means CLIA staffing requirements apply to ARNPs instead of the current clinical laboratory director qualification requirements.

### CLIA Certificates

Section 483.051, F.S., provides authority for AHCA to adopt rules to implement the provisions of part I of chapter 483, F.S. The rules must include, but are not limited to licensure qualifications. Section

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<sup>28</sup> S. 456.053(3)(h), F.S.

483.051(1), F.S., requires AHCA to provide for biennial licensure of all clinical laboratories and prescribe the qualifications necessary for such licensure.

Currently, AHCA processes federal CLIA certificates for all laboratories, but only processes state licenses for non-waived (complex) clinical laboratories. The federal Centers for Medicare and Medicaid Services conduct a test to determine qualification for a certificate of waiver under the CLIA's.

The bill amends s. 483.051(1), F.S., clarifying that AHCA must provide for biennial licensure of all "non-waived" clinical laboratories and provides a definition for non-waived laboratories to make sure the distinction is clear.

### **Multi-Phasic Health Testing Centers**

Multi-phasic health testing centers (centers) are facilities which take human specimens for delivery to clinical laboratories for testing and may perform other basic human measurement functions. Centers are licensed and regulated under part II of chapter 483, F.S. Section 483.294, F.S., requires AHCA to inspect centers at least annually.

The bill amends the inspection schedule requiring AHCA to inspect centers biennially.

### **Brain and Spinal Cord Injury Trust Fund**

Under current law, specified traffic fines may be used to provide an enhanced Medicaid rate to nursing homes that serve clients with brain and spinal cord injuries. According to AHCA, funds collected from these fines have not been sufficient to support a Medicaid nursing home supplemental rate for the estimated 100 adult ventilator-dependent patients.

The bill redirects the revenue to the Brain and Spinal Cord Injury Trust Fund within DOH, to be used for Medicaid recipients who have sustained a brain or spinal cord injury and who are technologically and respiratory dependent.

### **"Up-or-Out" Program**

The Medicaid "Up-or-Out" Quality of Care Contract Management Program authorized in s. 400.148, F.S., was created as a pilot program in 2001. The purpose of the program was to improve care in poor performing nursing homes and assisted living facilities by assigning trained medical personnel to facilities in select counties similar to Medicare models for managing the medical and supportive-care needs of long-term nursing home residents. The pilot was subject to appropriation; however, an appropriation was not allocated. Therefore, the program was never implemented. According to AHCA, the criteria specified to identify poor performing facilities has been replaced by more comprehensive information for consumers to make informed choices for care.

The bill repeals the Medicaid Up-or-Out Pilot Quality of Care Contract Management Program.

### **Medical Malpractice**

Sections 766.201-766.212, F.S., establish a process for prompt resolution of medical malpractice lawsuits including presuit investigation and arbitration. These sections apply to malpractice lawsuits against health care providers, which are:

- Hospitals, ambulatory surgical centers and mobile surgical facilities as defined and licensed under chapter 395;
- Birth centers licensed under chapter 383;
- Physicians licensed under chapter 458 or 459;
- Chiropractors licensed under chapter 460;
- Podiatrists licensed under chapter 461;
- Naturopaths licensed under chapter 462;

- Optometrists licensed under chapter 463;
- Nurses licensed under pt. I of chapter 464;
- Dentists, dental hygienists and dental labs licensed under chapter 466;
- Midwives licensed under chapter 467; or
- Physical therapists licensed under chapter 486;
- Clinical laboratories licensed under chapter 483;
- Health maintenance organization certified under pt. I of chapter 641;
- Blood banks;
- Plasma centers;
- Industrial clinics;
- Renal dialysis facilities; or
- Professional association partnerships, corporations, joint ventures, or other associations for professional activity by health care providers.

The bill adds orthotic, pedorthic and prosthetic providers licensed under part XIV of chapter 468, F.S., to the definition of “health care providers” for purposes of medical malpractice lawsuits governed by ss. 766.201-766.212, F.S.

