

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 651

Agency for Health Care Administration

SPONSOR(S): Hudson

TIED BILLS:

IDEN./SIM. BILLS:

	REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1)	Health Care Regulation Policy Committee		Ciccone/Calamas	Calamas
2)	Health & Family Services Policy Council			
3)	Health Care Appropriations Committee			
4)	Full Appropriations Council on General Government & Health Care			
5)				

SUMMARY ANALYSIS

House Bill 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. Specifically, the bill:

- Eliminates regulation of private utilization review agents and homemaker companion organizations;
- 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;
- Clarifies record retention requirements;
- Authorizes uniform rules for emergency preparedness and inspections;
- Revises disqualifying criminal offenses for persons who work in health care; and
- Attaches certain background screening forms to licensure renewal.

The bill will have a significant positive fiscal impact to the Health Care Trust Fund in the Agency for Health Care Administration (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:

The Agency for Health Care Administration, ("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.

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.

House Bill 651 amends or deletes duplicative and possibly unnecessary regulatory and reporting requirements. The bill also repeals or revises redundant or obsolete statutory language.

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,

¹ The Agency for Health Care Administration: General Overview February, 2009, on file with the Health Care Policy Committee staff.

² *Id.*

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.³ Registered private utilization review agents pay a \$514 biennial registration fee.

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.⁴

Homemaker and Companion Service Agencies

Homemaker and companion service agencies are registered (not licensed) by the agency pursuant to section 400.509, F.S. A homemaker and companion service organization provides limited services by "homemakers," or persons who perform household chores that include housekeeping, meal planning and preparation, shopping assistance and routine household activities for an elderly, handicapped, or convalescent individual.⁵ "Companions" or "sitters," are persons who spend time with or care for an elderly, handicapped, or convalescent individual and may accompany such individuals on trips and outings and prepare and serve meals to such individuals.⁶ A homemaker, a companion, or a sitter cannot provide hands-on personal care such as bathing, dressing, or personal hygiene, ambulation, or administer medication to a client.⁷

According to the agency, there are 1,892 registered organizations providing homemaker and companion services in Florida as of February 2009.⁸ To date, the agency has handled 168 complaints (231 separate allegations) 64 of which were confirmed, 44 (3%) of which resulted in citations.⁹ Registration costs are not paid for by these providers and over 60 percent of the cost is subsidized by other programs.¹⁰ There are no inspections and no statutory or regulatory minimum quality standards for these providers.

The bill eliminates the requirement that homemaker and companion agencies register with the agency. The elimination of the registration fee would save providers more than \$94,600 every two years due to biennial registration fees and application processing.¹¹

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.¹²

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.¹³ Tests performed using a microscope are not waived.¹⁴ Laboratories that

³ Agency for Health Care Administration: 2009 Bill Analysis & Economic Impact Statement of HB 651.

⁴ Agency for Health Care Administration: 2009 Bill Analysis & Economic Impact Statement of the Proposed Strike-all Amendment to HB 651.

⁵ Section 400.462(16), F.S.

⁶ Section 400.462(7), F.S.

⁷ *Id.*

⁸ Agency for Health Care Administration: 2009 Bill Analysis & Economic Impact Statement of HB 651.

⁹ *Id.*

¹⁰ *Id.*

¹¹ *Id.*

¹² *Id.*

¹³ *Id.*

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.¹⁵ According to the agency, the number of clinical laboratories has continued to grow without the addition of staff, which has affected limited agency resources.

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.¹⁶

Nursing Homes

Nursing home facilities are regulated by the agency pursuant to part II of chapter 400, F.S. Nursing home facilities must notify the agency in writing within one business day of any adverse incident, as defined by statute.¹⁷ Subsequently, the facility must initiate an investigation and provide a complete report to the agency within 15 calendar days of the event. If the facility's risk manager determines that the event in question does not constitute an "adverse incident", the facility must include this information in report submitted to the agency.

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.¹⁸ The various classes of deficiencies are as follows:¹⁹

- 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, 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.

¹⁴ 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 (CFR 42 §493.2).

¹⁵ Agency for Health Care Administration: 2009 Bill Analysis & Economic Impact Statement of HB 651.

¹⁶ Agency for Health Care Administration, email to committee staff March 16, 2009, on file with the Health Regulation Policy Committee.

¹⁷ Section 400.147(7), F.S.

¹⁸ Section 400.23(7), F.S.

¹⁹ Section 400.23(8), F.S.

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.

