HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/CS/CS/HB 1143 Reduction and Simplification of Health Care Provider Regulation

SPONSOR(S): Health & Family Services Policy Council; Health Care Appropriations Committee; Health Care Regulation Policy Committee; Hudson

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

	REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1)	Health Care Regulation Policy Committee	14 Y, 0 N, As CS	Calamas	Calamas
2)	Health Care Appropriations Committee	11 Y, 0 N, As CS	Pridgeon	Pridgeon
3)	Health & Family Services Policy Council	14 Y, 1 N, As CS	Calamas	Gormley
4)				
5)				

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 and allows a fee to be charged for monitoring visits. 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 precludes the collection of Lease Alternative Bond Fund (Fund) payments by certain nursing homes when the Fund exceeds $25 million based on certain calculations. The bill limits the frequency of food safety inspections by the Department of Health (DOH) and 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 exempt from licensure 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, and entities owned or controlled, 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 health care practitioners.
- 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 amends regulation of prescription drug wholesale distribution by DOH. It eliminates the requirement for exempt entities to maintain separate inventories for drugs purchased under the federal 340B discount drug program and other drugs, but clarifies that claims billed to the state Medicaid program must meet specific criteria or payment will be denied. The bill exempts sealed medical convenience kits meeting certain specifications from pedigree paper requirements.

The bill adds orthotic, pedorthic and prosthetic licensees to the list of “health care providers” for purposes of medical malpractice lawsuits.

The bill appears to have a positive fiscal impact on AHCA. See Fiscal Comments section.

The bill has an effective date of July 1, 2010.

HOUSE PRINCIPLES

Members are encouraged to evaluate proposed legislation in light of the following guiding principles of the House of Representatives

- Balance the state budget.
- Create a legal and regulatory environment that fosters economic growth and job creation.
- Lower the tax burden on families and businesses.
- Reverse or restrain the growth of government.
- Promote public safety.
- Promote educational accountability, excellence, and choice.
- Foster respect for the family and for innocent human life.
- Protect Florida's natural beauty.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Health Care Licensing Procedures Act (Act)

The 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.).
- Multiphasic health testing centers (Pt. II of Ch. 483, F.S.).
- Organ, tissue, and eye procurement organizations (Pt. V of Ch. 765, F.S.).

Providers are regulated under individual licensing statutes and the 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.

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 $55,700 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 are 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 intermediate care facilities for the developmentally disabled, the amount of fines for Class I, II, and II 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.

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. If notice is not received early in the process, finding alternative resident placement can become difficult and create a hardship for clients.

The bill amends s. 408.806, 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. If the property upon which a licensed provider operates is encumbered by a mortgage or is leased, the bill requires the licensee to notify the mortgage holder or landlord that the property will provide services that require licensure and instruct the mortgage holder or landlord to notify AHCA if action is initiated against the licensee, such as eviction or foreclosure.

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.

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.

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. However, other authorizing statutes are silent on billing standards.

For calendar year 2009, AHCA received 693 complaints that alleged billing-related issues. Of those, 269 were for providers that have billing standards in their licensure statutes. The remaining 424 were related to billing issues where 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 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 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.

Nursing Home Licensure

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

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.

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 registered nurses or advanced registered nurse practitioners.

Nursing Home Records

Nursing home medical records regulations exist under both state law and federal regulations. Section 400.141(1) (j), F.S., requires licensees to maintain full patient records. Rule 59A-4.118, F.A.C., also 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 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. 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 specifies that a facility must maintain medical records in accordance with accepted professional standards and practices. AHCA reports that this modification in language will allow the repeal of rules related to the credentials of medical records personnel. In addition, the bill removes the requirement that nursing homes report grievance information at the time of relicensure. The bill retains the requirement for nursing homes to maintain all grievance records and makes them available for inspection by AHCA.

Nursing Home Staffing Ratios

Nursing homes must comply with staff-to-resident ratios requirements. Under s. 400.141(1) (o), F.S., 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 2009.

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.

