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 1884
INTRODUCER:	Health Regulation Committee and Senator Garcia
SUBJECT:	Health Regulation by the Agency for Health Care Administration
DATE:	February 2, 2012 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Stovall	HR	**Fav/CS**
2.			BI	
3.				
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:

The bill streamlines regulations for providers regulated by the Agency for Health Care Administration (AHCA) by repealing obsolete or duplicative provisions in licensing laws and reforming regulations related to inspections, electronic publication of documents and reports, timeframes for reporting licensure changes, and financial information and bonds.

Additionally, the bill makes the following substantive changes:

- Expands the authorized staffing of a geriatric outpatient clinic in a nursing home to include a licensed practical nurse under the direct supervision of a registered nurse, advanced registered nurse practitioner, or physician;
- Eliminates the requirement for a resident care plan to be signed by certain persons;
- Authorizes home health agencies and nurse registries to provide small token items of minimum value (up to $15 individually) to referring entities without penalty;
- Authorizes an administrator of a nurse registry to manage up to five nurse registries in certain circumstances;
- Expands the definition of a portable equipment provider within the requirements for a health care clinic license to include a portable *health service* or equipment provider;
- Provides additional exemptions for licensure and regulation as a health care clinic;

- Enhances the general licensing provisions of part II of ch. 408, F.S., to:
  - Provide that the license renewal notice that the AHCA sends is a *courtesy* notice;
  - Authorize the AHCA to impose an administrative fine, not to exceed $500 per violation, for violations that do not qualify within the classification scheme of class I – class IV violations; an
  - Prohibit activities related to altering, defacing, or falsifying a license certificate;
- Authorizes the AHCA to impose an administrative fine for class IV violations that are uncorrected or repeated by a licensed intermediate care facility for developmentally disabled persons;
- Effective May 1, 2012, limits the applicability of the subscriber assistance program to health plans that meet the grandfathered provisions under the federal Patient Protection and Affordable Care Act;
- Authorizes the AHCA to post prior-authorization and step-edit criteria related to certain drugs on the AHCA's website within 21 days after approval;
- Revises the membership of the Medicaid Pharmaceutical and Therapeutics Committee and requires a minimum amount of time for each presenter at the committee meetings;
- Effective upon the act becoming a law, declares that each essential provider and each hospital that are necessary for a managed care plan to demonstrate an adequate network for enrollment in the statewide Medicaid Managed Care Program are part of that plan's network, and provides for a payment rate for those providers;
- Authorizes advanced registered nurse practitioners to license and operate a clinical laboratory in certain situations;
- Prohibits a licensed clinical laboratory from placing a specimen collector in any physician's office unless they are co-owned, and establishes a private cause of action to an aggrieved person;
- Authorizes a virtual inventory for certain prescription drugs that were purchased under the 340B program;
- Effective May 1, 2012, requires certain individual, group, blanket, and franchise health insurance policies to comply with the NAIC's Uniform Health Carrier External Review Model Act in accordance with rules adopted by the Office of Insurance Regulation and certain provisions of the ERISA relating to internal grievances;
- Designates the Florida Hospital/Burnham Translational Research Institute as a state resource for research in diabetes diagnosis, prevention, and treatment; and
- Directs the Division of Statutory Revision to assist the substantive committees of the Senate and House of Representatives with drafting legislation to correct the names of accrediting organizations in the Florida Statutes.

This bill substantially amends the following sections of the Florida Statutes: 83.42, 112.0455, 318.21, 395.002, 395.003, 395.0161, 395.0193, 395.1023, 395.1041, 395.1055, 395.3025, 395.3036, 395.602, 400.021, 400.275, 400.474, 400.484, 400.506, 400.509, 400.601, 400.606, 400.915, 400.931, 400.967, 400.9905, 400.991, 408.033, 408.034, 408.036, 408.037, 408.043, 408.061, 408.07, 408.10, 408.7056, 408.804, 408.806, 408.8065, 408.809, 408.810, 408.813, 409.91195, 409.912, 409.975, 429.294, 429.915, 430.80, 430.81, 483.035, 483.051, 483.245, 483.294, 499.003, 627.602, and 651.118.

