HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/CS/HB 651 Agency for Health Care Administration
SPONSOR(S): Health & Family Services Policy Council, Health Care Regulation Policy, Committee, Hudson and others
TIED BILLS: **IDEN./SIM. BILLS:** CS/SB 2286

	REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1)	Health Care Regulation Policy Committee	7 Y, 0 N, As CS	Ciccone/Calamas	Calamas
2)	Health & Family Services Policy Council	23 Y, 0 N, As CS	Lowell	Gormley
3)	Health Care Appropriations Committee	6 Y, 0 N, As CS	Hicks	Pridgeon
4)	Full Appropriations Council on General Government & Health Care			
5)				

SUMMARY ANALYSIS

CS/CS/HB 651 amends several sections of law relating to the regulation, reporting, accessibility and service delivery of health care to individuals in Florida under the jurisdiction of the Agency for Health Care Administration (referred to alternately as AHCA or agency). Specifically, the bill:

- Eliminates regulation of private utilization review agents;
- Eliminates regulation of clinical laboratories that only perform tests waived by the federal Clinical Laboratory Improvement Amendment program;
- Revises long term care risk management to focus on incidents involving provider liability;
- Eliminates duplicative census reporting and quarterly monitoring visits of nursing homes;
- Eliminates certain workgroups and annual reports;
- Authorizes interim licensure for health care clinics replacing equipment;
- Eliminates agency requirements related to assisted living facility residency and consultation;
- Eliminates certain activities related to unlicensed activity;
- Allows electronic access to information;
- Revises criteria for provisional licenses;
- Authorizes uniform rules for emergency preparedness and inspections;
- Revises disqualifying criminal offenses for persons who work in health care;
- Attaches certain background screening forms to licensure renewal;
- Amends the insurance code to update the definition of standard reference compendium for cancer drugs;
- Amends the Health Care Clinic Act to provide an exemption from licensure for entities that do not bill personal injury protection (PIP) carriers and create an enforcement mechanism;
- Amends the content of the Nursing Home Guide and eliminates other print publications;
- Eliminates the requirement that volunteer members of the boards of licensed health care providers submit affidavits to the AHCA to document their volunteer status;
- Eliminates the requirement that the AHCA certify Florida 211 Network providers, and requires private accreditation or approval; and
- Makes numerous conforming changes.

The bill will have a significant positive fiscal impact to the Health Care Trust Fund in the AHCA (see Fiscal Comments).

The bill provides an effective date of upon becoming a law.

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:

House Bill 651 amends or deletes duplicative and possibly unnecessary regulatory and reporting requirements, repeals or revises redundant or obsolete statutory language, and imposes new regulatory requirements.

Background

The agency was statutorily created by s. 20.42, F.S., as the chief health policy and planning entity for the state. As such, the agency oversees the regulation of over 36,000 health care providers through the Division of Health Quality Assurance ("the division").[1] The division is charged with the task of protecting the health, safety and welfare of Florida citizens through regulation and oversight of health care service providers. The division has 630 staff and is funded with more than $64 million in state and federal funds.[2]

The division is charged with licensure or certification of 29 types of health care service providers, including abortion clinics, adult family care homes, adult day care centers, ambulatory surgical centers, assisted living facilities, birth centers, clinical laboratories, health care clinics, health care services pools, home health agencies, home medical equipment programs, hospices, hospitals, nursing homes, nurse registries, organ and tissue procurement, residential treatment centers for adolescents, risk managers, and other entities. In addition, the agency provides regulatory oversight for 11 other health care provider types including health maintenance organizations, rural health clinics, community mental health programs, and worker's compensation managed care and comprehensive outpatient rehab facilities.

Current Situation: Health Care Licensing Procedures Act

In 2006, the Legislature established the Health Care Licensing Procedures Act (Act).[3] The Act was created to address unnecessary duplication and variation in the requirements for licensure by the agency.[4] The Act was intended to streamline and create a consistent set of basic licensing

[1] The Agency for Health Care Administration: General Overview February, 2009, on file with the Health Care Regulation Policy Committee staff.
[2] *Id.*
[3] Ch. 2006-192, Laws of Florida.
[4] s. 408.801(2), F.S.

requirements for all providers in order to minimize confusion, standardize terminology, and include issues that are otherwise not adequately addressed in the Florida Statutes pertaining to specific providers.[5]

The Act, part II of ch. 408, F.S., provides uniform licensing standards for health care providers regulated by the agency. These standards include licensure application information and processing, facility ownership disclosure, management and personnel background screening, inspections, unlicensed activity and applied sanctions. In addition to the uniform standards established by rule or in law, individual provider types are subject to a set of independent licensing criteria specific to the health care service provided. The Act applies to the following types of health care providers[6]:

- Certain laboratories;
- Birth centers;
- Abortion clinics;
- Crisis stabilization units;
- Short-term residential treatment facilities;
- Residential treatment facilities;
- Residential treatment centers for children and adolescents;
- Hospitals;
- Ambulatory surgical centers;
- Mobile surgical facilities;
- Private review agents;
- Health care risk managers;
- Nursing homes;
- Assisted living facilities;
- Home health agencies;
- Nurse registries;
- Companion services or homemaker services providers;
- Adult day care centers;
- Hospices;
- Adult family-care homes;
- Homes for special services;
- Transitional living facilities;
- Prescribed pediatric extended care centers;
- Home medical equipment providers;
- Intermediate care facilities for persons with developmental disabilities;
- Health care services pools;
- Health care clinics;
- Clinical laboratories;
- Multiphasic health testing centers; and,
- Organ and tissue procurement agencies.