Section 400.23(5), F.S., provides that AHCA, in collaboration with the Division of Children's Medical Services within DOH, is required to adopt rules for minimum standards of care for persons under 21 years of age who reside in nursing home facilities. To comply with this statutory requirements AHCA drafted rule 59A-4.1295, F.A.C., providing standards of care for persons 0-25 years of age. AHCA has tried several times to adopt the staffing ratio for nursing home facilities that serve pediatric patients, but have been unsuccessful due to delays in the process. In addition, AHCA may have insufficient authority to adopt a lower nursing home staffing ratio specific to pediatrics, because the rule technically conflicts with the standards in s. 400.23(3), which requires a higher level of certified nursing assistants for all nursing home facilities.

The bill codifies the proposed AHCA rule into statute. The bill provides minimum staffing requirements for nursing home facilities that serve individuals less than 21 years of age:

- For individuals 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 who are fragile, each nursing home facility 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.

Nursing Home Do Not Resuscitate Orders

Section 400.142, F.S., requires AHCA to develop rules relating to implementation of Do Not Resuscitate Orders for nursing home residents. According to AHCA, draft rules have been developed but are not final. Criteria for Do Not Resuscitate Orders are found in s. 401.45, F.S.

The bill removes the requirement for AHCA to promulgate rules related to the implementation of Do Not Resuscitate Orders for nursing home residents. The statutory requirements for such orders in s. 401.45, F.S., are clear and do not require rule implementation.

Nursing Home Property Statements

Section 400.162, F.S., requires nursing homes to provide quarterly property statements to residents when they hold property or funds for a resident.

The bill maintains the requirement for a quarterly property statement for funds, but amends the requirement for other types of property. Instead of furnishing quarterly property statements, nursing homes must provide a property statement annually and within 7 calendar days after a request.

Nursing Home Lease Bond Alternative Fund (Fund)

Nursing homes that are leased and choose to participate in the Medicaid program must either post a bond or pay into a Fund annually pursuant to s. 400.179, F.S. Most leased nursing homes choose to pay into the Fund. Of the 674 licensed nursing homes in Florida, 519 are leased and participate in the Medicaid program. Of those, 505 nursing homes pay into the Fund and 14 post a leased surety bond. Chapter 2009-82 provided a reprieve from payments for Medicaid leased nursing homes for one year. The reprieve expires July 1, 2010. The bill specified that all nursing facilities licensees operating a leased facility shall not be required to submit the nonrefundable 1 percent lease bond fee or be required to provide proof of lease bond.

This bill creates an automatic mechanism to provide relief from payments into the Fund when receipts minus payments for nursing homes overpayments exceed $25 million. This bill protects nursing homes from having to make additional payments into the Fund if the balance has been reduced as a result of transfers pursuant to s. 215.32 (2) (b) 4. a, F.S. The Fund would be reviewed annually to determine if payments during the next year will be required.

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 Litigation Notices

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. Information is reported in aggregate for all facilities.

The bill eliminates the requirement to report notices of intent to litigate and civil complaints.

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 care giver.

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 Kitchen Inspections

DOH operates a food safety program pursuant to s. DOH issues food establishment licenses or permits, conducts food safety inspections and enforces regulations through fines and other disciplinary actions.[1] DOH licenses facilities that serve high-risk populations such as hospitals, nursing homes, group care facilities, child care facilities, detention centers, and schools.[2] DOH policy is to inspect nursing homes four times per year.[3]

In addition to DOH food safety standards, nursing homes licensed and regulated by AHCA are subject to federal food safety standards which require a kitchen inspection by a surveyor who has been trained, passed the Surveyor Minimum Qualifications Test and is qualified to conduct a Quality Indicator Survey Process.[4]

The bill limits kitchen inspections of nursing homes by DOH to twice a year. DOH may make additional inspections in response to a complaint. The bill requires DOH to coordinate inspection timing with AHCA, such that a DOH inspection occurs at least 60 days after an AHCA inspection.

Nursing Home Fire Inspections

The Florida Fire Prevention Code is established in ch. 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

[1] Office of Program Policy Analysis & Government Accountability, State Food Safety Programs Should Improve Performance and Financial Self-Sufficiency, Report No. 08-67 (December 2008).
[2] Section 381.0072, F.S.
[3] *Supra*, note 1 at 7.
[4] Email correspondence with AHCA staff on file with the Health Care Regulation Policy Committee (March 16, 2010).