The bill repeals the following sections of the Florida Statutes: 383.325, 395.1046, 395.3037, 408.802(11), 429.11, and 440.102(9)(d).

The bill creates the following sections of the Florida Statutes: 385.2031, 627.6513, and, 641.312, and three undesignated sections of law.

II. Present Situation:

Health Care Licensing

The AHCA regulates over 41,000 health care providers under several regulatory programs based upon individual licensing statutes and the general licensing provisions in part II of ch. 408, F.S. The health care providers include:

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

- Organ, tissue, and eye procurement organizations, as provided under part V of ch. 765, F.S.

The general licensing provisions contain standards for licensure application requirements, ownership disclosure, staff background screening, inspections, and administrative sanctions. Each provider type has an authorizing statute (as listed above) that includes unique provisions for licensure beyond the general licensing provisions. If a conflict exists between the general licensing provisions and the authorizing statute, s. 408.832, F.S., provides that the general licensing provisions prevail.

There are several references in the authorizing statutes that conflict or duplicate regulations in the general licensing provisions, including references to the classification of deficiencies, penalties for an intentional or negligent act by a provider, provisional licenses, proof of financial ability to operate, inspection requirements, and plans of corrections from providers.

The AHCA mails license renewal notices by certified mail to over 30,000 providers every 2 years. Reminder notices are sent by certified mail to verify receipt by the providers. Many other regulatory agencies send postcards or some other form of license reminder notices that are less expensive and more easily delivered.

Section 408.10(2), F.S., provides authority to review billing complaints across all programs and gives the impression that the AHCA can take issue with all billing practices. However, without a specific regulatory standard in the licensing standards of a provider, the AHCA cannot cite violations. Several licensing regulations include billing standards for providers such as nursing homes and assisted living facilities. When a complaint is received for one of the providers where the AHCA has authority over billing matters, a review for regulatory compliance would still occur. Violations found are made public as part of routine inspection reports which are posted online.

For calendar year 2011, the AHCA received 436 complaints that alleged billing-related issues. Of those, 126 were for providers that have billing standards in their licensure statutes. The remaining 310 were related to billing issues where no regulatory authority existed for billing matters. In these cases, the AHCA does not have authority to require a health care provider to act in a particular manner. There is no regulatory standard for "unreasonable and unfair" billing practices as used in s. 408.10(2), F.S.[1]

Nursing Homes

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, Agency for Health Care Administration 2012 Bill Analysis for SB 1884, on file with the Senate Health Regulation Committee near the end of their lives. Such residents who live in an environment where they are totally dependent on others are especially vulnerable to abuse, neglect, and exploitation.

[1] Agency for Health Care Administration *2012 Bill Analysis for SB 1884*, on file with the Senate Health Regulation Committee.

Nursing homes are subject to regulation under part II of ch. 400, F.S., the general licensing provisions of part II, of ch. 408, F.S., and the minimum standards for nursing homes found in Rule chapter 59A-4, F.A.C. In addition, nursing homes that receive funding from Medicare or Medicaid are subject to federal standards and conditions of participation as certified Medicare or Medicaid providers.

Rule 59A-4.1295(8), F.A.C., sets forth the minimum staffing requirements for residents less than 21 years of age, who require skilled care. For those residents there must be one registered nurse onsite 24 hours a day where the children reside, and the facility must provide an average of 3.5 hours of nursing care per patient day. This number includes registered nurses (RN), licensed practical nurses (LPN), respiratory therapists (RT), respiratory care practitioners and certified nursing assistants (CNA). In determining the nursing hours, there may be no more than 1.5 hours per patient day of CNA care and no less than 1.7 hours per patient day of LPN care. For fragile residents less than 21 years of age, one RN is required onsite 24 hours per day with an average of 5.0 hours of nursing care required per patient day. This also includes RNs, LPNs, and respiratory therapists, respiratory care practitioners and CNAs. If more than 42 children are in the facility, there can be no fewer than two RNs on duty onsite for 24 hours per day. Section 400.23, F.S., requires at least 3.9 hours of licensed nursing and CNA direct care per resident per day.

