The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Health Regulation Committee

BILL:	CS/SB 2286
INTRODUCER:	Health Regulation Committee and Senator Gardiner
SUBJECT:	Agency for Health Care Administration
DATE:	March 26, 2009 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Wilson	HR	**Fav/CS**
2.			JU	
3.			HA	
4.				
5.				
6.				

Please see Section VIII. for Additional Information:

A. COMMITTEE SUBSTITUTE.....	X	Statement of Substantial Changes
B. AMENDMENTS.....		Technical amendments were recommended
		Amendments were recommended
		Significant amendments were recommended

I. Summary:

This committee substitute reduces, simplifies, and facilitates regulation by the Agency for Health Care Administration (Agency) of licensed health care facilities by:

- Eliminating the registration requirements for private utilization review agents, monitoring of nursing homes by quality-of-care monitors, and certification of certain exempt clinical laboratories;
- Eliminating duplicative reporting, certain annual reports, and a multi-agency workgroup;
- Revising conditions which qualify as an adverse event that must be reported by nursing homes and assisted living facilities. Abuse, neglect, or exploitation is no longer classified as an adverse incident and is required to be reported to the Agency within 5 days and immediately to the central abuse hotline;
- Providing additional uniform provisions for facilities licensed by the Agency, including but not limited to: classification rankings of facility deficiencies and submission of plans of correction; additional application submission requirements and timeframes; emergency management provisions; and authority for the Agency to issue provisional or inactive licenses;
- Revising the definition of a change in ownership for facilities licensed by the Agency and under Medicaid;

- Designating additional disqualifying offenses for persons who work with facilities licensed by the Agency; and
- Authorizing access to certain information electronically or from the Agency's internet website.

This committee substitute substantially amends the following sections of the Florida Statutes: 395.405; 400.0712; 400.141; 400.147; 400.162; 400.195; 400.23; 400.506; 400.9935; 400.995; 408.803; 408.806; 408.808; 408.809; 408.810; 408.811; 408.813; 408.820; 408.831; 409.221; 409.901; 429.08; 429.14, 429.19; 429.23; 430.80; 435.04; 435.05; 483.031; 483.041; 483.172; and 651.118.

This committee substitute creates the following section of the Florida Statutes: 408.821.

This committee substitute repeals the following sections of the Florida Statutes: 395.0199; 400.118(2); 429.071; 429.26(9); and 483.106.

II. Present Situation:

Agency for Health Care Administration

The Agency is created in s. 20.42, F.S. The head of the Agency is the Secretary of Health Care Administration. The Agency is the chief health policy and planning entity for the state. It is responsible for health facility licensure, inspection, and regulatory enforcement; investigation of consumer complaints related to health care facilities and managed care plans; the implementation of the certificate-of-need program; the operation of the Florida Center for Health Information and Policy Analysis; the administration of the Medicaid program; the administration of the contracts with the Florida Healthy Kids Corporation; the certification of health maintenance organizations and prepaid health clinics; and other duties prescribed by statute or agreement.

The Agency is responsible for licensing, certifying, or registering the following health care facilities, providers, or programs:

- Abortion Clinics;
- Adult Day Care Centers;
- Adult Family Care Homes;
- Ambulatory Surgical Centers;
- Assisted Living Facilities;
- Birth Centers;
- Clinical Laboratories;
- Commercial HMOs/PHCs/EPOs;
- Comprehensive Outpatient Rehabilitation Facilities;
- Certificate of Need/Financial Analysis (CON/FA);
- Crisis Stabilization Units and Short Term Residential Treatment Facilities;
- Diagnostic Imaging Services;
- Drug-free Workplace Laboratories;
- Extended Congregate Care;
- Health Care Clinics;

- Health Care Services Pools
- Health Flex Plan Program;
- Homes for Special Services;
- Home Health Aides;
- Home Health Agencies;
- Homemaker Companion Organizations;
- Home Medical Equipment Providers;
- Hospices;
- Hospitals;
- Intermediate Care Facilities for the Developmentally Disabled Persons;
- Limited Mental Health;
- Limited Nursing Services;
- Medicaid HMOs;
- Multiphasic Health Testing Centers;
- Nurse Registries;
- Nursing Homes;
- Organ, Tissue and Eye Procurement Organizations;
- Partial Hospitalization Program;
- Portable X-rays;
- Prescribed Pediatric Extended Care Centers;
- Rehabilitation Agencies;
- Residential Treatment Centers for Children and Adolescents;
- Residential Treatment Facilities;
- Risk Management and Patient Safety;
- Risk Managers;
- Rural Health Clinics;
- Transitional Living Facilities; and
- Utilization Review.