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 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.

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) (l), 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 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.

Health Care Clinic Licensure

Part X of ch. 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[5] requires motor vehicle owners to maintain $10,000 of personal injury protection (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…".[6] 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 2 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

[5] 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.
[6] Section 400.9905(4), F.S.

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 ch. 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.

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; and
- Orthotic or prosthetic facilities owned by publicly-traded corporations.

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.

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. 499.991(4) 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.

Assisted Living Facility Licensure

Currently, an ALF that wishes to provide certain nursing services must also have a LNS 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 February 2010, there are a total of 2,853 ALFs with standard licenses with a total of 81,038 beds. Of the 2,853 ALFs in Florida, 995 have a LNS specialty license and 313 have an ECC specialty license. Of those 995 ALFs, 77 have both a LNS and an ECC license.

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 (1197) of ALFs are currently enrolled in this system.

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 increases ALF licensure fees to compensate for the loss of LNS licensure fees and maintain the licensure program. The bill authorizes $356 for a standard license fee, $67.50 per private pay bed and $18,000 for a total fee cap. The bill repeals the requirement to monitor extended congregate care facilities, and replaces it with a requirement to monitor based upon citation of serious violations (Class I or Class II) in any ALF. The bill allows AHCA to charge a fee for monitoring visits.

The bill modifies AHCA's consultation duties and 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.

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.

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 spinal cord injury and who are technologically and respiratory dependent.

Pilot Projects

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.

Reports

Section 400.195, F.S., required AHCA to provide a semi-annual report on nursing homes from December 2002 through June 2005 as a tool to provide information about litigation in Florida nursing homes. The report included demographic and regulatory information about nursing homes in Florida and aggregate numbers of notices of intent to litigate and civil complaints filed with the clerks of courts against Florida nursing homes. The reporting requirement ended June 2005. The statutory obligation to publish this report has been met and by law expired on June 30, 2005.

Section 409.221(4)(k), F.S., required AHCA, DOEA, and the Agency for Persons with Disabilities (APD) to provide an annual update and to provide recommendation for improvement on the Consumer Directed Care Plus (CDC+) program. In March 2008, the CDC program was approved to be under the 1915(j) self directed option as a Medicaid state plan amendment instead of an 1115 Research and Demonstrative waiver. The 1915(j) state plan amendment requires annual and three (3) year comprehensive reporting to the federal Centers for Medicare and Medicaid Services (CMS). The report to CMS communicates current status of the CDC program, data on CDC enrollment, demographics, consumer satisfaction, and cost effectiveness. This federal report is required by CMS to be available for public review.

The Assisted Living Facility Extended Congregate Care Report mandated in s. 429.07, F.S., is produced by the DOEA. This report requires an annual description of assisted living facilities with an ECC specialty license including the number of beds, resident characteristics, services, availability, deficiencies, admission sources, and recommendations for changes to the ECC license. The requirement to publish this report was created when the ECC licensure type was implemented to monitor effectiveness. ECC facilities must report information to the DOEA for this report. According to AHCA, the need for this report has diminished.

The bill repeals these three reporting requirements.

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 ch. 395;
- Birth centers licensed under ch. 383;
- Physicians licensed under ch. 458 or 459;
- Chiropractors licensed under ch. 460;
- Podiatrists licensed under ch. 461;
- Naturopaths licensed under ch. 462;
- Optometrists licensed under ch. 463;
- Nurses licensed under pt. I of ch. 464;
- Dentists, dental hygienists and dental labs licensed under ch. 466;
- Midwives licensed under ch. 467; or
- Physical therapists licensed under ch. 486;
- Clinical laboratories licensed under ch. 483;
- Health maintenance organization certified under pt. I of ch. 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 pt. XIV of ch. 468 to the definition of "health care providers" for purposes of medical malpractice lawsuits governed by ss. 766.201-766.212, F.S.