The Act requires applicants for licensure to submit an application under oath including the name, address and social security number of the applicant and each controlling interest.[7] "Controlling interest" means the applicant (if a person), officers and members of the board of directors, and persons with a five percent or greater ownership interest in the applicant, but does not include voluntary board members.[8] Applicants are not required to submit this information for the administrator or the financial officer. According to the agency, the lack of this information makes it difficult to assess those individuals' licensure and Medicaid standing, if any. To prove they are voluntary board members, such members must submit a document affirming volunteer status.[9]

[5] *Id.*
[6] s. 408.802, F.S.
[7] s. 408.809(1), F.S.
[8] s. 408.803(7), F.S.
[9] s. 408.803(13), F.S.

The Act defines a change of provider ownership as an event in which the licensee changes to a different entity, or in which 45 percent or more of the ownership changes hands over a two-year period.[10] According to the agency, this requirement has been difficult to manage and has resulted in the agency missing changes of ownership. The Act allows the agency to issue a provisional license to an applicant when the required background screening by the Florida Department of Law Enforcement has been accomplished, but the agency is waiting for screening results from the Federal Bureau of Investigation.[11]

The Act requires applicants for license renewal to submit an application to be received by the agency at least 60 days prior to the statutory expiration of the license.[12]

The Act governs inspections required for licensure applications. Current law requires that inspections for licensure, other than those conducted for initial applications, be unannounced. The Act provides exceptions to unannounced licensure inspections for birth centers, hospitals and clinical laboratories.[13] In addition, the Act provides that the agency may accept a facility's inspection conducted in conjunction with certification in lieu of a complete licensure inspection.[14]

The Act provides for Level 2 background screening for each of the following individuals of the facilities and providers[15]:

- the licensee, if an individual;
- the administrator or a similarly-titled person who is responsible for the day-to-day operation of the provider;
- the financial officer or similarly-titled individual who is responsible for the financial operation of the licensee or provider; and
- any person who is a controlling interest if the agency has reason to believe that such person has been convicted of any offense prohibited by s. 435.04, F.S.

The Act governs administrative actions by the agency. It provides that the agency may impose an administrative fine for any violations of the Act, and authorizes the agency to make rules to set fine amounts.[16]

Effect of Proposed Changes: Health Care Licensing Procedures Act

The bill requires the applicant for a license to submit the name, address and social security number of the administrator and the financial officer. The bill removes the requirement that voluntary board members submit affidavits of their volunteer status.

The bill amends the definition of "change of ownership" to mean an event in which the licensee changes to a different entity, or in which 51 percent or more of the ownership changes in any manner, over any period of time. The bill also allows the agency to issue a provisional license to an applicant for a change of ownership, if the required background screening by the Florida Department of Law Enforcement has been accomplished, but the agency is waiting for screening results from the Federal Bureau of Investigation. Such provisional licenses are limited to a duration specified by the agency, not to exceed 12 months.

The bill prohibits applicants for license renewal from submitting an application more than 120 days prior to the statutory expiration of the license, and requires the agency to return applications submitted earlier than 120 days. The bill applies the same time frame to all other applications and requests, counted back from the requested effective date. The bill provides that applicants and licensees may submit required documents by providing the agency electronic access to the information. The bill also

[10] s. 408.803(5), F.S.
[11] ss. 408.809(3), 402.808, F.S.
[12] s. 408.806(1), F.S.
[13] s. 408.806(7), F.S.
[14] s. 408.811(2), F.S.
[15] s. 408.809, F.S.
[16] s. 408.813, F.S.

requires licensees to report changes in licensing information within 21 days of the change, and requires licensees to report changes in required insurance or bonds.

The bill provides an exemption from unannounced licensure inspections for adult family care homes. According to the agency, adult family care homes are private homes that care for a small number of persons, and do not have regular business hours like other facilities. The bill also allows the agency to accept inspections conducted in conjunction with comparable licensure requirements or an approved accrediting organization in lieu of full licensure inspections by the agency. The bill authorizes the agency to require an applicant or licensee to submit a plan of correction for deficiencies found in an inspection, and to set a timeframe for plan submission. The bill also requires applicants or licensees to correct deficiencies within the time set by the agency.

The bill adds additional disqualifying offenses for persons requiring background screening and provides uniformity among provider types. The additional disqualifying offenses include certain types of assault, battery, Medicaid fraud, stalking, theft, fraud, forgery, grand theft, identity theft and robbery. These new offenses apply to persons hired on or after October 1, 2009. The bill provides an exception to the rescreening requirements for employees and controlling interests that provide evidence of a prior background screening, and permits the agency to provide exemptions from screening for those who apply an exemption before September 30, 2009. The bill also ties the requirement to submit certain background screening forms due annually to the biennial licensure renewal process.

The bill establishes a uniform statutory structure for classifying violations of the Act. The bill establishes definitions for "isolated deficiency", "patterned deficiency" and "widespread deficiency", and for four classes of violations, setting correction and fining requirements for each class.

The bill creates a new section of the Act related to emergency management. The new section requires licensees to designate a primary contact person for emergency operations, and provides for licensees to temporarily exceed their licensed capacity in emergency situations and under certain circumstances. In addition, the bill requires licensees providing residential or inpatient services to use the agency's online data reporting system to report on the licensee's status in an emergency.[17] The bill authorizes the agency to make rules for licensees related to emergency planning requirements, and moves existing provisions governing inactive license status caused by emergency-related damage to this new section.