The bill amends nursing home regulation by:

- **Allowing federal and state (DCF) abuse and neglect reporting to satisfy the adverse incident reporting requirements for abuse and neglect;**
- **Clarifying the definition of an adverse incident to link to facility responsibility;**
- **Removing the monthly bed vacancy reporting requirement and replaces it with a requirement to report bed availability into the Emergency Status System (ESS) when requested by the Agency;**
- **Eliminating the annual report on adverse incidents and liability claims; and**
- **Eliminating the quarterly nurse monitoring function.**

Assisted Living Facilities

Part I of chapter 429, F.S., provides for the licensure and oversight of assisted living facilities by the agency, including a requirement that the agency order or perform assessments to determine client residency needs and provide corrective suggestions prior to issuing a deficiency. 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.²⁰ In addition, the agency is required to host workgroups related to unlicensed activities at each agency office. According to the agency, unlicensed activity is well 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.²¹

In 2005, the Legislature established a pilot program to create an intergenerational assisted living facility and directed the agency to report on its effectiveness.²² To date, the agency has received no requests to participate in the pilot. With regard to adverse incident reporting, abuse, neglect and exploitation are included in the definition of an adverse incident, and must also be reported to the Department of Children and Families' Abuse Hotline.

The bill amends assisted living facility regulation by:

- **Clarifying the definition of an adverse incident to link to facility responsibility;**
- **Eliminating the annual report on adverse incidents and liability claims;**
- **Eliminating the requirement for Agency to order or perform an assessment to determine client residency needs for a decision of a person's continued residency;**
- **Eliminating the requirement for the Agency to offer correction suggestions prior to providing a written deficiency statement;**
- **Eliminating the unlicensed workgroup that is facilitated at each local Agency office; and**
- **Repealing a pilot project for an intergenerational assisted living facility.**

Background Screening in Licensed and Regulated Facilities

Chapter 435, F.S., provides that the Level 1 and 2 screening standards set forth within the chapter apply to employees and employers licensed or regulated pursuant to chapters 400 and 429. In addition, Part II of ch. 408, F.S., the Health Care Licensing Procedures Act, imposes additional requirements on the management of these facilities and entities.

Section 408.809, F.S., provides for Level 2 background screening for each of the following individuals of the facilities and providers:

²⁰ Agency for Health Care Administration: 2009 Bill Analysis & Economic Impact Statement of HB 651.

²¹ *Id.*

²² Section 429.071, F.S.

- 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 provider screening requirements to participate in Florida's Medicaid program are set forth in section 409.907, F.S. That section specifies that each provider, or principal of the provider, seeking to participate in the Medicaid program must submit a complete set of fingerprints to the agency for the purpose of conducting a criminal history record check according to the Level 2 state and national screening standards. In deciding whether to enroll or deny a provider applying to participate as a contractor in the Medicaid program, the agency may consider whether the provider, or any officer, director, agent, managing employee, or affiliated person²³ has been proven to have violated one or more of 11 criminal, civil or other legal offenses enumerated in s. 409.907(10) (a-k), F.S.

The bill adds additional disqualifying offenses for persons requiring background screening and provides uniformity among provider types. These new offenses apply to persons hired after October 1, 2009. The bill also ties the requirement to submit certain background screening forms due annually to the biennial licensure renewal process.

Health Care Clinics

The Agency for Health Care Administration 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. Section 409.991, F.S., provides licensure requirements to ensure that clinics meet basic standards, and provides administrative oversight. An entity that meets the definition of a "clinic" must be licensed as such and must maintain a valid license with the agency. Each clinic location must be licensed separately.

Section 400.9935, F.S., prohibits the medical director of a licensed clinic from making 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.

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.

Uniform Licensing Criteria

In 2006, the Legislature established the Health Care Licensing Procedures Act.²⁴ The Act was created to address unnecessary duplication and variation in the requirements for licensure by the agency.²⁵ The Act was intended to streamline and create a consistent set of basic licensing requirements for all providers in order to minimize confusion, standardize terminology, and include issues that are

²³ This includes any partner or shareholder having an ownership interest equal to 5 percent or greater in the provider if the provider is a corporation.

²⁴ Chapter 2006-192, L.O.F.