Regulation of Drugs, Devices and Cosmetics

Part I of Chapter 499 requires DOH to regulate drugs, devices, and cosmetics. A significant majority of the regulations relate to the distribution of prescription drugs into and within Florida. In particular, the regulations require licensure of various entities in the distribution chain, including prescription drug wholesale distributors. Among many other provisions, the chapter provides for:

- Criminal prohibitions against the distribution of contraband and misbranded prescription drugs.
- Establishment of permits for distributing drugs, devices, and cosmetics.
- Regulation of the wholesale distribution of prescription drugs, which includes pedigree papers to track the distribution chain of possession.
- Regulation of the provision of drug samples.
- Establishment of numerous enforcement avenues for DOH, including seizure and condemnation of drugs, devices, and cosmetics.

Section 499.01212, F.S., requires each person engaged in drug wholesale distribution to provide a pedigree paper to the person receiving the drug, for the purpose of tracking the distribution chain of possession, and specifies the format and content of the required pedigree papers. DOH is empowered to inspect wholesale distributor facilities and records, and seize drugs for violations of pedigree requirements. Section 499.01212, F.S., section also provides for exceptions to the pedigree paper requirement for various entities and activities, including distribution:

- By the manufacturer or by a third party logistics provider performing distribution for a manufacturer;
- By a freight forwarder within the authority of a freight forwarder permit;
- By a limited prescription drug veterinary wholesale distributor to a veterinarian;
- Of a compressed medical gas;

- Of a veterinary prescription drug;
- Of a drop shipment;
- By a warehouse within an affiliated group to a warehouse or retail pharmacy within its affiliated group; and
- As repackaging by a repackager solely for distribution to its affiliated group members for exclusive distribution to and among retail pharmacies that are members of the affiliated group to which the repackager is a member.

Section 499.003(53), 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.[7] To qualify for exclusion from state wholesale distribution regulation, s. 499.003(53)(a)4.d., F.S., requires such entities to maintain separate inventories for drugs purchased under the 340B program and other drugs.

The bill amends s. 499.003(53), F.S., to eliminate the requirement that purchasers of prescription drugs under the federal 340B program separate the 340B inventory from other inventory. In addition, 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;
- Contain a national drug code[8]; and
- Be billed at the actual acquisition cost.

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

The bill amends s. 499.01212(3), F.S., to exempts sealed medical convenience kits meeting certain specifications from pedigree paper requirements.

Emergency Related Products

Section 381.00315, F.S., provides the authority for the State Health Officer to declare a public health emergency[9] which continues until the threat or danger has been dealt with to the extent that the emergency conditions no longer exist and the State Health Officer terminates the declaration. A declaration may not continue for longer than 60 days unless the Governor concurs in the renewal of the declaration. The State Health Officer, upon declaration of a public health emergency, may take actions the following actions necessary to protect the public health, but not limited to:

- Directing manufacturers of prescription drugs or over-the-counter drugs to give priority to the shipment of specified drugs to pharmacies and health care providers. The State Health Officer must identify the drugs to be shipped. Manufacturers and wholesalers located in the state must respond to priority shipping directive before shipping the specified drugs.

- Directing pharmacists employed by the department to compound bulk prescription drugs and provide the bulk prescription drugs to physicians and nurses of county health departments or any authorized person for administration to individuals as part of a prophylactic or treatment regimen.

[7] *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 April 1, 2010).
[8] Drug products are identified and reported using a unique, three-segment number, which is a universal product identifier for human drugs.
[9] A public health emergency is any occurrence, or threat which results in substantial injury or harm to the public health from infectious disease, chemical agents, nuclear agents, biological toxins, or situations involving mass casualties or natural disasters. *See* s. 381.00315(1)(b), F.S.

- Temporarily reactivating an unencumbered inactive license to respond to a public health emergency, at the request of the following practitioners: physicians; physician assistants; licensed practical nurses, registered nurses, and advanced registered nurse practitioners; respiratory therapists; emergency medical technicians and paramedics. An inactive license that is reactivated returns to inactive status when the public health emergency ends or prior to the end of the public health emergency if the State Health Officer determines that the health care practitioner is no longer needed. Such licenses may only be reactivated for a period not to exceed 90 days.

- Ordering an individual to be examined, tested, vaccinated, treated, or quarantined for communicable diseases that have significant morbidity or mortality and present a severe danger to public health. Individuals, who are unable or unwilling to be examined, tested, vaccinated, or treated for reasons of health, religion, or conscience may be quarantined.