The minimum staffing requirements in s. 400.23, F.S., have changed since the rule language was last amended. During rule development, the Joint Administrative Procedures Committee (JAPC) informed the AHCA that according to rule 120.52(8)(c), F.A.C., a rule which "enlarges, modifies or contravenes the specific provisions of law implemented" is an "invalid exercise of delegated legislative authority." According to the JAPC, the rule's staffing requirements must comport with the current version of s. 400.23, F.S. The AHCA proposed amending language in rule to be consistent with these legal requirements of minimum staffing. The AHCA attempted to repeal portions of the current rule. Opponents to this action challenged the rule.[2]

Home Health Agencies and Nurse Registries

Home health agencies and nurse registries are regulated under part III of ch. 400, F.S., the general licensing provisions of part II, of ch. 408, F.S., and applicable rules found in Rule chapters 59A-8 and 59A-18, F.A.C.

Home health agencies are organizations that are licensed by the AHCA to provide home health services and staffing services. Home health services are health and medical services and medical supplies furnished to an individual in the individual's home or place of residence. The services include:

- Nursing care;
- Physical, occupational, respiratory, or speech therapy;
- Home health aide services, also referred to as personal services (assistance with daily living activities, such as bathing, dressing, eating, personal hygiene, ambulation, and assisting with the administration of medication if trained to do so);
- Dietetics and nutrition practice and nutrition counseling; and

[2] *Id.*

- Medical supplies, restricted to drugs and biologicals prescribed by a physician.[3]

A home health agency may also provide homemaker and companion services without additional licensing or registration. These services do not involve hands-on personal care to a client and typically include housekeeping, meal planning and preparation, shopping assistance, routine household activities, and accompanying the client on outings.

Section 400.474, F.S., authorizes the AHCA to deny, revoke, or suspend the license of a home health agency and requires the AHCA to impose a $5,000 fine against a home health agency that commits certain acts. One of these acts is the failure of the home health agency to submit a report, within 15 days after the end of each calendar quarter that includes the following information:

- The number of insulin-dependent diabetic patients receiving insulin-injection services from the home health agency;
- The number of patients receiving both home health services from the home health agency and hospice services;
- The number of patients receiving home health services from that home health agency; and
- The names and license numbers of nurses whose primary job responsibility is to provide home health services to patients and who received remuneration from the home health agency in excess of $25,000 during the calendar quarter.

These data items help identify possible fraud, such as billing for a high number of injection visits for insulin-dependent patients who could self-inject insulin, fraudulent billing for patients who did not receive the visits, possible duplicate payments for patients receiving both hospice and home health services, and nurses earning well above the average salary that could indicate false billing. The results of each quarter's reporting are shared with the U.S. Department of Health and Human Services Centers for Medicare and Medicaid Services' Medicare Program Integrity Miami Satellite Division, the AHCA's Medicaid Program Integrity Office, and the Medicare Fraud Investigations Manager at SafeGuard Services, LLC.

A nurse registry 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. Such personnel are compensated by fees as independent contractors. The contracts for services might include providing services to patients as well as providing private duty or staffing services to health care facilities or other business entities.[4]

Homemaker and Companion Services

Section 400.509, F.S., requires the registration of organizations that provide homemaker and companion or sitter services to disabled adults and elderly persons. Homemakers provide housekeeping, errands, shopping, and meal preparation. Companions or sitters keep people company and take them to recreational activities, shopping, or appointments. There are no

[3] Section 400.462(14), F.S.
[4] Section 400.462(21), F.S.

requirements of homemakers and companions other than background screening. Homemakers and companions or sitters may not provide any hands-on personal care according to state law.[5]

The AHCA currently has registered 2,203 homemaker and companion services organizations. Of that total, 503 are contractors of the Agency for Persons with Disabilities and provide companion services through the Developmental Disabilities Medicaid Waiver. The Agency for Persons with Disabilities requires training and experience as well as background screening.[6]

The 1999 Florida Legislature exempted from home health agency and nurse registry licensing, the companion and sitter organizations that were registered by the AHCA on January 1, 1999, and authorized them to provide personal services to developmentally disabled persons to any past, present and future clients who need personal care services[7] Currently there are seven organizations exempt under this law.[8]

Laboratory Licensure

Clinical laboratory providers seeking to perform non-waived tests must by licensed by the AHCA and hold a valid federal CLIA certificate before any testing may be done.[9] Non-waived testing is not currently defined.