In addition to specific authorizing statutes that provide the regulatory structure for these activities, part II of ch. 408, F.S., provides general licensing provisions. The purpose of this part is to provide a streamlined and consistent set of basic licensing requirements for all providers licensed by the Agency in order to minimize confusion, standardize terminology, and include issues that are otherwise not adequately addressed in the Florida Statutes pertaining to specific providers.[1]

Part II of chapter 408, F.S.:

- Provides definitions; the license application process; procedures for a change of ownership; general information about background screening; minimum licensure requirements and Agency action with respect to approving, denying or suspending licenses; inspectional authority; and rulemaking authority;
- Prohibits unlicensed activity; and

[1] s. 408.801, F.S.

- Authorizes the Agency to impose administrative fines and pursue other regulatory and enforcement actions.

Utilization Review Agents

This program consists of registration of an agent who performs utilization review services for third-party payers on a contractual basis for hospital (outpatient or inpatient) services. The registration process does not include full-time employees, personnel, or staff of health insurers, health maintenance organizations, or hospitals, or wholly owned subsidiaries thereof or affiliates under common ownership, when performing utilization review for their respective hospitals, health maintenance organizations, or insurers of the same insurance group. Agents contracted with the federal or state government that perform utilization review of Medicare or Medicaid claims or reviewing workers' compensation claims do not have to be registered under this section. Also, self-insurance funds or service organizations performing reviews of claims pursuant to chapter 440, F.S., or part VII of chapter 626, F.S., are not required to be registered under this section.

The Agency indicates that utilization review agents are not inspected and have no regulatory penalties. There are currently 111 registered agents, 75 of whom are located in other states.

Nursing Homes

Nursing homes are licensed and regulated by the Agency under part II of ch. 400, F.S., part II of ch. 408, F.S., and Chapter 59A-4, Florida Administrative Code (F.A.C.). Nursing homes provide long term and sub-acute care to persons in need of 24-hour nursing services or significant supportive services. Nursing home residents are generally frail, physically and psychosocially compromised, heavily dependent upon others for basic care and sustenance, and in some cases near the end of their lives. When residents live in an environment where they are totally dependent on others, they are especially vulnerable to abuse, neglect, and exploitation.

Nursing home deficiencies are classified according to the nature and scope of the deficiency as follows[2]:

- Class I is a deficiency that the Agency determines presents a situation in which immediate corrective action is necessary because the facility's noncompliance has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident receiving care in a facility.
- Class II is a deficiency that the Agency determines has compromised a resident's ability to maintain or reach his or her highest practicable physical, mental, and psychosocial well-being, as defined by an accurate and comprehensive resident assessment, plan of care, and provision of services.
- Class III is a deficiency that the Agency determines will result in no more than minimal physical, mental, or psychosocial discomfort to a resident or has the potential to compromise a resident's ability to maintain or reach his or her highest practical physical, mental, or psychosocial well-being, as defined by an accurate and comprehensive resident assessment, plan of care, and provision of services.

[2] s. 400.23, F.S.

- Class IV is a deficiency that the Agency determines has the potential for causing no more than a minor negative impact on a resident.

Assisted Living Facilities

Assisted Living Facilities (ALFs) are licensed and regulated by the Agency under part I of ch. 429, F.S., part II of ch. 408, F.S., and Chapter 59A-5, F.A.C.