Current Situation: Utilization Review

According to the agency, private utilization review agents perform utilization review services for third-party payers on a contractual basis for outpatient or inpatient hospital services. Section 395.0199(3), F.S., provides several exemptions to the registration requirements including health insurers, health maintenance organizations or hospitals, or subsidiaries under common ownership, and certain persons who contract with government agencies. There are currently 111 registered utilization review agents, 75 of which are located in states outside Florida. Currently, private utilization review agents incur no regulatory penalties for non-compliance. In addition, no inspections are conducted, and the registration offers no regulatory protections.[18] Registered private utilization review agents pay a $514 biennial registration fee.

Effect of Proposed Changes: Utilization Review

The bill eliminates the requirement that private utilization review agents register with the agency and repeals the registration program. The registration elimination would save the 111 registered providers approximately $57,054 in fees.[19]

[17] *See*, http://ahca.myflorida.com/MCHQ/Emergency_Activities/index.shtml and http://ess.myflorida.com/, Agency for Health Care Administration Emergency Status System.
[18] Agency for Health Care Administration: 2009 Bill Analysis & Economic Impact Statement of HB 651.
[19] Agency for Health Care Administration: 2009 Bill Analysis & Economic Impact Statement of the Proposed Strike-all Amendment to HB 651.

Current Situation: Clinical Laboratories

All facilities, including physician offices, performing any clinical laboratory testing, are required to obtain a state clinical laboratory license *and* a federal Clinical Laboratory Improvement Amendment (CLIA) certificate. The state clinical laboratory license is issued before the laboratory is authorized to perform testing. The Laboratory Licensure Unit at the agency handles applications and changes for both the state laboratory licensure and federal CLIA certification programs. Initial and biennial inspections are required for these facilities.[20]

A "waived test" is a test that the federal Centers for Medicare and Medicaid (CMS) have determined qualify for a certificate of waiver under the federal Clinical Laboratory Improvement Amendments of 1988, and the federal rules.[21] Tests performed using a microscope are not waived.[22] Laboratories that only do "waived" testing are issued a Certificate of Exemption by the State of Florida and a Certificate of Waiver by the CLIA program. Initial and biennial inspections are not required for these facilities that only perform "waived" tests.

Applications for both types of laboratories must be submitted to the Laboratory Licensure Unit. According to the agency, approximately 8,500 of the 12,800 licensed clinical laboratories perform only waived testing; such labs include physicians' offices (4,000+), hospitals (150), long term care facilities (659) and home health agencies.[23] According to the agency, the number of clinical laboratories has continued to grow without the addition of staff, which has affected limited agency resources.

Effect of Proposed Changes: Clinical Laboratories

The bill repeals the requirement that waived laboratories apply for a certificate of exemption from the agency. The elimination of licensure for *waived* laboratories would save providers between $800,000 and $900,000 in biennial licensure fees and application processing, and would avoid duplication of federal requirements.[24]

Current Situation: Nursing Homes

Nursing home facilities are regulated by the agency pursuant to part II of chapter 400, F.S. At least every 15 months, the agency is required to evaluate each nursing home facility to determine the degree of compliance with state licensure requirements. Following this evaluation, a nursing home is assigned either a standard or conditional licensure status. A "standard" licensure indicates that a facility has no class I or II deficiencies, and has successfully corrected all class III deficiencies within the time established by the agency. A "conditional" license is provided to a nursing facility that is not in substantial compliance with licensure standards at the time of the survey, due to the presence of one or more class I or II deficiencies, or to class III deficiencies left uncorrected within the time prescribed by the agency.[25] The various classes of deficiencies are as follows:[26]

- Class I – a deficiency that the agency determines requires immediate corrective action because the nursing home's noncompliance has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident receiving care in the nursing home.
- Class II – a deficiency that the agency determines has compromised a resident's ability to maintain or reach his or her highest practicable physical, mental, and psychological well-being,

[20] *Id.*
[21] *Id.*
[22] Agency for Health Care Administration, Division of Health Quality Assurance, Health Facility Regulation: Laboratory Licensure Unit. (2009) Available online at: http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Laboratory_Licensure/index.shtml (last viewed March 17, 2009). Non-waived test means any test system, assay, or examination that has not been found to meet the statutory criteria specified at section 353(d)(3) of the Public Health Service Act (42 C.F.R. 493.2).
[23] Agency for Health Care Administration: 2009 Bill Analysis & Economic Impact Statement of HB 651.
[24] Agency for Health Care Administration, email to committee staff March 16, 2009, on file with the Health Regulation Policy Committee.
[25] s. 400.23(7), F.S.
[26] s. 400.23(8), F.S.

as defined by an accurate and comprehensive resident assessment, plan of care, and provision of services.

- Class III – a deficiency that the agency determines will result in no more than minimal physical, mental, or psychological discomfort to the resident, or one that has the potential to compromise a resident's ability to maintain or reach his or her highest practicable physical, mental, or psychological well-being, as defined by an accurate and comprehensive resident assessment, plan of care, and provision of services.
- Class IV – a deficiency that the agency determines has the potential for causing no more than a minor negative impact on a resident.

A facility may be placed on a six-month survey cycle for a period of two years if it has been cited for a class I deficiency, two or more class II deficiencies from separate surveys/investigations within a 60-day period, or has received three substantiated complaints within a six-month period, each resulting in at least one class I or II deficiency.

Current law requires the agency to monitor nursing homes quarterly with unannounced visits by nurse monitors, who assess the overall quality of care in the facility.[27] These monitors function independently from regular agency surveyors, and report both positive and negative findings to the facility administrator.[28] According to the agency, the monitor visits are not regulatory in nature, have no measurable outcomes, and reports are confidential.