Clinical laboratory hospital providers are required to report any alternate testing locations within the hospital at the time of licensure renewal. All alternate locations are under the direction of the clinical laboratory director and documented in hospital laboratory records.

Clinical laboratories are prohibited from offering rebates, commissions, bonuses, split-fee arrangements, and kickbacks.[10] What constitutes a rebate, commission, bonus, split-fee arrangement or kickback is not defined in statute. The AHCA defined the term "kickback" under Rule 59A-7.020(14), F.A.C. The AHCA was petitioned for a declaratory statement related to the placing of specimen collections in physician offices when there was no lease agreement and whether or not laboratories could provide free specimen cups that also provided an on-site clinical laboratory test. The AHCA issued a declaratory statement in 2008, declaring that the placement of specimen collectors as described in the petition in a physician office was a violation of this regulation, as was the provision of free specimen cups that offered physicians an instant test reading on-site.[11] There is currently pending litigation related to the AHCA's interpretation of what constitutes a kickback as defined under this administrative rule. Clarification in other areas was provided in a letter to providers dated August 5, 2011.[12]

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[5] Section 400.462(7) and, (16), F.S.
[6] *Supra*, fn 1.
[7] Section 400.464(5)(b)4., F.S.
[8] *Supra*, fn 1.
[9] *See* part III of ch. 483, F.S.
[10] Section 483.245, F.S.
[11] The Declaratory Statement and Final Order is available at: <http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Laboratory_Licensure/docs/FinalOrderDominion2008.pdf.> (Last visited on January 29, 2012).
[12] This letter is available at: <http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Laboratory_Licensure/kickback.shtml> (Last visited on January 29, 2012).

Aggrieved parties are currently able to bring action in civil cases.

Advanced Registered Nurse Practitioners are not listed as practitioners with the ability to diagnose and treat their own patients using clinical laboratory tests even though they are authorized under practitioner regulations to operate their own practices.

Specialty-licensed Children's Hospitals / High Risk Pregnancies

There are three specialty-licensed children's hospitals in the state. All Children's Hospital in Tampa has 97 licensed neonatal intensive care unit (NICU) beds,[13] Miami Children's Hospital has 51 Level II and Level III NICU beds,[14] and Nemours Pediatric Partners at AtlantiCare in Jacksonville has 22 NICU beds.[15]

Risk factors for a high-risk pregnancy can include:
- Young or old maternal age;
- Being overweight or underweight;
- Having had problems with previous pregnancies; and
- Pre-existing health conditions, such as high blood pressure, diabetes, or HIV.[16]

Medicaid Pharmaceutical and Therapeutics Committee

The Medicaid Pharmaceutical and Therapeutics Committee (P&T) is established in s. 409.91195, F.S. The purpose of the P&T is to develop a Medicaid preferred drug list (PDL). The committee is composed of 11 members who are appointed by the Governor. Four members must be allopathic physicians licensed under ch. 458, F.S., one member must be an osteopathic physician licensed under ch. 459, F.S., five members must be pharmacists licensed under ch. 465, F.S., and one member must be a consumer representative.

The P&T is required to ensure that interested parties, including pharmaceutical manufacturers agreeing to provide a supplemental rebate, have an opportunity to present public testimony concerning information or evidence supporting inclusion of a product on the PDL before the P&T makes any recommendation for inclusion on or exclusion.

Currently, the AHCA limits public presentations at committee meetings to 10 speakers for 2 minutes each. Overall, the public testimony portion consumes about 30 minutes of the 4-hour meeting slot. Unlimited testimony could be accommodated by written submission in lieu of public testimony or by altering the amount of time available for public testimony based upon historic participation and allocating the amount of time to each speaker dependent upon the number of individuals wishing to speak.[17]

[13] See <http://www.allkids.org/body.cfm?id=14> (Last visited on January 28, 2012).
[14] See <http://www.mch.com/page/EN/256/Medical-Services/Neonatology.aspx> (Last visited on January 28, 2012).
[15] See <http://www.nemours.org/filebox/healthpro/patientreferral/npppomonanicu.pdf> (Last visited on January 28, 2012).
[16] National Institutes of Health <http://www.nichd.nih.gov/health/topics/high_risk_pregnancy.cfm> (Last visited on January 28, 2012).
[17] *Supra,* fn 1.