The ALFs provide housing, meals, personal care services, and supportive services to older persons and disabled adults who are unable to live independently. They are intended to be an alternative to more restrictive, institutional settings for individuals who need housing and supportive services, but who do not need 24-hour nursing supervision. Generally, the ALFs provide supervision, assistance with personal care services, such as bathing, dressing, eating, and assistance with or administration of medications.

The ALFs are licensed to provide routine personal care services under a standard license, or more specific services under the authority of various specialty licenses. The purpose of specialty licenses is to allow individuals to "age in place" in familiar surroundings that can adequately and safely meet their continuing health care needs.

Adverse Incident Reporting

Nursing Homes
Chapter 2001-45, L.O.F., established the internal risk management and quality assurance program for nursing homes. The purpose of this program is to assess patient care practices; review facility quality indicators, facility incident reports, deficiencies cited by the Agency, shared risk agreements, and resident grievances; and to develop plans of action to correct and respond quickly to identified quality deficiencies. Adverse incident reporting is one component of this program.

An adverse incident is defined in s. 400.147(5), F.S., as:

- An event over which facility personnel could exercise control and which is associated in whole or in part with the facility's intervention, rather than the condition for which such intervention occurred, and which results in one of the following:
  - Death,
  - Brain or spinal damage,
  - Permanent disfigurement,
  - Fracture or dislocation of bones or joints,
  - A limitation of neurological, physical, or sensory function,
  - Any condition that required medical attention to which the resident has not given his or her informed consent, including failure to honor advanced directives, or
  - Any condition that required the transfer of the resident, within or outside the facility, to a unit providing a more acute level of care due to the adverse incident, rather than the resident's condition prior to the adverse incident;
- Abuse, neglect, or exploitation as defined in s. 415.102, F.S.;
- Abuse, neglect and harm as defined in s. 39.01, F.S.;
- Resident elopement; or

- An event that is reported to law enforcement.

A facility must initiate an investigation and notify the Agency of minimal information about an incident within one business day after the risk manager has received an incident report from a health care provider, agent, or employee of the nursing home. The minimal information reported includes, but is not limited to, whether the events causing or resulting in the adverse incident represent a potential risk to any other resident. The facility is to complete an investigation into the incident and submit an adverse incident report to the Agency for each adverse incident within 15 calendar days after the occurrence. If, after investigation, the risk manager determines that the incident was not an adverse incident as defined, this determination must be reported to the Agency.

Based on adverse incident reports submitted during 2006, 77.1 percent of the 1-day notifications were subsequently reported by the facility as not meeting the definition of adverse incident upon completing the 15-day investigation. The Agency investigates a portion of the 1-day adverse incident notifications and two such investigations found serious deficiencies; however, both incidents were reported to the Agency as part of a 5-day Federal reporting requirement for mistreatment, neglect, abuse, including injuries of unknown source, and misappropriation of resident property required by federal law.[3]

Assisted Living Facilities
Section 429.23, F.S., provides a similar definition of "adverse incident" for assisted living facilities and has similar reporting requirements, but does not require an assisted living facility to employ a licensed risk manager.

Agency Reporting to the Legislature
The Agency is required to report annually to the Legislature on adverse incidents in nursing homes and assisted living facilities.[4] The report must include the following information arranged by county:

- A total number of adverse incidents;
- A listing, by category, of the types of adverse incidents occurring within each category and the type of staff involved;
- A listing, by category, of the types of injuries, if any, and the number of injuries occurring within each category,
- Types of liability claims filed based on an adverse incident report or reportable injury; and
- Disciplinary action taken against staff, categorized by the type of staff involved.

Health Care Clinics

Certain health care clinics are licensed by the Agency under part X of ch. 400, F.S. A clinic is defined as an entity at which health care services are provided to individuals and which tenders charges for reimbursement for such services, including a mobile clinic and a portable equipment provider.[5] However, there are numerous exceptions to the clinics that must be licensed and

[3] 42 C.F.R. §13(c).
[4] See s. 400.147(14), F.S., for nursing homes and s. 429.23(6), F.S., for assisted living facilities.
[5] s. 400.9905(4), F.S.

subject to regulation under this part. Each clinic subject to licensure must appoint a medical director or clinic director.