The bill authorizes DOH to accept funds provided by counties, municipalities, and other entities designated in the state emergency management plan for the purpose of participation in contacts and expend funds for the manufacture and delivery of licensable products used in response to a public health emergency. The bill provides that the funds are to be deposited into the Grants and Donations Trust Fund within DOH.

Statutory Revisions

The bill updates the name of the Statewide Advocacy Council, formerly known as The Human Rights Advocacy Committee, 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. 112.0455, F.S., relating to the Drug-Free Workplace Act.
Section 2: Amends s. 154.11, F.S., relating to powers of the board of trustees.
Section 3: Amends s. 318.21, F.S., relating to the disposition of civil penalties by county courts.
Section 4. Amends s. 381.00315, F.S., relating to public health advisories and public health emergencies.
Section 5: Amends s. 381.0072, F.S., relating to food service protection.
Section 6: Repeals s. 383.325, F.S., relating to inspection reports.
Section 7: Amends s. 394.4787, F.S., relating to specialty psychiatric hospitals.
Section 8: Amends s. 394.741, F.S., relating to accreditation requirements for providers of behavioral health care services.
Section 9: Amends s. 395.002, F.S., relating to accrediting organizations and specialty hospitals.
Section 10: Amends s. 395.003, F.S., relating to licensure; denial suspension, and revocation.
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. 395.602, F.S., relating to rural hospitals.
Section 22: Amends s. 400.021, F.S., relating to geriatric outpatient clinics.
Section 23: Amends s. 400.0239, F.S., relating to the quality of long-term care facility improvement trust fund.
Section 24: Amends s. 400.063, F.S., relating to resident protection.
Section 25: Amends s. 400.071, F.S., relating to applications for licensure.
Section 26: Amends s. 400.0712, F.S., relating to applications for inactive licenses.
Section 27: Amends s. 400.111, F.S., relating to disclosure of controlling interest.
Section 28: Amends s. 400.1183, F.S., relating to resident grievance procedures.
Section 29: Repeals s. 400.141, F.S., relating to administration and management of nursing home facilities.
Section 30: Amends s. 400.142, F.S., relating to emergency medication kits and orders not to resuscitate.
Section 31: Amends s. 400.147, F.S., relating to internal risk management and the quality assurance program.
Section 32: Repeals s. 400.148, F.S., relating to the Medicaid “Up-or-Out” quality of care contract management program.
Section 33: Amends s. 400.162, F.S., relating to property and personal affairs of residents.
Section 34: Amends s. 400.179, F.S., relating to liability for Medicaid underpayments and overpayments.
Section 35: Amends s. 400.19, F.S., relating to right of entry and inspection.
Section 36: Repeals s. 400.195, F.S., relating to agency reporting requirements.
Section 37: Amends s. 400.23, F.S., relating to rules, evaluation and deficiencies and licensure status.
Section 38: Amends s. 400.275, F.S., relating to agency duties.
Section 39: Amends s. 400.484, F.S., relating to right of inspection, violations and fines.
Section 40: Amends s. 400.606, F.S., relating to license application, renewal, conditional license or permits and certificates of need.
Section 41: Amends s. 400.607, F.S., relating to denial, suspension and revocation of a license; emergency actions and imposition of administrative fines.
Section 42: Amends s. 400.925, F.S., relating to accrediting organizations.
Section 43: Amends s. 400.931, F.S., relating to application for licensure.
Section 44: Amends s. 400.932, F.S., relating to administrative penalties.
Section 45: Amends s. 400.967, F.S., relating to rules and classification of violations.
Section 46: Amends s. 400.9905, F.S., relating to clinics and portable health service or equipment providers.
Section 47: Amends s. 400.991, F.S., relating to license requirements, background screenings and prohibitions.
Section 48: Amends s. 400.9935, F.S., relating to clinic responsibilities.
Section 49: Amends s. 408.034, F.S., relating to agency duties and responsibilities.
Section 50: Amends s. 408.036, F.S., relating to projects subject to review and exemptions.
Section 51: Amends s. 408.043, F.S., relating to special provisions.
Section 52: Amends s. 408.05, F.S., relating to the Florida Center for Health Information and Policy Analysis.
Section 53: Amends s. 408.061, F.S., relating to data collection; uniform systems of financial reporting; information relating to physician charges; confidential information; immunity.
Section 54: Amends s. 408.07, F.S., relating to rural hospitals.
Section 55: Amends s. 408.10, F.S., relating to consumer complaints.
Section 56: Amends s. 408.802, F.S., relating to applicability.
Section 57: Amends s. 408.804, F.S., relating to displaying of a license.
Section 58: Amends s. 408.806, F.S., relating to the license application process.
Section 59: Amends s. 408.810, F.S., relating to minimum licensure requirements.
Section 60: Amends s. 408.813, F.S., relating to administrative fines and violations.
Section 61: Amends s. 408.815, F.S., relating to license or application denial and revocation.
Section 62: Amends s. 409.221, F.S., relating to the consumer-directed care program.