Statewide Medicaid Managed Care

Medicaid is the medical assistance program that provides access to health care for low-income families and individuals. Medicaid also assists aged and disabled people with the costs of nursing facility care and other medical expenses. The AHCA is responsible for Medicaid. Medicaid serves approximately 3.19 million people in Florida. Estimated Medicaid expenditures for fiscal year 2011-2012 are approximately $20.3 billion. The statutory authority for the Medicaid program is contained in part III of ch. 409, F.S.

Part IV of ch. 409, F.S., requires all Medicaid recipients to enroll in a managed care plan unless they are specifically exempted. The statewide Medicaid managed care program includes the long-term care managed care program and the managed medical assistance program. The law directs the AHCA to begin implementation of the long-term care managed care program by July 1, 2012, with full implementation in all regions of the State by October 1, 2013. By January 1, 2013, the AHCA must begin implementation of the managed medical assistance program, with full implementation in all regions of the State by October 1, 2014.

Plans will compete for Medicaid contracts via an invitation-to-negotiate process based on specified qualifications, such as price, provider network adequacy, accreditation, community partnerships, additional benefit offerings, and performance history.[18] A limited number of plans will be selected for each of the 11 regions. Among other things, the AHCA must consider evidence that an eligible plan has written agreements or signed contracts, or has made substantial progress in establishing relationships with providers before the plan submits a response. The agency must evaluate and give special weight to evidence of signed contracts with essential providers.[19]

The AHCA, at a minimum, shall determine which providers in the following categories are essential Medicaid providers: federally qualified health centers, statutory teaching hospitals, trauma centers, and hospitals that are located at least 25 miles from any other hospital with similar services.[20]

Managed care plans that have not contracted with applicable essential providers must negotiate in good faith for one year or until an agreement is reached, whichever is first. Payment for services rendered by a nonparticipating essential provider shall be made at the applicable Medicaid rate as of the first day of the contract between the AHCA and the plan. After 1 year, managed care plans that are unable to contract with essential providers shall notify the AHCA and propose an alternative arrangement for securing the essential services. If the alternative arrangement is approved by the AHCA, payments to nonparticipating essential providers after the date of the AHCA's approval shall equal 90 percent of the applicable Medicaid rate. If the alternative arrangement is not approved by the AHCA, the payment rate to a nonparticipating provider shall equal 110 percent of the applicable Medicaid rate.

In addition, certain providers are statewide resources and essential providers for all managed care plans in all regions. All managed care plans must include these essential providers in their

[18] Section 409.966, F.S.
[19] Section 409.974, F.S.
[20] Section 409.975, F.S.

networks. Managed care plans that have not contracted with all statewide essential providers in all regions as of the first date of recipient enrollment must continue to negotiate in good faith. The statewide essential providers and applicable payment rates for the nonparticipating statewide essential providers set forth in statute are:[21]

- For facility plans of Florida medical schools, payment shall be made at the applicable Medicaid rate;
- For regional perinatal intensive care centers, payment shall be made at the applicable Medicaid rate as of the first day of the contract between the AHCA and the plan; and
- For specialty children's hospitals, payment shall equal the highest rate established by contract between that provider and any other Medicaid managed care plan.
- Certain accredited and integrated systems serving medically complex children are identified as statewide essential providers; however no payment rate is specified in statute.