²⁵ Section 408.801(2), F.S.

otherwise not adequately addressed in the Florida Statutes pertaining to specific providers.²⁶ The Act applies to the following health care entities:²⁷

- Drug Free Workplace Laboratories, as provided under ss. 112.0455 and 440.102, F.S.;
- Birth Centers, as provided under chapter 383, F.S.;
- Abortion Clinics, as provided under chapter 390, F.S.;
- Crisis Stabilization Units, as provided under parts I and IV of chapter 394, F.S.;
- Short Term Residential Treatment Units, as provided under parts I and IV of chapter 394, F.S.;
- Residential Treatment Facilities, as provided under part IV of chapter 394, F.S.;
- Residential Treatment Centers for Children and Adolescents, as provided under part IV of chapter 394;
- Hospitals, as provided under part I of chapter 395, F.S.;
- Ambulatory Surgical Centers, as provided under part I of chapter 395, F.S.;
- Mobile Surgical Facilities, as provided under part I of chapter 395, F.S.;
- Private Review Agents, as provided under part I of chapter 395, F.S.;
- Health Care Risk Managers, as provided under part I of chapter 395, F.S.;
- Nursing Homes, as provided under part II of chapter 400, F.S.; and
- Assisted Living Facilities, as provided under part III of chapter 400, F.S.

The bill amends the uniform licensing requirements:

- **Simplifying the definition for “change of ownership”;**
- **Establishing a maximum amount of time an application can be submitted in advance to eliminate an application submitted too early and requiring subsequent information updates;**
- **Authorizing the agency to provide electronic information access in lieu of mailing information;**
- **Creating a provisional license for a change of ownership application to allow new operator to demonstrate compliance during an interim period within 6 months of obtaining a license;**
- **Requiring changes in significant information be submitted within 21 days, same as insurance and bonds;**
- **Clarifying record retention and timely deficiency-correction requirements;**
- **Creating uniform definition of classification and scope of deficiencies;**
- **Requiring accreditation documents when accreditation substitutes for licensure inspections;**
- **Allowing the agency to define by rule “acceptance of affidavits” in lieu of conducting certain onsite inspections;**
- **Authorizing uniform rules for emergency planning requirements; and**
- **Requiring participation in the Emergency Status System.**

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.

²⁶ *Id.*

²⁷ Section 408.802, F.S.

- Section 7. Amends s. 400.195, F.S., relating to agency reporting requirements. .
- Section 8. Amends s. 400.464, F.S., relating to home health agencies.
- Section 9. Amends s. 400.497, F.S., relating to rules establishing minimum standards.
- Section 10. Amends s. 400.506, F.S., relating to licensure of nurse registries.
- Section 11. Repeals s. 400.509, F.S., relating to the registration homemaker and companion services.
- Section 12. Amends s. 400.512, F.S., relating to background screening of home health agency, nurse registry, and homemaker and companion personnel.
- Section 13. Amends s. 400.9935, F.S., relating to health care clinic responsibilities.
- Section 14. Amends s. 400.995, F.S., relating to administrative penalties.
- Section 15. Amends s. 408.803, F.S., providing definitions.
- Section 16. Amends s. 408.806, F.S., relating to licensure application processes.
- Section 17. Amends s. 408.807, F.S., relating to change of ownership for health care providers.
- Section 18. Amends s. 408.808, F.S., relating to licensure 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 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. 409.221, F.S., relating to consumer-directed care.
- Section 27. Amends s. 409.901, F.S., providing definitions.
- Section 28. Repeals s. 429.071, F.S., relating to intergenerational respite care assisted living facility pilot program.
- Section 29. Amends s. 429.08, F.S., relating to unlicensed assisted living facilities.
- Section 30. Amends s. 429.14, F.S., relating to administrative penalties.
- Section 31. Amends s. 429.19, F.S., relating to administrative fines.
- Section 32. Amends s. 429.23, F.S., relating to internal risk management of assisted living facilities.

Section 33. Amends s. 429.26, F.S., relating to placements and examination of assisted living facility residents.

Section 34. Amends s. 430.80, F.S., relating to a teaching nursing home pilot project.

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

Section 36. Amends s. 435.05, F.S., relating to background screening requirements for employees.

Section 37. Amends s. 483.031, F.S., relating to clinical laboratories.

Section 38. Amends s. 483.041, F.S., providing definitions.

Section 39. Repeals s. 483.106, F.S., relating to clinical laboratory certificate of exemption.

Section 40. Amends s. 483.172, F.S., relating to clinical laboratory licensure fees.

Section 41. Amends s. 483.23, F.S., relating to offenses and criminal penalties.

Section 42. Amends s. 651.118, F.S., relating to certificates of need.

Section 43. Provides an effective date of the bill 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:
None.
2. Expenditures:
None.

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 in Health Care Trust Fund by the elimination of nurse monitor positions. Costs savings would also be realized through the implementation of electronic notifications and publication of documents. This would greatly cut 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 \$476,000 that are deposited into Health Care Trust Fund due to deregulating the private review agents, homemaker/companion registries, and waived laboratories.

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