### **Medicaid Prescribed Drug Spending-Control Program**

Section 499.003(54), F.S., defines “wholesale distribution” as distribution of prescription drugs to people other than consumers or patients. It expressly excludes certain activities, which effectively excludes these activities from wholesale drug distribution regulation.

One such excluded activity is the sale, purchase, trade or transfer of prescription drugs from or for entities able to purchase drugs at discount prices pursuant to the federal “340B” program. The 340B program limits the cost of certain drugs to certain federal grantees, federally-qualified health center look-alikes and qualified disproportionate share hospitals.<sup>29</sup> To qualify for exclusion from state wholesale distribution regulation, s. 499.003(54)(a)4.d., F.S., requires such entities to maintain separate inventories for drugs purchased under the 340B program and other drugs.

Under federal statute, 340B purchased drugs must be billed to Medicaid at actual acquisition cost. The Medicaid agency must then carve these claims out of the rebate pool so that state Medicaid programs can collect federal rebates on the non-340B purchased drugs. Collection of rebates requires the addition of national drug code (NDC) numbers.<sup>30</sup> The requirement for an NDC number on a claim means that the State Medicaid program must reject claims that lack NDC numbers.<sup>31</sup>

The bill amends s. 409.912(39)(a), F.S., stipulating that a claim billed as a 340B prescribed medication must :

- Meet the requirements of the Deficit Reduction Act of 2005;
- Meet the requirements of the federal 340B program; and
- Contain a national drug code.

If a claim does not meet all of these requirements, the claim will be denied by the state Medicaid program.

The bill also amends s. 499.003(54)(a)4.d, F.S., to remove the requirement that participants of the 340B program maintain separate inventories for drugs purchased under the 340B program and other drugs.

<sup>29</sup> See, Introduction to 340B Drug Pricing Program, U.S. Department of Health and Human Services, Health Resources and Services Administration, available at <http://www.hrsa.gov/opa/introduction.htm> (last viewed February 14, 2011).

<sup>30</sup> Drug products are identified and reported using a national drug code: a unique, three-segment number, which is a universal product identifier for human drugs.

<sup>31</sup> AHCA, *Staff Analysis and Economic Impact, House Bill Number 119* (February 7, 2011).

## Statutory Revisions

The bill updates the name of The Joint Commission, formerly known as the Joint Commission of the Accreditation of Healthcare Organizations, and the Commission on Accreditation on Rehabilitation Facilities, formerly known as CARF - the Rehabilitation Accreditation Commission.

The bill deletes definitions for and references to private review agents and utilization review in s. 395.002, F.S., to conform to the repeal made in chapter 2009-223, L.O.F. The bill repeals unused or unnecessary definitions, including definitions for “department” and “agency”.

The bill makes technical corrections and repeals requested by the Division of Statutory Revision, such as repealing obsolete dates, amending cross-references, and updating the reference to an obsolete rule.