Current law provides that "adverse incidents" in nursing homes must be reported to the agency.[29] Adverse incidents include events reported to law enforcement, resident elopement, and abuse, neglect and exploitation of residents.[30] Florida law also requires instances of abuse, neglect and exploitation to be reported to the Department of Children and Family Services.[31] Similarly, federal long term care regulation requires nursing homes to report mistreatment, neglect or abuse "in accordance with state law".[32] The agency is required to submit an annual report to the Legislature on nursing home adverse incidents, including a listing of liability claims.[33] According to the AHCA, this report is an aggregate data report that does not appear to be used.

Current law also requires nursing homes to submit a monthly report to the agency on the number of vacant beds in the facility which are available for resident occupancy.[34] Nursing homes are also required to post facility polices related to residents' personal property, and to present a copy to the resident upon admission.[35] Current law requires the agency to adopt rules allowing certain staff to assist residents with eating.[36] According to the agency, federal legislation has implemented a dining assistant program addressing all the components of the agency's current rules on assisted eating.

Current law requires the AHCA to publish certain information as part of a Nursing Home Guide.[37] In 2008, the U.S. Centers for Medicare and Medicaid services (CMS) initiated an online nursing home comparison tool. The CMS Nursing Home Compare Five-Star Quality Ranking System rates nursing homes based on inspections, quality measures, and staffing.[38]

Effect of Proposed Changes: Nursing Homes

The bill eliminates the quarterly nurse monitoring function.

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[27] s. 400.118, F.S.
[28] *Id.*
[29] s. 400.147(8), F.S.
[30] s. 400.147(5), F.S.
[31] s. 415.1034, F.S. Similarly, Florida law also requires "any person" who knows of an instance of abuse, abandonment or neglect of a child to report it to the Department of Children and Family Services. Section 39.201, F.S.
[32] 42 C.F.R. 483.13(c) (2008).
[33] s. 400.147(14), F.S.
[34] s. 400.141(16), F.S.
[35] s. 400.162, F.S.
[36] s. 400.23(3), F.S.
[37] s. 400.191, F.S.
[38] Centers for Medicare and Medicaid Services, Five-Star Quality Ranking System. Available at http://www.cms.hhs.gov/CertificationandComplianc/13_FSQRS.asp#TopOfPage (last viewed April 13, 2009).

The bill amends adverse incident reporting requirements for nursing homes. Regarding reports of events reported to law enforcement, the bill provides that nursing homes need report only those events if they were reported to law enforcement "for investigation". The bill limits reports of resident elopement to those in which the elopement places the resident at risk of harm or injury. The bill requires facilities to report abuse, neglect or exploitation to the agency as required by federal regulations, and to the Department of Children and Family Services as required by state law. The bill eliminates the requirement for the agency to submit an annual report on nursing home adverse incidents and liability claims to the Legislature.

The bill eliminates the monthly bed vacancy report requirement. The bill also eliminates the requirement to post facility polices related to residents' personal property, and adds a requirement to give a copy of the policy to the resident's representative, if appropriate, and to provide new copies upon revision. The bill eliminates the agency's rulemaking authority to allow certain staff to assist residents with eating.

The bill eliminates the requirement that the AHCA publish a summary of the deficiency data for each nursing home facility in the Nursing Home Guide on its website. Similarly, the bill eliminates the requirement that the AHCA publish certain nursing home information in printed form, including information on each facility: owners, religious affiliations, number of beds, languages spoken, programs available, and a summary of deficiency data.

The bill exempts nursing homes from the deficiency classifications created by the bill's amendments to the Health Care Licensing Procedures Act.

Current Situation: Assisted Living Facilities

Part I of chapter 429, F.S., provides for the licensure and oversight of assisted living facilities (ALFs) by the agency.

Current law authorizes the agency to take administrative action for ALF violations of part II of chapter 408 (the Health Care Licensing Procedures Act) and of part I of chapter 429 (the authorizing statute for ALF licensure and regulation).[39] Violations are categorized by law into four classes, each subject to different levels of fines.[40]

Current law requires that the agency order or perform assessments to determine client residency needs and provide corrective suggestions prior to issuing a deficiency.[41] According to the agency, these exams are not currently ordered or performed by the agency, these requirements place the agency in the position of directing provider operations, and corrective action is best identified by the caregivers based on resident needs.[42]

Current law contains several provisions addressing unlicensed ALFs. The agency is required to provide a list of licensed ALFs, by county, to the Department of Elder Affairs and the Department of Children and Families to assist people in finding a licensed ALF.[43] The agency is also required to host work groups related to unlicensed activities.[44] In addition, current law prohibits referral of people to unlicensed ALFs, and prohibits hospitals and community mental health centers from discharging a patient to an unlicensed ALF. The agency must provide annual notices of this prohibition to persons responsible for referring patients, including physicians, hospitals, nursing homes, and the Departments of Elder Affairs and Children and Families.[45] According to the agency, unlicensed activity is well

[39] s. 429.19(1), F.S.
[40] s. 429.19(2), F.S.
[41] s. 429.19(8), F.S.
[42] Agency for Health Care Administration: 2009 Bill Analysis & Economic Impact Statement of HB 651.
[43] ss. 429.08(1)(e), 429.08(2)(e), F.S.
[44] s. 429.08(2), F.S.
[45] s. 429.08(2), F.S.

integrated into the full spectrum of compliance monitoring and no longer requires special handling; reports and citations for unlicensed activity have been stable for the last several years.[46]

Current law requires assisted living facilities to report "adverse incidents".[47] Adverse incidents include events reported to law enforcement, resident elopement, and abuse, neglect and exploitation of residents.[48] Florida law also requires instances of abuse, neglect and exploitation to be reported to the Department of Children and Family Services.[49] The agency is required to submit an annual report to the Legislature on ALF adverse incidents, including a listing of liability claims.[50] According to the AHCA, this report is an aggregate data report that does not appear to be used.