Each licensed clinic engaged in magnetic resonance imaging services must be accredited and maintain accreditation by the Joint Commission on Accreditation of Healthcare Organizations, the American College of Radiology, of the Accreditation Association for Ambulatory Health Care, within one year after licensure. However, a clinic may request a single, 6-month extension.

Clinical Laboratories

Certain clinical laboratories are licensed by the Agency under part I of ch. 483, F.S. This part applies to all clinical laboratories within the state except a clinical laboratory:

- Operated by the United States government;
- That performs only waived tests and has received a certificate of exemption from the Agency under s. 483.106, F.S., or
- Operated and maintained exclusively for research and teaching purposes that does not involve patient or public health service.

A waived test is a test that the federal government has determined qualifies for a certificate of waiver under the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA), and the federal rules adopted thereunder.[6] Waived tests include finger sticks for glucose, swabs for strep throat, and pregnancy tests. Laboratories performing waived tests are generally located in physicians' offices or in otherwise licensed health care providers such as nursing homes or home health agencies. Approximately 8,500 of the 12,800 licensed clinical laboratories perform only waived tests.[7]

III. Effect of Proposed Changes:

Section 1. Repeals s. 395.0199, F.S., related to private utilization review and the registration of private utilization review agents.

Section 2. Amends s. 395.405, F.S., to delete the authorization for the department to adopt rules related to s. 395.0199, F.S., which is repealed in section 1 of this committee substitute.

Section 3. Amends s. 400.0712, F.S., to delete a reference to s. 408.831(4), F.S., which is repealed in section 22 of this committee substitute. The substantive legislation, authorizing an inactive license under certain circumstances, is amended into s. 408.821, F.S., in section 21 of this committee substitute.

Section 4. Repeals s. 400.118(2), F.S., to eliminate the quality-of-care monitors for nursing homes.

[6] s. 483.041(10), F.S.
[7] Data received from the Agency.

Section 5. Amends s. 400.141, F.S., to eliminate the requirement for a nursing home to report monthly the number of vacant beds in the facility which are available for resident occupancy on the day the information is reported and to renumber the subsections and paragraphs.

Section 6. Amends s. 400.147, F.S., related to the requirement for a nursing home to report adverse incidents to the Agency, to amend the definition of an adverse incident to include an event over which the nursing home personnel could exercise control and that is reported to a law enforcement Agency or its personnel for investigation. All resident elopements are not required to be reported, only those in which the elopement places the resident at risk of harm or injury. A nursing home is no longer required to report as an adverse incident all instances of abuse, neglect, or exploitation as defined in s. 415.102, F.S., related to adult protective services or abuse, neglect and harm as defined in s. 39.01, F.S., addressing proceedings relating to children. Instead, the committee substitute requires abuse, neglect, or exploitation to be reported to the Agency as required by 42 C.F.R. s. 483.13(c) (within five working days after the incident) and to the Department of Children and Family Services as required by ch. 39, F.S., (proceedings related to children) and ch. 415, F.S., (adult protective services) immediately to the Central Abuse Hotline.

In addition, this committee substitute eliminates the requirement for the Agency to annually submit to the Legislature a report on adverse incidents in nursing homes.

Section 7. Amends s. 400.162, F.S., to require a nursing home to provide a copy of the policy pertaining to minimizing the risk of theft or loss of the personal property of residents to the resident's representative, if appropriate, and to provide a copy of the policy when revised to every employee, resident and resident's representative. The facility is no longer required to post this policy in places accessible to residents.

Section 8. Amends s. 400.195, F.S., related to the Agency's reporting requirements to the Governor and Legislature regarding nursing homes to conform a cross-reference.

Section 9. Amends s. 400.23, F.S., to eliminate the rulemaking authority granted to the Agency regarding nursing home staff providing residents with eating assistance.

Section 10. Amend s. 400.506, F.S., to provide an exception to the prohibition against nurse registries giving remuneration to persons involved in discharge planning or to physicians and their staff for a nurse registry that does not participate in the Medicaid or Medicare program.