### B. SECTION DIRECTORY:

- Section 1:** Amends s. 83.42, F.S., relating to exclusions from application of part.
- Section 2:** Amends s. 112.0455, F.S., relating to the Drug-Free Workplace Act.
- Section 3:** Amends s. 154.11, F.S., relating to powers of the board of trustees.
- Section 4:** Amends s. 318.21, F.S., relating to the disposition of civil penalties by county courts.
- Section 5:** Repeals s. 383.325, F.S., relating to inspection reports.
- Section 6:** Amends s. 394.4787, F.S., relating to specialty psychiatric hospitals.
- Section 7:** Amends s. 394.741, F.S., relating to accreditation requirements for providers of behavioral health care services.
- Section 8:** Amends s. 395.002, F.S., relating to accrediting organizations and specialty hospitals.
- Section 9:** Amends s. 395.003, F.S., relating to licensure; denial suspension, and revocation.
- Section 10:** Amends s. 395.0161, F.S., relating to licensure inspection.
- Section 11:** Amends s. 395.0193, F.S., relating to licensed facilities; peer review; disciplinary powers; agency or partnership with physicians.
- Section 12:** Amends s. 395.1023, F.S., relating to child abuse and neglect cases.
- Section 13:** Amends s. 395.1041, F.S., relating to access to emergency services and care.
- Section 14:** Repeals s. 395.1046, F.S., relating to complaint investigation procedures.
- Section 15:** Amends s. 395.1055, F.S., relating to rules and enforcement.
- Section 16:** Amends s. 395.10972, F.S., relating to the Health Care Risk Manager Advisory Council.
- Section 17:** Amends s. 395.2050, F.S., relating to routine inquiry for organ and tissue donation.
- Section 18:** Amends s. 395.3036, F.S., relating to confidentiality of records and meetings of corporations that lease public hospitals or other public health care facilities.
- Section 19:** Repeals s. 395.3037, F.S., relating to definitions of “department” and “agency”.
- Section 20:** Amends s. 395.3038, F.S., relating to state-listed primary stroke centers and comprehensive stroke centers, and notification of hospitals.
- Section 21:** Amends s. 395.4025, F.S., relating to trauma center selection, quality assurance, and records.
- Section 22:** Amends s. 395.602, F.S., relating to rural hospitals.
- Section 23:** Amends s. 400.021, F.S., relating to geriatric outpatient clinics.
- Section 24:** Amends s. 400.0239, F.S., relating to the quality of long-term care facility improvement trust fund.
- Section 25:** Amends s. 400.0255, F.S., relating to resident transfer or discharge.
- Section 26:** Amends s. 400.063, F.S., relating to resident protection.
- Section 27:** Amends s. 400.071, F.S., relating to applications for licensure.
- Section 28:** Amends s. 400.0712, F.S., relating to applications for inactive licenses.
- Section 29:** Amends s. 400.111, F.S., relating to disclosure of controlling interest.
- Section 30:** Amends s. 400.1183, F.S., relating to resident grievance procedures.
- Section 31:** Repeals s. 400.141, F.S., relating to administration and management of nursing home facilities.