Section 63. Amends s. 409.91196, F.S., relating to supplemental rebate agreements and public records and public meetings exemption.
Section 64. Amends s. 409.912, F.S., relating to cost-effective purchasing of health care.
Section 65: Amends s. 429.07, F.S., relating to license requirements, fees and inspections.
Section 66: Amends s. 429.11, F.S., relating to initial applications for licensure.
Section 67: Amends s. 429.12, F.S., relating to the sale or transfer of ownership of a facility.
Section 68: Amends s. 429.14, F.S., relating to administrative penalties.
Section 69: Amends s. 429.17, F.S., relating to license expiration, renewal and conditional licenses.
Section 70: Amends s. 429.19, F.S., relating to violations and the imposition of administrative fines.
Section 71: Amends s. 429.23, F.S., relating to the internal risk management and quality assurance program.
Section 72: Amends s. 429.255, F.S., relating to the use of personnel and emergency care.
Section 73: Amends s. 429.28, F.S., relating to the resident bill of rights.
Section 74: Amends s. 429.35, F.S., relating to the maintenance of records and reports.
Section 75: Amends s. 429.41, F.S., relating to rules establishing standards.
Section 76: Amends s. 429.53, F.S., relating to consultation by the agency.
Section 77: Amends s. 429.54, F.S., relating to collection of information; local subsidy.
Section 78: Amends s. 429.71, F.S., relating to classification of violations and administrative fines.
Section 79: Amends s. 429.911, F.S., relating to the denial, suspension, or revocation of a license; emergency action; administrative fines; investigations and inspections.
Section 80: Amends s. 429.915, F.S., relating to conditional licensure.
Section 81: Amends s. 430.80, F.S., relating to the implementation of a teaching nursing home pilot project.
Section 82: Amends s. 440.13, F.S., relating to medical services and supplies; penalty for violations and limitations.
Section 83: Amends s. 483.294, F.S., relating to the inspection of centers.
Section 84: Amends s. 499.003, F.S., relating to wholesale distribution.
Section 85: Amends s. 499.01212, F.S., relating to pedigree paper.
Section 86: Amends s. 627.645, F.S., relating to the restriction of denied health insurance claims.
Section 87: Amends s. 627.668, F.S., relating to optional coverage for mental and nervous disorders.
Section 88: Amends s. 627.669, F.S., relating to optional coverage requirement for substance abuse impaired persons.
Section 89: Amends s. 627.736, F.S., relating to required personal injury protection benefits.
Section 90: 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 91: Amends s. 641.495, F.S., relating to the requirements for issuance and maintenance of certificates.
Section 92: Amends s. 651.118, F.S., relating to the Agency for Health Care Administration.
Section 93: Amends s. 766.1015, F.S., relating to civil immunity for members of or consultants to certain boards, committees, or other entities.
Section 94: Amends s. 766.202, F.S., relating to health care providers.
Section 95: Provides an effective date of July 1, 2010.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   See Fiscal Comments.

2. Expenditures:

   See Fiscal Comments.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill will save nursing home providers up to $4.2 million annually by providing relief from lease bond fund requirements if adequate Fund receipts exist.

Assisted living facility provider fees will be increased to offset the elimination of the LNS licensure fee. This will result in a neutral net impact to the industry. (See Fiscal Comments)

D. FISCAL COMMENTS:

License Renewal Notices

AHCA estimates that the bill will save approximately $55,700 in the Health Care Trust Fund annually in administrative costs through the discontinuation of certified mail service to deliver licensure renewal notices.