Section 11. Amends s. 400.9935, F.S., related to licensed health care clinics to:

- Authorize an accredited clinic, or one that is within the original year after licensure, that replaces its core magnetic resonance imaging equipment 1 year after the equipment is replaced to attain accreditation;
- Require a clinic that files a change-of-ownership application to comply with the original accreditation time requirements of the transferor, otherwise the Agency must deny the application; and
- Require that if the accrediting Agency requires new accreditation because a clinic has added, replaced, or modified equipment for magnetic resonance imaging, then the clinic must be

accredited within 1 year after the addition, replacement, or modification, unless it receives a single 6-month extension from the Agency based on evidence of good cause.

Section 12. Amends s. 400.995(6), F.S., to require the Agency to make a reasonable attempt, during an inspection, to discuss each violation at a health care clinic with the owner, medical director, or clinic director. The committee substitute also eliminates a provision authorizing the Agency to request a plan of corrective action rather than requiring a date certain for compliance with standards to conform with section 18 of the committee substitute which amends the general licensing provisions for facilities licensed by the Agency to authorize the Agency to require an applicant or licensee to submit a plan of correction for deficiencies.

Section 13. Amends s. 408.803, F.S., to revise the definition of "change of ownership" in the general licensing provisions for all facilities licensed by the Agency to mean:

- An event in which the licensee sells or otherwise transfers its ownership to a different individual or other entity as evidenced by a change in federal employer identification number or taxpayer identification number; or
- An event in which 51 percent or more of the ownership, shares, membership, or controlling interest of a licensee is in any manner transferred or otherwise assigned. This paragraph does not apply to a licensee that is publicly traded on a recognized stock exchange.

A change solely in the management company or board of directors is not a change of ownership.

Section 14. Amends s. 408.806, F.S., to revise the general licensing provisions for all facilities licensed by the Agency. In addition to information that is currently required, an application for licensure must include the name, address, and social security number of the administrator or a similarly titled person who is responsible for the day-to-day operation of the provider and the financial officer or similarly titled person who is responsible for the financial operation of the provider. The Agency is required to return a renewal licensure application or any other application or request that is submitted more than 120 days before expiration of the current license or the requested effective date. A licensed adult family-care home is added to the list of facilities that does not require an unannounced inspection. The committee substitute authorizes the Agency to provide electronic access to information or documents as opposed to sending documents.

Section 15. Amends s. 408.408, F.S., to revise the general licensing provisions for all facilities licensed by the Agency to authorize the Agency to issue a provisional license for a limited duration, not to exceed a period of 12 months, to an applicant submitting an application for a change of ownership.

Section 16. Amends s. 408.809, F.S., to revise the general licensing provisions for all facilities licensed by the Agency to require:

- The employer's annual affidavit of compliance with the background screening requirements and annual updates of covered employees to be submitted at the time of license renewal, and
- Effective October 1, 2009, employees required to undergo background screening for employment must not have been found guilty of, regardless of adjudication, or entered a plea of nolo contendere or guilty to an offense prohibited by law or any similar statute of another jurisdiction identified in:
    - Any authorizing statute, if the offense was a felony,

- Chapter 408, F.S., relating to healthcare administration, if the offense was a felony, or
- An additional 17 statutory sections or chapters.

The committee substitute exempts a person who serves as a controlling interest of or is employed by a licensee on September 30, 2009, from rescreening for these offenses if the person has been screened and qualified under the standards specified in s. 435.03 or s. 435.04, relating to level I and level II background screening, and authorizes such a person to apply for an exemption before September 30, 2009, and continue working, upon agreement by the employer, pending the Agency's decision on the exemption request.

This section of the committee substitute also deletes the exemption from background screening requirements for clinical laboratories applying for a certificate of exemption to conform to the repeal of the application for certificate of exemption provisions in section 36 of the committee substitute.

Section 17. Amends s. 408.810, F.S., to revise the general licensing provisions for all facilities licensed by the Agency to provide that, unless otherwise specified, any information required to be reported to the Agency must be submitted within 21 calendar days after the report period or effective date of the information, *whichever occurs earlier* and specifies that this includes, but is not limited to any change of information contained in the most recent application for licensure and required insurance or bonds.