- Section 32:** Amends s. 400.142, F.S., relating to emergency medication kits and orders not to resuscitate.
- Section 33:** Repeals s. 400.145, F.S., relating to records of care and treatment of residents; copies to be furnished.
- Section 34:** Amends s. 400.147, F.S., relating to internal risk management and the quality assurance program.
- Section 35:** Repeals s. 400.148, F.S., relating to the Medicaid “Up-or-Out” quality of care contract management program.
- Section 36:** Amends s. 400.179, F.S., relating to liability for Medicaid underpayments and overpayments.
- Section 37:** Amends s. 400.19, F.S., relating to right of entry and inspection.
- Section 38:** Amends s. 400.23, F.S., relating to rules, evaluation and deficiencies and licensure status.
- Section 39:** Amends s. 400.275, F.S., relating to agency duties.
- Section 40:** Amends s. 400.462, F.S., relating to home health agency remuneration.
- Section 41:** Amends s. 400.484, F.S., relating to right of inspection, violation and fines.
- Section 42:** Amends s. 400.506, F.S., relating to licensure of nurse registries; requirements; penalties.
- Section 43:** Amends s. 400.509, F.S., relating to registration of particular service providers exempt from licensure.
- Section 44:** Amends s. 400.606, F.S., relating to license application, renewal, conditional license or permits and certificates of need.
- Section 45:** Amends s. 400.607, F.S., relating to denial, suspension and revocation of a license; emergency actions and imposition of administrative fines.
- Section 46:** Amends s. 400.915, F.S., relating to construction and renovation requirements.
- Section 47:** Amends s. 400.925, F.S., relating to accrediting organizations.
- Section 48:** Amends s. 400.931, F.S., relating to application for licensure.
- Section 49:** Amends s. 400.932, F.S., relating to administrative penalties.
- Section 50:** Amends s. 400.967, F.S., relating to rules and classification of violations.
- Section 51:** Amends s. 400.9905, F.S., relating to clinics and portable health service or equipment providers.
- Section 52:** Amends s. 400.991, F.S., relating to license requirements, background screenings and prohibitions.
- Section 53:** Amends s. 400.9935, F.S., relating to clinic responsibilities.
- Section 54:** Amends s. 408.033, F.S., relating to local and state health planning.
- Section 55:** Amends s. 408.034, F.S., relating to agency duties and responsibilities.
- Section 56:** Amends s. 408.036, F.S., relating to projects subject to review and exemption.
- Section 57:** Amends s. 408.037, F.S., relating to application content.
- Section 58:** Amends s. 408.043, F.S., relating to special provisions for Hospice applications for certificates of need.
- Section 59:** Amends s. 408.05, F.S., relating to the Florida Center for Health Information and Policy Analysis.
- Section 60:** Amends s. 408.061, F.S., relating to data collection; uniform systems of financial reporting; information relating to physician charges; confidential information; immunity.
- Section 61:** Amends s. 408.07, F.S., relating to rural hospitals.
- Section 62:** Amends s. 408.10, F.S., relating to consumer complaints.
- Section 63:** Amends s. 408.802, F.S., relating to applicability.
- Section 64:** Amends s. 408.804, F.S., relating to displaying of a license.
- Section 65:** Amends s. 408.806, F.S., relating to the license application process.
- Section 66:** Amends s. 408.8065, F.S., relating to additional licensure requirements for home health agencies, home medical equipment providers, and health care clinics.
- Section 67:** Amends s. 408.809, F.S., relating to background screening; prohibited offenses.
- Section 68:** Amends s. 408.810, F.S., relating to minimum licensure requirements.
- Section 69:** Amends s. 408.813, F.S., relating to administrative fines and violations.
- Section 70:** Amends s. 408.815, F.S., relating to license or application denial and revocation.
- Section 71:** Amends s. 409.91196, F.S., relating to supplemental rebate agreements and public records and public meetings exemption.
- Section 72:** Amends s. 409.912, F.S., relating to cost-effective purchasing of health care.
- Section 73:** Amends s. 429.07, F.S., relating to license requirements, fees and inspections.

- Section 74:** Amends s. 429.11, F.S., relating to initial applications for licensure.
- Section 75:** Amends s. 429.12, F.S., relating to sale or transfer of ownership of a facility.
- Section 76:** Amends s. 429.14, F.S., relating to administrative penalties.
- Section 77:** Amends s. 429.17, F.S., relating to license expiration, renewal and conditional licenses.
- Section 78:** Amends s. 429.195, F.S., relating to prohibited rebates for assisted living facilities.
- Section 79:** Amends s. 429.23, F.S., relating to the internal risk management and quality assurance program.
- Section 80:** Amends s. 429.255, F.S., relating to the use of personnel and emergency care.
- Section 81:** Amends s. 429.28, F.S., relating to the resident bill of rights.
- Section 82:** Amends s. 429.41, F.S., relating to rules establishing standards.
- Section 83:** Amends s. 429.53, F.S., relating to consultation by the agency.
- Section 84:** Amends s. 429.71, F.S., relating to classification of violations and administrative fines.
- Section 85:** Amends s. 429.915, F.S., relating to conditional licensure.
- Section 86:** Amends s. 430.80, F.S., relating to the implementation of a teaching nursing home pilot project.
- Section 87:** Amends s. 440.102, F.S., relating to drug-free workplace program requirements.
- Section 88:** Amends s. 440.13, F.S., relating to medical services and supplies; penalty for violations and limitations.
- Section 89:** Amends s. 456.053, F.S., relating to financial arrangements between referring health care providers and providers of health care services.
- Section 90:** Amends s. 483.035, F.S., relating to clinical laboratories operated by practitioners for exclusive use.
- Section 91:** Amends s. 483.051, F.S., relating to powers and duties of the agency.
- Section 92:** Amends s. 483.294, F.S., relating to the inspection of centers.
- Section 93:** Amends s. 499.003, F.S., relating to wholesale distribution of prescription drugs.
- Section 94:** Amends s. 627.645, F.S., relating to the restriction of denied health insurance claims.
- Section 95:** Amends s. 627.668, F.S., relating to optional coverage for mental and nervous disorders.
- Section 96:** Amends s. 627.669, F.S., relating to optional coverage requirement for substance abuse impaired persons.
- Section 97:** Amends s. 627.736, F.S., relating to required personal injury protection benefits.
- Section 98:** Amends s. 633.081, F.S., relating to the inspection of buildings and equipment; orders; fire safety inspection training requirements; certification and disciplinary action.
- Section 99:** Amends s. 641.495, F.S., relating to the requirements for issuance and maintenance of certificates.
- Section 100:** Amends s. 651.118, F.S., relating to the Agency for Health Care Administration; certificates of need; sheltered beds; and community beds.
- Section 101:** Amends s. 766.1015, F.S., relating to civil immunity for members of or consultants to certain boards, committees, or other entities.
- Section 102:** Amends s. 766.202, F.S., relating to health care providers.
- Section 103:** Amends s. 817.505, F.S., relating to prohibited patient brokering.
- Section 104:** Provides chapter law relating to assisted living facility licensure fees.
- Section 105:** Provides an effective date of July 1, 2011.