Health Maintenance Organization (HMO) Subscriber Grievance Resolution

Parts I and III of ch. 641, F.S., govern HMOs in Florida. Section 641.185, F.S., relating to HMO subscriber protections, establishes standards to be followed by the Financial Services Commission, the Office of Insurance Regulation (OIR), the Department of Financial Services, and the AHCA in exercising their powers and duties, in exercising administrative discretion, in administrative interpretations of the law, in enforcing its provisions, and in adopting rule. Two of these standards relate to subscriber grievances and provide the following:

- An HMO subscriber should receive timely and, if necessary, urgent review of grievances and appeals *within* the HMO pursuant to:
  - s. 641.228, F.S., relating to the Florida HMO Consumer Assistance Plan that is established to protect subscribers against the failure of an HMO to perform its contractual obligations due to its insolvency;
  - s. 641.31(5), F.S., relating to HMO subscriber contracts, which must provide information about resolution of subscriber grievances, including subscribers' rights and responsibilities under the grievance process;
  - s. 641.47, F.S., which defines the term "grievance"; and
  - s. 641.511, F.S.; which establishes internal HMO subscriber grievance reporting and resolution requirements.
- An HMO should receive timely and, if necessary, urgent review by an independent state external review organization for unresolved grievances and appeals pursuant to s. 408.7056, F.S., the Subscriber Assistance Program.

Under s. 641.511, F.S., the Employee Retirement Income Security Act of 1974 (ERISA), as implemented by 29 C.F.R. s. 2560.503-1, is adopted and incorporated by reference as applicable to all HMOs that administer small and large group health plans that are subject to 29 C.F.R. s. 2560.503-1. The claims procedures of the regulations of the ERISA, are the minimum standards for grievance processes for claims for benefits for applicable small and large group health plans.

[21] *Id.*

Subscriber Assistance Program

Under s. 408.7056, F.S., the AHCA administers the Subscriber Assistance Program to provide assistance to subscribers of managed care entities who have grievances that have not been resolved by the internal grievance process of the managed care entity. Managed care entities covered by the program include HMOs or a prepaid health clinics certified under ch. 641, F.S., Medicaid prepaid health plans authorized under s. 409.912, F.S, or exclusive provider organizations certified under s. 627.6472, F.S.

The subscriber must first complete the entire grievance process of the managed care entity before filing a grievance with the program, unless the grievance is of an urgent nature. If the subscriber's grievance meets the required criteria, the program's staff schedules it for a hearing before an independent panel. After the hearing, the panel makes a recommendation based on the finding of fact either to the AHCA or the OIR. The recommendation may include specific actions the managed care entity must take to comply with state laws or rules regulating managed care entities. The AHCA or the OIR may issue a proposed order under ch. 120, F.S., that requires the managed care entity to take a specific action. The proposed order is subject to a summary hearing in accordance with s. 120.574, F.S., unless all of the parties agree otherwise.

Uniform Health Carrier External Review Act[22]

In April 2010 the National Association of Insurance Commissioners (NAIC) adopted the Uniform Health Carrier External Review Model Act (the Act). The purpose of the Act is to provide uniform standards for the establishment and maintenance of external review procedures to assure that covered persons have the opportunity for an independent review of an adverse determination or final adverse determination by a health carrier. Adverse determination is defined to mean "a determination by a health carrier or its designee utilization review organization that an admission, availability of care, continued stay, or other health care service that is a covered benefit has been reviewed and, based upon the information provided, does not meet the health carrier's requirements for medical necessity, appropriateness, health care setting, level of care or effectiveness, and the requested service or payment for the service is therefore denied, reduced or terminated."

III. Effect of Proposed Changes:

Section 1 amends s. 83.42, F.S., relating to the Florida Residential Landlord and Tenant Act, to clarify that state law on evictions under this act does not apply to nursing home transfers and discharges. Instead, transfers and discharges related to residents of a nursing home are governed by s. 400.0255, F.S.

Section 2 repeals s. 112.0455(10)(e) and (12)(d), F.S., to remove an obsolete provision concerning drug testing within the Drug-Free Workplace Act. The Division of Statutory Revision requested clarification of this provision. Also, this bill repeals a monthly reporting requirement for a laboratory to notify the AHCA of statistical information regarding drug testing.

[22] National Association of Insurance Commissioners, *Uniform Health Carrier External Review Model Act*, April 2010. Found at: <http://www.naic.org/documents/committees_b_uniform_health_carrier_ext_rev_model_act.pdf> (Last visited on January 28, 2012).

Section 3 amends s. 318.21, F.S., to direct 50 percent of certain traffic fines to be deposited into the Brain and Spinal Cord Injury Trust Fund of the DOH to benefit Medicaid recipients who have a brain and spinal cord injury and are medically complex and technologically and respiratory dependent. These funds could be used for Medicaid recipients who are in settings other than nursing homes.