Section 18. Amends s. 408.811, F.S., to revise the general licensing provisions for all facilities licensed by the Agency to:

- Authorize an inspection conducted in conjunction with a comparable licensure requirement or a recognized or approved accreditation organization to be accepted in lieu of a complete licensure inspection;
- Require a licensee to send to the Agency, upon request, copies of all provider records required during an inspection or other review at no cost to the Agency, including records requested during an off-site review;
- Require a licensee to correct deficiencies within 30 calendar days after the last day of an inspection unless an alternative timeframe is required or approved by the Agency;
- Authorize the Agency to require an applicant or licensee to submit a plan of correction for deficiencies within 10 calendar days after notification unless an alternative timeframe is required.

Section 19. Amends s. 408.813, F.S., to revise the general licensing provisions for all facilities licensed by the Agency to provide for a uniform classification ranking for violations of requirements imposed by law or rule on a licensee. Violations are classified according to the nature of the violation and the gravity of its probable effect on clients. The scope may be cited as isolated, patterned, or widespread. The violations are classified ranging from a class I violation, which is the most severe, to a class IV violation.

Section 20. Amends s. 408.820, F.S., to revise the general licensing provisions for all facilities licensed by the Agency to:

- Remove the exemptions related to private review agents to conform to the repeal of private review agents in section 1 of the committee substitute;

- Exempt a health care risk manager from minimum licensure requirements that relate to operation of a provider and providing services to a client rather than all licensure requirements. As a result, a health care risk manager is required to comply with background screening requirements; provide an explanation of any exclusions, suspensions, or terminations from Medicare or Medicaid; and comply with reporting deadlines;
- Require transitional living facilities to comply with insurance provisions, if proof of insurance is required by the authorizing statutes. Currently proof of insurance is not a statutory requirement in part V of ch. 400, F.S., for transitional living facilities; and
- Subject health care clinics to the background screening provisions in s. 408.809, F.S., which are more comprehensive than the background screening provisions in part X of ch. 400, F.S., specifically related to health care clinics.

Section 21. Creates s. 408.821, F.S., within the general licensing provisions for all facilities licensed by the Agency to address emergency management planning, emergency operations, and inactive licensure status. Specifically this section:

- Requires a licensee that is required to have an emergency operations plan to designate a liaison officer to serve as primary contact related to emergency operations;
- Authorizes a licensee to exceed its licensed capacity to act as a receiving provider, in accordance with an approved emergency operations plan, for up to 15 days. This period may be extended upon Agency approval of a request providing satisfactory justification and need. This provision is moved from s. 408.831(3), F.S., which is repealed in section 22 of this committee substitute;
- Authorizes the Agency to issue an inactive license when a provider is located in a geographic area where a state of emergency was declared by the Governor and certain other conditions are met. An inactive license may be issued for a period not to exceed 12 months, and may be renewed by the Agency for up to an additional 12 months. This provision is moved from s. 408.831(4), F.S., which is repealed in section 22 of this committee substitute; and
- Authorizes the Agency to adopt rules related to emergency management planning, communications, and operations.

Section 22. Amends s. 408.831, F.S., to delete provisions regarding a licensee exceeding its licensed capacity and the issuance of an inactive license during a state of emergency. The substance of these provisions is re-enacted in s. 408.821, F.S., in section 21 of this committee substitute.

Section 23. Amends s. 409.221, F.S., related to consumer-directed care to conform a cross-reference.

Section 24. Amends s. 409.901, F.S., to revise the definition for "change of ownership" related to the Medicaid program. "Change in ownership" means:

- An event in which the provider ownership changes to a different individual entity as evidenced by a change in federal employer identification number or taxpayer identification number;
- An event in which 51 percent or more of the ownership, shares, membership, or controlling interest of the provider is in any manner transferred or otherwise assigned. This paragraph does not apply to a licensee that is publicly traded on a recognized stock exchange; or

- When the provider is licensed or registered by the Agency, an event considered a change of ownership for licensure as defined in s. 408.803, F.S.