## II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

### A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

The bill is expected to result in annual savings of over \$131,000 in the Health Care Trust Fund for the state. (See fiscal comments.)

### B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill is expected to result in combined savings of over \$1 million for providers and applicants.<sup>32</sup> The following provisions are expected to save providers an estimated \$335,000 annually:

- Allowing more practitioner types to staff nursing home outpatient clinics;
- Streamlining nursing home rules related to medical records;
- Establishing standards for respite services in nursing homes and staffing standards for pediatric residents.

Modifying certificate of need requirements to allow audited financial statements of an applicant's parent corporation is expected to result in savings of \$703,000 annually for applicants.

Assisted living facility provider fees will be increased to offset the elimination of the LNS license fee and to reflect the Consumer Price Index adjustment, as authorized in s. 408.805, F.S. This will result in a neutral net impact to the industry as a whole; the per-resident fees will go up for all licensees and LNS licensees will no longer have a LNS license fee. (See Fiscal Comments.)

D. FISCAL COMMENTS:

**Health Care Assessment Fee**

The bill consolidates billing for the health care assessment fee and inspection fees so they are all paid at the time of licensure, which voids the cost of providing a separate invoice. This provision is expected to save the state \$75,000 annually.<sup>33</sup>

**License Renewal Notices**

AHCA estimates that the bill will result in savings of \$56,000 in administrative costs annually in the Health Care Trust Fund through the discontinuation of certified mail service to deliver license renewal notices.<sup>34</sup>

**License Display**

The bill grants AHCA the authority to impose a fine of up to \$1,000 per day when a licensee displays an altered, defaced or falsified license. However, AHCA reports that it does not anticipate that this fine will generate any additional revenues, but instead act as a deterrent.<sup>35</sup>

**Assisted Living Facility Limited Nursing Specialty License**

Fees

The bill increases the biennial license fee for standard ALFs to offset the elimination of the LNS specialty licensure fees. ALF fees are adjusted each year by the Consumer Price Index, as authorized by s. 408.805, F.S. AHCA reports that the adjustment in fees for ALF licensure has a neutral fiscal impact on fee collections.<sup>36</sup>

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<sup>32</sup> AHCA email dated March 14, 2011 on file with Subcommittee staff.

<sup>33</sup> Id.

<sup>34</sup> Id.

<sup>35</sup> AHCA email dated February 8, 2011 on file with Subcommittee staff.

<sup>36</sup> AHCA, *Staff Analysis and Economic Impact, House Bill Number 119* (February 7, 2011).