Section 4 repeals s. 383.325, F.S., related to public access to governmental inspection reports for birth centers, since this is required in the general licensing provisions in part II of ch. 408, F.S.

Section 5 creates s. 385.2031, F.S., to designate the Florida Hospital/Sanford-Burnham Translational Research Institute for Metabolism and Diabetes as a resource in this state for research in the prevention and treatment of diabetes.

Section 6 amends s. 395.002, F.S., to redefine the term "accrediting organizations" as it relates to hospitals and other licensed facilities to delete the list of four organizations that are identified in statute. The term is redefined to mean national accrediting organizations that are approved by the Centers for Medicare and Medicaid Services (CMS) and whose standards incorporate comparable licensure regulations required by the state.

Section 7 amends s. 395.003, F.S., to remove obsolete language concerning emergency departments located off-site from licensed hospitals.

The bill also authorizes a specialty-licensed children's hospital that has at least 50 licensed neonatal intensive care unit beds to provide obstetrical services, which are restricted to the diagnosis, care, and treatment of certain pregnant women. The pregnant women may be of any age but must have at least one maternal or fetal characteristic or condition that would characterize the pregnancy or delivery as high-risk, or have received medical advice or a diagnosis indicating their fetus will require at least one perinatal intervention. The services may include labor and delivery. The AHCA is authorized to adopt rules that establish standards and guidelines for admission to these programs.

Section 8 amends s. 395.0161, F.S., to allow for payment of the per-bed licensure inspection fee and lifesafety inspection fee at the time of the hospital's licensure renewal.

Section 9 amends s. 395.0193, F.S., related to peer review of physicians within hospitals and licensed facilities, to correct references to the Division of Medical Quality Assurance of the DOH.

Section 10 amends s. 395.1023, F.S., related to reporting actual or suspected cases of child abuse, abandonment, or neglect by hospitals and licensed facilities, to clarify that references to the Department mean the Department of Children and Family Services (DCF).

Section 11 amends s. 395.1041, F.S., to remove obsolete language pertaining to services within a hospital's service capability for purposes of access to emergency services and care in an emergency department. The Division of Statutory Revision requested clarification of this provision.

Section 12 repeals s. 395.1046, F.S., related to the AHCA's investigation procedures for complaints against a hospital for violations of the access to emergency services and care provisions under s. 395.1041, F.S. Complaint procedures exist in the general licensing provisions in part II of ch. 408, F.S. The federal process for emergency access complaints dictates that access to emergency services and care complaints be handled similarly to routine complaints.

Section 13 amends s. 395.1055, F.S., to require that the AHCA's rulemaking concerning licensed facility beds conform to standards specified by the AHCA, the Florida Building Code, and the Florida Fire Prevention Code.

Section 14 amends s. 395.3025, F.S., relating to patient and personnel records, to correctly reflect that the DOH, rather than the AHCA, is authorized under s. 456.071, F.S., to subpoena records for purposes of disciplinary proceedings against health care professionals by the DOH or the appropriate regulatory board. The DOH will pay the fee established in statute for records provided to patients.

Section 15 amends s. 395.3036, F.S., to correct a cross-reference concerning the confidentiality of records and meetings of corporations that lease public health care facilities. The Division of Statutory Revision requested clarification of this provision.

Section 16 repeals s. 395.3037, F.S., relating to definitions of "Department" and "Agency" as they pertain to stroke centers. These terms are already defined in s. 395.002, F.S., which provides definitions for all of ch. 395, F.S.

Section 17 amends s. 395.602, F.S., to eliminate one of the conditions that qualifies a hospital as a rural hospital. This condition is a hospital in a constitutional charter county with a population of over 1 million persons that has imposed a local option health service tax, in an area that was directly impacted by a catastrophic event on August 24, 1992, for which the Governor of Florida declared a state of emergency, has 120 beds or less and serves an agricultural community with an emergency room utilization of no less than 20,000 visits, and a Medicaid inpatient utilization rate greater than 15 percent. No hospitals meet this condition.