A change solely in the management company or board of directors is not a change of ownership.

Section 25. Repeals s. 429.071, F.S., related to a pilot program enacted in 2005 for intergenerational respite care assisted living facilities.

Section 26. Amends s. 429.08, F.S., to authorize the Agency to publish certain information related to ALFs electronically and to eliminate the requirement for a local coordinating workgroup of various state agencies, ombudsman councils, and advisory committees charged with identifying unlicensed ALFs. The committee substitute also removes the non-criminal penalty and fine for knowingly referring a person to an ALF that does not have a valid and unencumbered license; expands the prohibition of knowingly discharging a patient or client to an unlicensed ALF to all providers as defined in the general licensing provisions; and eliminates requirements that the Agency must provide to various persons information regarding licensed ALFs.

Section 27. Amends s. 429.14, F.S., to conform language related to administrative penalties and deficiencies.

Section 28. Amends s. 429.19, F.S., to delete the definitions of a class I, class II, class III, and class IV violation related to ALFs and refer to the definition of these classes of violations in the general licensing provisions for all facilities licensed by the Agency in section 19 of this committee substitute, which amends s. 408.813, F.S. The administrative fines associated with these classes of violations remain unchanged, within this section. The Agency is required to document, during an inspection, any action taken to correct a violation and the requirement for the Agency to recommend corrective action has been removed from the law. Potential corrective action is deleted from this section since this provision is included within section 18 of this committee substitute, which amends s. 408.811, F.S.

Section 29. Amends s. 429.23, F.S., related to the requirement for an ALF to report adverse incidents to the Agency. An adverse incident is amended to include an event over which the ALF personnel could exercise control and that is reported to a law enforcement Agency or its personnel for investigation. All resident elopements are not required to be reported, only those in which the elopement places the resident at risk of harm or injury. An ALF is no longer required to report as an adverse incident all instances of abuse, neglect, or exploitation as defined in s. 415.102, F.S., related to adult protective services or abuse, neglect and harm as defined in s. 39.01, F.S., addressing proceedings relating to children. Instead, the committee substitute requires abuse, neglect, or exploitation to be reported to the Agency as required by 42 C.F.R. s. 483.13(c) (within five working days after the incident) and to the Department of Children and Family Services as required by ch. 39, F.S., (proceedings related to children) and ch. 415, F.S., (adult protective services) immediately to the Central Abuse Hotline.

In addition, this committee substitute eliminates the requirement for the Agency to annually submit to the Legislature a report on adverse incidents in ALFs.

Section 30. Repeals s. 429.26(9), F.S., requiring a medical assessment of a resident in an ALF when the resident appears to need care beyond that which the facility is licensed to provide and the determination by a medical review team of the appropriateness of the resident's continued placement in that facility.

Section 31. Amends s. 430.80, F.S., related to implementation of a teaching nursing home pilot project to conform a cross-reference.

Section 32. Amends s. 435.04, F.S., to allow employers of employees who are in positions of trust or responsibility and are subject to background screening as a part of being licensed or registered by a state Agency to submit to the licensing agency, either annually or *at the time of license renewal*, an affidavit of compliance with the requirement that the employees attest to meeting the requirement for qualifying for employment and agree to inform the employer immediately if convicted of any disqualifying offenses while employed by the employer.

Section 33. Amends s. 435.05, F.S., to allow each employer that is required to conduct level 2 background screening to sign an affidavit annually *or at the time of license renewal*, stating that all covered employees have been screened or are newly hired and are awaiting the results of the required screening checks.

Section 34. Amends s. 483.031, F.S., to conform a provision related to a clinical laboratory to reflect the repeal of the certificate of exemption in section 36 of this committee substitute.

Section 35. Amends s. 483.041, F.S., to substitute "Centers for Medicare and Medicaid Services" for Health Care Financing Administration in a definition related to clinical laboratories.

Section 36. Repeals s. 483.106, F.S., to eliminate the requirement for a certificate of exemption for a clinical laboratory that performs only waived tests.