In 2005, the Legislature established a pilot program to create an intergenerational assisted living facility and directed the agency to report on its effectiveness.[51] To date, the agency has received no requests to participate in the pilot.

Effect of Proposed Changes: Assisted Living Facilities

The bill eliminates the current statutory classification structure for ALF violations, and replaces it with the uniform structure created in the bill as part of the Health Care Licensing Procedures Act. That part of the bill establishes definitions for "isolated deficiency," "patterned deficiency," and "widespread deficiency," and for four classes of violations. The bill maintains the fining levels for ALF violations in current law.

The bill eliminates the requirement for the agency to order or perform an assessment to determine client residency needs for a decision of a person's continued residency, and the requirement for the agency to offer correction suggestions prior to providing a written deficiency statement.

The bill eliminates the requirement for the agency to submit a list of licensed ALFs to the Departments of Elder Affairs and Children and Families, and replaces it with a requirement to publish that information on the agency's website. The bill imposes the prohibition on referral to unlicensed ALFs on all providers governed by s. 408.803 (see above), and eliminates the requirement for the agency to notify providers of this requirement. The bill also eliminates the requirement for the agency to conduct an unlicensed activity work group at each local agency office.

The bill amends adverse incident reporting requirements for ALFs. Regarding reports of events reported to law enforcement, the bill provides that ALFs need report only those events it they were reported to law enforcement "for investigation". The bill limits reports of resident elopement to those in which the elopement places the resident at risk of harm or injury. The bill requires facilities to report abuse, neglect or exploitation to the Department of Children and Family Services as required by state law. The bill eliminates the requirement for the agency to submit an annual report on ALF adverse incidents and liability claims to the Legislature.

The bill repeals the pilot project for an intergenerational assisted living facility.

Current Situation: Health Care Clinics

The agency licenses and regulates health care clinics under part X of chapter 400, F.S., the Health Care Clinic Act (Act). The Act was passed in 2003 to reduce fraud and abuse occurring in the personal injury protection (PIP) insurance system. Florida's Motor Vehicle No-Fault Law requires motor vehicle owners to maintain $10,000 of PIP insurance. PIP benefits are available for certain express damages

[46] *Id.*
[47] s. 429.23(2), F.S.
[48] s. 429.23(2)(a), F.S.
[49] s. 415.1034, F.S. Similarly, Florida law also requires "any person" who knows of an instance of abuse, abandonment or neglect of a child to report it to the Department of Children and Family Services. Section 39.201, F.S.
[50] s. 429.23(6), F.S.
[51] s. 429.071, F.S.

sustained in a motor vehicle accident, regardless of fault. Section 409.991, F.S., provides licensure requirements to ensure that clinics meet basic standards, and provides administrative oversight.

Pursuant to the act, the AHCA ensures that such clinics meet basic standards, and provides administrative oversight. Any entity that meets 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…") must be licensed as a clinic. Every entity that meets the definition of a "clinic" must maintain a valid license with the AHCA at all times, and each clinic location must be licensed separately. A clinic license lasts for a 2- year period. Each clinic must file in its application for licensure information regarding the identity of the owners, medical providers employed, and the medical director and proof that the clinic is in compliance with applicable rules. The clinic must also present proof of financial ability to operate a clinic. A level 2 background screening pursuant to ch. 435, F.S., is required of each applicant for clinic licensure. A license may not be granted to a clinic if the applicant has been found guilty of, regardless of adjudication, or has entered a plea of nolo contendere or guilty to any offense prohibited under the level 2 standards for screening or a violation of insurance fraud under s. 817.234, F.S., within the past 5 years.

Although all clinics must be licensed with the AHCA, 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 of the specified practice acts and that only provide services within the scope of their license;
- Entities that own, directly or indirectly, an entity licensed or registered by the state under one or more of the specified practice acts and that only provide services within the scope of their license;
- Entities that are under common ownership, directly or indirectly, with an entity licensed or registered by the state under one or more of the specified practice acts and only provides services within the scope of their license.
- Entities that are exempt from federal taxation under 26 U.S.C. sec. 501(c)(3) or sec. 501(c)(4);
- A community college or university clinic;
- Entities owned or operated by the federal or state government, including agencies, subdivisions and municipalities;
- Clinical facilities affiliated with an accredited medical school at which training is provided for medical students, residents, or fellows;
- Entities that provide only oncology or radiation therapy services by physicians licensed under chs. 458 or 459, F.S.; and
- Clinical facilities affiliated with a college of chiropractic accredited by the Council on Chiropractic Education at which training is provided for chiropractic students.

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 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.

Licensed clinics are subject to unannounced inspections by Division of Insurance Fraud personnel and must allow full and complete access to the premises and to billing records. The agency 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. The most common types of PIP fraud are health care clinic fraud and staged accidents. In fiscal year, 2007-2008, nearly half of the Division of Insurance Fraud's convictions involved fraudulent claims for PIP benefits and there were 1,176 complaints of fraudulent activity committed by health care providers.

Section 400.9935, F.S., prohibits the medical director of a licensed clinic from referring a patient from his or her own practice to the clinic, if the clinic provides magnetic resonance imaging (MRI), static radiographs, computed tomography, or positron emission tomography. That section makes such referrals third degree felonies.

Section 400.995, F.S. requires the agency to make a reasonable attempt to discuss clinic law violations with the clinic owner and recommended corrective action prior to taking disciplinary action.