License Display

This 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.

Nursing Home Lease Bond Fund

The bill will save up to $1,264,448 ($486,307 in GR) annually in Medicaid expenditures for nursing home lease bond payments. Nursing home providers include the costs of the lease bond payments in their cost reports as allowable costs, which impacts Medicaid expenditures.

To date, AHCA has expended $10,466,138[10] from the Fund for nursing home overpayments. The Fund net balance is $28,845,366[11] as of February 2010. The net balance represents the amount to be used in determining whether nursing home providers pay into the fund.

Assisted Living Facility Limited Nursing Specialty License

This bill increases the biennial license fee for standard ALFs and eliminates the LNS specialty licensure fees. AHCA reports that the adjustment in fees for ALF licensure has a neutral fiscal impact on fee collections.

Based on the number of LNS specialty licenses (995) and beds (25,883) in February 2010, the LNS specialty license is projected to generate approximately $554,000 in revenues biennially. The revenues are calculated as follows:

$296 per license plus $10 per bed = $553,350 based on current numbers
($294,520 + $258,830) = $553,350

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

$553,350 divided by 65,298 beds = $8.47/bed
(81,038 total beds less 15,740 OSS)

[10] E-mail correspondence with Agency for Health Care Administration staff (March 11, 2010).
[11] *Id.*

The proposed fee is calculated as follows:

$59 per bed + 8.50 per bed = $67.50 per bed.

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:

AHCA has sufficient rule-making authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COUNCIL OR COMMITTEE SUBSTITUTE CHANGES

On March 9, 2010, the Health Regulation Policy Committee adopted seven amendments. The amendments:

- Expand the ability of nursing homes to provide respite services, and provide criteria for the provision of such services.
- Update the name of the Commission on Accreditation on Rehabilitation Facilities (formerly known as CARF-the Rehabilitation Accreditation Commission).
- Removes current provisions related bankruptcy reporting which conflicts with amendments made by the bill.
- Correct a drafting error to avoid conflict with existing laws which dictate fine amounts.
- Reduce the time for an extended license provided by the bill from 60 days to 30 days.
- Restore provisions deleted by the bill which exempt facilities from a fine for submitting a license renewal application after the deadline if the canceled postmark is dated timely.
- Conform a cross-reference.

The bill was reported favorably as a Committee Substitute.

On March 26, 2010, the Health Care Appropriations Committee adopted nine amendments. The amendments:

- Amend bill language on geriatric clinic staffing to clarify that licensed practical nurses are supervised by physicians (not physician assistants).
- Create an exemption from licensure under the Health Care Clinic Act 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.
- Limit DOH kitchen inspections of nursing homes to twice a year and upon complaint, and requires coordination with AHCA inspections.

- Limit State Fire Marshal inspections of nursing homes to once a year and upon complaint and upon identifying violations through non-inspection activities.
- Correct the calculation for the cap on the nursing home lease bond collections.
- Eliminate the requirement that purchasers of prescription drugs under the federal 340B program separate the 340B inventory from other inventory.
- Add orthotic, pedorthic and prosthetic licensees to the list of "health care providers" defined in ch. 766 (medical malpractice).
- Amend bill's ALF reporting requirements to eliminate rule-making authority to require reporting more frequently than semi-annually, and eliminate reporting on resident funding sources.
- Exempt sealed medical convenience kits meeting certain specifications from pedigree paper requirements.

The bill was reported favorably as a Committee Substitute.

On April 6, 2010, the Health & Family Services Policy Council adopted four amendments. The amendments:

- Exempt entities that are owned or controlled, 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 health care practitioners from licensure as a health care clinic.
- Clarify that claims billed to the state Medicaid program as 340B prescribed medication must meet specific criteria or payment will be denied.
- Authorize the Department of Health to accept funds provided by counties, municipalities, and other entities designated in the state emergency management plan for the purpose of participation in contacts and expend funds for the manufacture and delivery of licensable products used in response to a public health emergency.
- Create minimum staffing requirements for nursing home facilities that serve individuals less than 21 years of age.

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