Section 37. Amends s. 483.172, F.S., to remove the biennial license fee of $100 for a certificate of exemption to conform to the repeal of the certificate of exemption in section 36 of this committee substitute.

Section 38. Amends s. 651.118, F.S., related to certificates of need to conform a cross-reference.

Section 39. Provides an effective date upon becoming a law.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this committee substitute have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of the committee substitute have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this committee substitute have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The Agency indicates that elimination of the:

- Registration of private utilization review agents will save the 111 providers currently registered approximately $57,054 based on a $514 biennial registration fee; and
- Certification of waived labs will save providers between $800,000 and $900,000 in fees every two years and avoid duplication of federal requirements and litigation costs for late or "failed to renew" applicants, which are numerous.

C. Government Sector Impact:

The elimination of the interagency workgroup will provide for greater efficiency and use of limited staff resources.

VI. Technical Deficiencies:

None.

VII. Related Issues:

Governor Crist vetoed Senate Bill 686 that passed during the 2008 Legislative session. This committee substitute made several changes to nursing home regulatory rules. Notably, the committee substitute revised the manner in which nursing facilities report and investigate adverse incidents related to residents. The veto message stated that under current Florida law, nursing facilities must notify [the Agency] within one business day of an adverse incident. Senate Bill 686 deleted this requirement and instead permitted the facility's internal risk manager to determine if an incident was adverse before filing the report. Current law provides the opportunity for the Agency to investigate incidents, as it deems appropriate, in order to prescribe measures that should be taken. Governor Crist stated that he believes that facilities responsible for providing care to our most vulnerable citizens must remain under strict scrutiny and existing law provides for this accountability and oversight. He stated that he is committed to ensuring the highest standards of care to protect the safety and dignity of Florida's seniors. He further stated

that throughout his career, he worked to reduce abuse and neglect against seniors, and he does not believe that the state should take any steps backwards in these efforts. Accordingly, to the extent that this committee substitute (CS/SB 2286) changes the definition of an adverse incident in a nursing home and the accompanying immediate reporting to the Agency of abuse, neglect, or exploitation, the committee substitute contains a similar provision that might prompt the Governor to veto the bill.

VIII. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Regulation Committee on March 25, 2009:
The committee substitute makes the following substantive changes:

- Eliminates the quality-of-care monitors for nursing homes;
- Requires a nursing home to provide a copy of the policy pertaining to minimizing the risk of theft or loss of the personal property of residents to the resident's representative, if appropriate, and to provide a copy of the policy when revised to every employee, resident and resident's representative. The facility is no longer required to post this policy in places accessible to residents;
- Eliminates the rulemaking authority granted to the Agency regarding nursing home staff providing residents with eating assistance;
- Provides an exception to the prohibition against nurse registries giving remuneration to persons involved in discharge planning or to physicians and their staff for a nurse registry that does not participate in the Medicaid or Medicare program;
- Reinstates the requirement that homemaker and companion organizations register with the Agency;
- Reinstates the prohibition on a medical director referring a patient to the licensed clinic if the clinic performs magnetic resonance imaging or related types of testing;
- Reinstates the requirement for the Agency to discuss with appropriate management at a licensed medical clinic or ALF each violation noted during an inspection;
- Revises the (revised) definition of a change of ownership in the general licensing provisions and under Medicaid;
- Eliminates the proposed requirement that an applicant for a change in ownership provide the Agency with the effective date of the change and final closing documents;
- Extends the period of time for a provisional license related to a change in ownership from 6 months to 12 months;
- Substitutes "a person who serves as a controlling interest of a licensee" for "a person affiliated with a licensee" in the provisions related to exemption requests for new disqualifying offenses;
- Eliminates the requirement for the Agency to consult with the Department of Community Affairs when it adopts rules relating to emergency management planning, communications, and operations;
- Expands the prohibition of knowingly discharging a patient or client to an unlicensed ALF to all providers as defined in the general licensing provisions;
- Eliminates requirements that the Agency must provide to various persons information regarding licensed ALFs; and

- Eliminates the section of the bill revising the criminal offenses related to clinical laboratories.

B. Amendments:

None.