Effect of Proposed Changes: Health Care Clinics

The bill authorizes interim licensure for health care clinics replacing MRI equipment; eliminates the prohibition on medical director referral to clinics that perform MRIs and other diagnostic imaging; and eliminates the requirement for the agency to provide corrective suggestions prior to issuing a written deficiency statement.

The bill also provides a licensure exemption from for entities that do not seek reimbursement from PIP carriers. In addition, the bill requires the AHCA to issue a unique identification number to each licensed or certified exempt clinic which requests it, and authorizes PIP carriers to decline reimbursement to clinics not possessing such a number. The bill requires the AHCA to publish the identification numbers and provider names on its website in a searchable format.

Current Situation: Nurse Registries

The agency licenses and regulates nurse registries under section 400.506, F.S. A nurse registry is any person that procures, offers, promises, or attempts to secure health-care-related contracts for registered nurses, licensed practical nurses, certified nursing assistants, home health aides, companions, or homemakers, who are compensated by fees as independent contractors.[52]

Current law prohibits a nurse registry from giving remuneration to a case manager, discharge planner, facility-based staff member, or third-party vendor who is involved in the discharge planning process of certain facilities, and from whom the nurse registry receives referrals. The agency may deny, suspend, or revoke the license of a nurse registry, and shall impose a fine of $5,000 against a nurse registry which violates that prohibition.[53]

Effect of Proposed Changes: Nurse Registries

The bill amends the prohibition on a nurse registry giving remuneration to persons involved in discharge planning for facilities from which the nurse registry receives referrals: this prohibition does not apply to nurse registries that do not participate in the Medicaid or Medicare programs.

Current Situation: Medicaid Provider Change of Ownership

In addition to the regulatory functions described above, the agency is the single state agency that administers the state Medicaid plan under federal law.[54] The Medicaid program is required by federal law to contract with any willing, qualified health care provider, but may set the qualifications for enrolling providers.[55] Provider contracting is governed by s. 409.907, F.S., and by rules promulgated by the agency. Current law permits Medicaid to terminate the provider contract as the result of a change in

[52] s. 400.462(21), F.S.
[53] s. 400.506(15), F.S.
[54] ss. 409.901(2) and (14), F.S. The Medicaid DME and medical supplies program is authorized by Title XIX of the Social Security Act and 42 C.F.R. Part 440.70. The program was implemented through ch. 409, F.S., and Chapter 59G, F.A.C.
[55] s. 409.907(6), F.S.

ownership, requires providers involved in a change of ownership to notify Medicaid and submit a new provider contract application, and provides for successor liability. A "change of ownership" is an event in which the provider changes to a different entity or in which 45 percent or more of the ownership changes over a two-year period.[56] This is consistent with current law governing licensure of many provider types.[57]

Effect of Proposed Changes: Medicaid Provider Change of Ownership

The bill amends the definition of "change of ownership" to mean an event in which the licensee changes to a different entity, or in which 51 percent or more of the ownership changes in any manner, over any period of time. This matches the new definition in the bill governing licensure of many provider types.

Current Situation: Standard Reference Compendium

In a variety of legislative contexts for Medicare and Medicaid, Congress and the Centers for Medicare and Medicaid Services ("CMS") have endorsed the value of recognized medical compendia for ascertaining the medical appropriateness of off-label uses of cancer drugs. The "compendia" are comprehensive listings of FDA-approved drugs and biologicals or comprehensive listings of a specific subset of drugs and biologicals in a specialty compendium, for example a compendium of anti-cancer treatment. A compendium includes a summary of how each drug works in the body, as well as information for health care practitioners about proper dosing and whether the drug is recommended or endorsed for use in treating a specific disease.

The Social Security Act and the Medicare and Medicaid regulations specify that Medicare carriers and state Medicaid programs must provide reimbursement for drugs used for off-label cancer indications when they are recognized as safe and effective by either the FDA, any of the recognized compendia or in peer-reviewed literature. Medicare local contractors, which process and pay Medicare claims and approve coverage for drugs under Medicare Part B, use compendia as one of several tools to determine whether an anti-cancer drug may be covered under Medicare Part B. CMS also recognizes compendia for determination of covered drugs under Medicare Part D.

The approved compendia change over time. The current CMS approved national compendia are: the American Hospital Formulary Service-Drug Information (AFHS-DI), the NCCN Drugs & Biologics Compendium, Thomson Micromedex DrugDex, and Elsevier Gold Standard's Clinical Pharmacology.

In Florida, the compendia are used in health insurance regulation. Section 627.4239(2), F.S., provides that an insurer may not exclude coverage for the treatment of cancer for any drug prescribed for the treatment of cancer on the ground that the drug is not approved by the U.S. Food and Drug Administration for a particular indication, if that drug is recognized for treatment of that indication in a standard reference compendium or recommended in the medical literature. Section 627.4239 expressly lists those compendia: United Stated Pharmacopeia Drug Information; American Medical Association Drug Evaluation; and American Hospital Formulary Service Drug Information. However, that section of Florida law has not been updated since CMS updated its compendia list. Of these three compendia only one is still being published: the American Hospital Formulary Service Drug Information. Similarly, three compendia recognized by CMS are not listed in section 627.4239: the NCCN Drugs & Biologics Compendium, Thomson Micromedex DrugDex, and Elsevier Gold Standard's Clinical Pharmacology.

Effect of Proposed Changes: Standard Reference Compendium

The bill amends the definition of "standard reference compendium" to remove the names of specific compendia and instead defers to the Centers for Medicare and Medicaid Services to recognize the compendia. This allows Florida's insurance code to remain current without annual amendment to update the compendia list based on federal changes.