Based on the number of LNS specialty licenses (1,038) and beds (26,602) in January 2011, the LNS specialty license is projected to generate approximately \$586,762 in revenues biennially. The revenues are calculated as follows:

\$309 per license plus \$10 per bed = \$586,762 based on current numbers  
(\$320,742 + \$266,020) = \$586,762

The additional fee increase in the bill is intended to offset the loss in revenues from the elimination of the specialty license fee. The fee increase is calculated as follows:

\$586,762 divided by 66,666 beds = \$8.80/bed  
(82,176 total beds less 15,510 OSS)

The proposed fee is calculated as follows:

\$62 per bed + \$8.80 per bed = \$70.80 per bed, however, numbers are typically rounded up to avoid errors. The new per bed fee for standard ALF licensure is \$71.

### Monitoring

The bill replaces the specialty license monitoring for ECC and LNS licensees with monitoring based on the citation of class I or II deficiencies in the last two years. As of February 20, 2011, there were 242 ALFs that had been cited for a Class I or II deficiency in the prior two years. Assuming an average monitoring of three times per year for these facilities, AHCA expects to make 726 monitor visits per year. In comparison, AHCA conducted a total of 667 monitoring visits during Fiscal Year 2009-2010. The monitoring workload of LNS and ECC licensees lost as a result of the bill will be replaced by the monitoring workload of ALFs with a class I or II deficiency in the last two years.<sup>37</sup>

## III. COMMENTS

### A. CONSTITUTIONAL ISSUES:

#### 1. Applicability of Municipality/County Mandates Provision:

This bill does not appear to require counties or municipalities to take an action requiring the expenditure of funds, reduce the authority that counties or municipalities have to raise revenue in the aggregate, nor reduce the percentage of state tax shared with counties or municipalities.

#### 2. Other:

None.

### B. RULE-MAKING AUTHORITY:

The bill provides sufficient rule-making authority to AHCA, DOH, and DOEA to implement the provisions of the bill.

### C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

## IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

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<sup>37</sup> AHCA email dated February 22, 2011 on file with Subcommittee staff.

On March 15, 2011, the Health and Human Services Quality Subcommittee adopted a strike-all amendment. The amendment:

- Amends s. 83.42, F.S., to reiterate the applicable law for nursing home resident transfer;
- Removes s. 381.0072, F.S., related to nursing home kitchen inspections, from the bill;
- Amends s. 318.21, F.S. to reverse deletion of inclusion of Medicaid recipients with brain injuries in the bill;
- Removes the requirement in s. 395.0161, F.S., that hospital inspection fees be paid at the time of inspection, providing for collection with the license renewal fee;
- Removes the requirement in s. 400.021(16), F.S., that a nurse sign the care plan of a nursing home resident;
- Removes the requirement in s. 400.071, F.S., that nursing homes submit copies of civil judgments to AHCA;
- Amends s. 400.141, F.S., to revise requirements related to AHCA encouragement of nursing homes to provide additional services;
- Amends s. 400.145, F.S., to delete medical record copying provisions redundant to federal law;
- Removes the requirement in s. 400.147, F.S., that nursing homes submit a report to AHCA within one business day of receiving an adverse incident report;
- Amends s. 400.23, F.S., to revise AHCA rule-making authority related to nursing homes which serve only persons under 21 years of age;
- Amends s. 400.506, F.S., to broaden an exemption from penalties for referral remuneration by nurse registries which bill the Medicaid program;
- Amends s. 400.509, F.S., to exempt from licensure as home health agencies organizations which provide only companion services under contract with the Agency for Persons with Disabilities;
- Amends s. 400.931, F.S., to require out-of-state home medical equipment providers to be accredited in order to obtain a license in Florida;
- Amends s. 408.033, F.S., to specify the time of payment of local health council assessment fees;
- Removes the requirement of ss. 112.0455 and 440.102, F.S., that laboratories submit a report of data on employment-based drug testing;
- Removes the requirement of s. 408.036, F.S., for AHCA to submit an annual Certificate of Need exemption report to the Legislature;
- Amends s. 408.037, F.S. to allow Certificate of Need applicants to submit audited financial statements of parent corporations if applicant statements do not exist;
- Amends s. 408.8065, F.S., to make a technical correction to accounting terms;
- Amends s. 408.809, F.S., to create a schedule for criminal background screening;
- Removes s. 408.810(6)(a), F.S., related to nursing home licensure, from the bill;
- Removes s. 409.91255, F.S., related to Federally Qualified Health Centers, from the bill;
- Amends s. 429.07, F.S., to amend per bed fees for assisted living facilities;
- Amends s. 429.07, F.S. to amend the time of AHCA consultation with the ombudsman council;
- Amends s. 429.07, F.S. to amend the requirements for nurse participation in nursing home licensure monitoring;
- Removes s. 429.14(1), F.S., related to nursing home disciplinary actions, from the bill;
- Removes s. 429.19(7), F.S., related nursing home monitoring fees, from the bill;
- Removes s. 429.911(2)(a), F.S., related to adult day care centers, from the bill;
- Removes the requirement of s. 440.102, F.S., that workers' compensation program laboratories submit a report of data on employment-based drug testing;
- Amends s. 483.035, F.S., to add advanced registered nurse practitioners to the list of health care practitioners which can operate clinical laboratories for exclusive use; and
- Amends s. 483.051, F.S., to define "non-waived" laboratories and clarify that biennial AHCA licensure applies to such laboratories.