[56] s. 409.901(5), F.S.
[57] s. 408.803(5), F.S.

Current Situation: Florida 211 Network

On July 21, 2000, the Federal Communications Commission (FCC) adopted Order No. FCC 00-256, in CC Docket No. 92-105, relating to the 211 dialing code. The FCC reserved the 211 dialing code for community information and referral services. The 211 code is intended to be an easy-to-remember and universally-recognizable number that would enable a critical connection between individuals and families in need and the appropriate community-based organizations and government agencies. Dialing 211 helps, for example, the elderly, the disabled, those who do not speak English, those who are having personal crises, the illiterate, or those who are new to communities, by providing referrals to and information about health and human services organizations and agencies.

In 2002, the Legislature established the Florida Health and Human Services Access Act (Act) and authorized the AHCA to develop a comprehensive, automated system for access to health care services. The system, known as the Florida 211 Network, was implemented as a pilot project and was intended to serve as a single entry point for information and referrals to publicly funded health and human service programs.[58] The 2002 legislation further authorized the planning, development and implementation of a statewide Florida 211 network to serve as a single entry point for information and referrals to publicly funded health and human service programs.[59] Due to loss of funding, the pilot project, scheduled to be completed on December 31, 2003, was terminated on June 30, 2003.

Current law requires the AHCA to develop criteria that organizations must satisfy to become certified Florida 211 Network providers.[60] Previously, any organization could obtain a 211 number without meeting specific standards or qualifications. The agency developed the Florida 211 Network Provider Certification Rule (Chapter 59G-11, Florida Administrative Code), adopted April 28, 2003, to ensure, through certification, that quality, consistent information and services are provided to persons seeking health and human services. To receive certification, a candidate must demonstrate that its organization works collaboratively and have written agreements with specialized information and referral systems, including crisis centers, child care resource and referral programs, elder help-lines, homeless coalitions, designated emergency management systems, 911 and 311 systems, and must pass an on-site visit by AHCA.[61] The AHCA rules require that applicants for certification be accredited by, or be in the process of obtaining accreditation from, the Alliance for Information and Referral Services (AIRS), and must meet the standards set by that organization.[62]

The AIRS is a private non-profit organization of information and referral systems throughout the country. It also administers an accreditation program for new 211 networks and providers.[63] The accreditation process assesses providers based on standards for six areas: service delivery; resource database; reports and measures; cooperative relationships; organizational requirements; and disaster services. Accreditation requires a site visit and a consultation fee of $4,500 ($3,000 for Alliance members).[64]

Effect of Proposed Changes: Florida 211 Network

The bill eliminates the requirement that the AHCA certify 211 network providers. The bill allows providers accredited or authorized by the AIRS or authorized by the Florida Alliance for Information and Referral Services to request the 211 dialing code directly from the local exchange company.

[58] Chapter 2002-223, LOF; Passed as SB 1276
[59] s. 408.918, F.S.
[60] s. 418.918(2), F.S.
[61] 59G-11.003, F.A.C.
[62] Id.
[63] *See,* Florida Alliance for Information and Referral Services at http://www.airs.org/i4a/pages/index.cfm?pageid=1.
[64] Accreditation Application, Florida Alliance for Information and Referral Services, available at http://www.airs.org/i4a/pages/index.cfm?pageid=1.

B. SECTION DIRECTORY:

Section 1. Repeals s. 395.0199, F.S., relating to private utilization review of health care services.

Section 2. Amends s. 395.405, F.S., relating to agency rulemaking authority.

Section 3. Amends s. 400.0712, F.S., relating to inactive licenses for nursing home facilities.

Section 4. Amends s. 400.118, F.S., relating to nursing home quality assurance.

Section 5. Amends s. 400.141, F.S., relating to administration and management of nursing home facilities.

Section 6. Amends s. 400.147, F.S., relating to internal risk management of nursing homes.

Section 7. Amends s. 400.162, F.S., relating to property and personal affairs of residents.

Section 8. Amends s. 400.191, F.S, relating to reports and records.

Section 9. Amends s. 400.195, F.S., relating to agency reporting requirements.

Section 10. Amends s. 400.23, F.S., relating to rules, evaluation and deficiencies, licensure status.

Section 11. Amends s. 400.474, F.S., relating to administrative penalties for home health agencies.

Section 12. Amends s. 400.506, F.S., relating to licensure of nurse registries.

Section 13. Amends s. 400.9905, F.S., providing definitions.

Section 14. Amends s. 400.9935, F.S., relating to health care clinic responsibilities.

Section 15. Amends s. 400.995, F.S., relating to administrative penalties.

Section 16. Amends s. 408.803, F.S., providing definitions.

Section 17. Amends s. 408.806, F.S., relating to licensure application processes.

Section 18. Amends s. 408.808, F.S., relating to license categories.

Section 19. Amends s. 408.809, F.S., relating to background screening for health care providers.

Section 20. Amends s. 408.810, F.S., relating to minimum licensure requirements.

Section 21. Amends s. 408.811, F.S., relating to licensure inspections.

Section 22. Amends s. 408.813, F.S., relating to administrative fines.

Section 23. Amends s 408.820, F.S., relating to exemptions.

Section 24. Creates s. 408.821, F.S., relating to emergency management planning and operations for health care providers.

Section 25. Amends s. 408.831, F.S., relating to denial, suspension, or revocation of a license.

Section 26. Amends s. 408.910, F.S., relating to the Florida 211 Network.

Section 27. Amends s. 409.221, F.S., relating to consumer-directed care.

Section 28. Amends s. 409.901, F.S., providing definitions.