The bill was reported favorably as a Committee Substitute. This analysis reflects the Committee Substitute.

On April 20, 2011, the Health and Human Services Committee adopted a strike-all amendment, and two amendments to the amendment. The amendments:

- Amend s. 395.1055, F.S., to require hospital housekeeping and sanitation staff to wear masks and gloves while cleaning patient rooms, and disinfect environmental surfaces in patient rooms in accordance with the time restrictions on the label of the disinfectant used;
- Amend s. 395.4025, F.S., to provide two, six-month extensions to hospitals who apply to become trauma centers under certain circumstances;
- Amend s. 400.021, F.S., to allow licensed practical nurses to provide patient care in a geriatric outpatient clinic under the direct supervision of a physician assistant;
- Amend s. 400.147, F.S., to remove the requirement that nursing homes must notify AHCA within one business day after receipt of an incident report;
- Amend s. 400.462, F.S., to revise the definition of “remuneration” to allow home health agencies to distribute items with a value of up to \$15;
- Amend s. 400.506, F.S., to broaden the exemption to nurse registry marketing restrictions by exempting nurse registries that bill Medicaid, but not Medicare;
- Amend s. 408.815, F.S., to allow AHCA to consider certain mitigating circumstances before licensure applications are denied due to previous adverse actions;
- Amend s. 409.912, F.S., to remove the requirement that prescription drugs billed as 340B prescribed medication must be billed at the actual acquisition cost;
- Amend s. 400.9905, F.S., to exempt from licensure as clinics organizations that employ 50 or more physicians where the billing for medical services is under a single tax identification number;
- Removes bill changes to restore current ALF license fee language and adds chapter law language to clarify the redistribution of ALF licensure fees;
- Amend s. 429.195, F.S., to provide that certain activities are not to be considered prohibited patient brokering by ALFs and are not punishable as third degree felonies;
- Amend s. 456.053, F.S., to revise the definition of “group practice” to require group practices that include radiation therapy services to provide a full range of such services;
- Amend s. 499.003, F.S., to remove the requirement that government agency contractors must maintain a separate inventory for 340B drugs in order not to be considered a wholesale distributor;
- Remove s. 626.9541, F.S., related to wellness programs, from the bill; and
- Amend s. 817.505, F.S., to provide that certain activities are not prohibited patient brokering and are not punishable as third degree felonies.

The bill was reported favorably as a Committee Substitute. This analysis reflects the Committee Substitute.