Section 29. Repeals s. 429.071, F.S., relating to intergenerational respite care assisted living facility pilot program.

Section 30. Amends s. 429.08, F.S., relating to unlicensed assisted living facilities.

Section 31. Amends s. 429.14, F.S., relating to administrative penalties.

Section 32. Amends s. 429.19, F.S., relating to administrative fines.

Section 33. Amends s. 429.23, F.S., relating to internal risk management of assisted living facilities.

Section 34. Amends s. 429.26, F.S., relating to placements and examination of assisted living facility residents.

Section 35. Amends s. 435.04, F.S., relating to level 2 background screening standards.

Section 36. Amends s. 430.80, F.S., relating to a teaching nursing home pilot project.

Section 37. Amends s. 435.05, F.S., relating to background screening requirements for employees.

Section 38. Amends s. 483.031, F.S., relating to clinical laboratories.

Section 39. Amends s. 483.041, F.S., providing definitions.

Section 40. Repeals s. 483.106, F.S., relating to clinical laboratory certificate of exemption.

Section 41. Amends s. 483.172, F.S., relating to clinical laboratory licensure fees.

Section 42. Amends s. 627.4239, F.S., relating to coverage for use of drugs for cancer treatment.

Section 43. Amends s. 627.736, F.S., relating to personal injury protection benefits.

Section 44. Amends s. 651.118, F.S., relating to certificates of need.

Section 45. Provides the bill is effective upon becoming a law.

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:

   See Fiscal Comments.

2. Expenditures:

   See Fiscal Comments.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill deletes duplicate regulatory and reporting requirements positively impacting businesses that have to pay fees to support the cost of regulation.

D. FISCAL COMMENTS:

The bill would create an annual reduction of $817,383 in the agency's expenditures in the Health Care Trust Fund by the elimination of twelve nurse monitor positions. Costs savings would also be realized through the implementation of electronic notifications and publication of documents. This would greatly reduce mailing costs and staff time to prepare documents for distribution. The elimination of duplicative reporting would allow more efficient processing of licensure applications and enforcement activities.

The bill would also create a reduction in annual fee collections of $428,700 that are deposited into Health Care Trust Fund due to deregulating the private review agents, homemaker/companion registries, and waived laboratories.

The amendments to the Health Care Clinic Act would also create an indeterminate reduction in annual fee collections and expenditures by the AHCA. According to the AHCA, the number of clinics that accept personal injury protection payments cannot be determined.[65] The amendments also have the potential of creating an indeterminate increase in expenditures associated with the issuance of a unique identification number. The AHCA reports the number of licensed or exempt clinics that accept personal injury protection payments, and will seek a unique identification number, cannot be determined, but does not appear to be significant.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   Not applicable. This bill does not appear to: require counties or municipalities to spend funds or take an action requiring the expenditure of funds; reduce the authority that counties or municipalities have to raise revenues in the aggregate; or reduce the percentage of a state tax sharing with counties or municipalities.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

Current law provides 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 18, 2009, the Health Regulation Policy Committee adopted a strike-all amendment and two amendments to the strike-all amendment and reported the bill favorably as a committee substitute. The strike-all amendment, as amended:

[65] Correspondence from AHCA on file with the Insurance, Business & Financial Affairs Policy Committee.

- Eliminates regulation of private utilization review agents;
- Eliminates regulation of clinical laboratories that only perform tests waived by the federal Clinical Laboratory Improvement Amendment program;
- Revises long term care risk management to focus on incidents involving provider liability;
- Eliminates duplicative census reporting and quarterly monitoring visits of nursing homes;
- Eliminates certain workgroups and annual reports;
- Authorizes interim licensure for health care clinics replacing equipment;
- Eliminates assisted living directives related to residency and consultation;
- Eliminates certain activities related to unlicensed activity;
- Clarifies application time frames;
- Allows electronic access to information;
- Revises criteria for provisional licenses;
- Authorizes uniform rules for emergency preparedness and inspections;
- Revises disqualifying criminal offenses for persons who work in health care;
- Attaches certain background screening forms to licensure renewal and
- Makes numerous conforming changes.

On April 1, 2009, the Health and Families Policy Council adopted three amendments (including two amendments to an amendment), and reported the bill favorably as a council substitute. The amendments maintain the entirety of the CS/HB 651. In addition, the amendments changed the insurance code to update the definition of "standard reference compendium" for cancer drug coverage. In addition, the amendments changed the Health Care Clinic Act to:

- Provide an exemption from health care clinic licensure requirements for entities that do not seek reimbursement from insurance companies for medical services paid pursuant to personal injury protection (PIP) coverage;
- Require the Agency for Health Care Administration to issue a unique identification number to each licensed or certified exempt clinic which requests it; and
- Authorize PIP carriers to decline reimbursement to clinics not possessing such a number.

On April14, 2009, the Health Care Appropriations Committee adopted four amendments and reported the bill favorably as a committee substitute. The amendments maintain the entirety of the CS/CS/HB 651. In addition, the amendments:

- Eliminate the requirement that the AHCA publish a summary of the deficiency data for each nursing home facility in the Nursing Home Guide on its website;
- Eliminate the requirement that the AHCA publish certain nursing home information in printed form;
- Eliminate the requirement that volunteer members of the boards of licensed health care providers submit affidavits to the AHCA to document their volunteer status;
- Make technical corrections to retain language relating to homemaker-companion registries;
- Exempt nursing homes from the standard deficiency classifications contained in the bill; and
- Eliminate the requirement that the AHCA certify Florida 211 Network providers, and requires private accreditation or approval.

The analysis is drafted to the committee substitute.