Section 18 amends s. 400.021, F.S., to authorize a licensed practical nurse who is under the direct supervision of a registered nurse, an advanced registered nurse practitioner, a physician assistant, or a physician to staff a geriatric outpatient clinic.

The bill also removes the requirement that a resident care plan for a nursing home resident be signed by the director of nursing or alternate and the resident or the resident's designee or legal representative. The prohibition on a facility using an agency or temporary registered nurse to complete the resident care plan is removed.

Section 19 amends s. 400.275, F.S., to strike the requirement that a newly hired nursing home surveyor must be assigned full-time to a licensed nursing home for at least 2 days to observe facility operations as a part of basic training. Also, the bill relaxes the number of years that must elapse before an individual who was an employee of a nursing home may participate on a survey team of that nursing home from 5 years to 2 years.

Section 20 amends s. 400.474, F.S., to reduce the fine that the AHCA currently must impose on a home health agency that fails to submit, within 15 days after the end of each calendar quarter, the report that includes certain fraud detection information. The bill changes the penalty to a mandatory $200 per day fine for each day the report is late, with a maximum fine not to exceed $5,000 per quarter. This is in lieu of the current permissive denial, revocation, or suspension of the home health agency's license and a mandatory fine of $5,000.

Section 21 amends s. 400.484, F.S., relating to violations in part II of ch. 400, F.S., relating to home health agencies and related providers. The term "deficiency" is changed to "violation," and instead of repeating a description of each class of violation, the bill refers to the general licensing provisions in part II of ch. 408, F.S.

Section 22 amends s. 400.506, F.S., to authorize an administrator of a nurse registry to manage up to five registries if all five have identical controlling interests and are located within one AHCA-geographic service area or an immediately contiguous county. The administrator must designate in writing a qualified alternate administrator to serve at each licensed entity when the administrator is not present.

Section 23 amends s. 400.509, F.S., to exempt from registration as a companion service or homemaker service an organization that contracts with the Agency for Persons with Disabilities to provide companion services only for persons with a developmental disability.

Section 24 amends s. 400.601, F.S., to revise the definition of a hospice to include a limited liability company as an entity that might obtain licensure.

Section 25 amends s. 400.606, F.S., to eliminate the requirement for an applicant for a hospice license to submit the projected annual operating cost of the hospice. Under the general licensing provisions, in part II of ch. 408, F.S., an applicant for licensure must submit information pertaining to the applicant's financial ability to operate. The term "primarily" is removed to clarify that a certificate of need is required to provide inpatient services in any facility that is not already licensed as a health care facility, such as a hospital skilled nursing facility.

Section 26 amends s. 400.915, F.S., to correct an obsolete cross-reference to an administrative rule concerning the construction or renovation of a prescribed pediatric extended care center. This correction was requested by the Joint Administrative Procedures Committee.

Section 27 amends s. 400.931, F.S., to require an applicant that is located outside of the state to submit documentation of accreditation, or a copy of an application for accreditation, when applying for a home medical equipment provider license. The applicant must provide proof of accreditation that is not conditional or provisional within 120 days after the AHCA's receipt of the application for licensure or the application shall be withdrawn from further consideration. Further, the accreditation must be maintained by the home medical equipment provider in order to maintain licensure. The bill also repeals the option for an applicant for a home medical equipment provider license to submit a $50,000 surety bond in lieu of proof of financial ability to operate.

Section 28 amends s. 400.967, F.S., related to violations by intermediate care facilities for developmentally disabled persons, to cross-reference the definitions of the classes of violations in the general licensing provisions in part II of ch. 408, F.S., thereby eliminating redundant definitions for deficiencies in this section. In addition, the bill requires the AHCA to impose an administrative fine not to exceed $500 for each occurrence and each day that an uncorrected or repeated class IV violation exists.

Section 29 amends s. 400.9905, F.S., to revise the definitions related to the Health Care Clinic Act. This includes an entity that contracts with or employs a person to provide portable *health services or* equipment to multiple locations, which bills third-party payors for those services, and that otherwise, meets the definition of a clinic, even though they do not deliver care at the clinic's location.

The bill also exempts the following entities from the definition and regulation as a health care clinic:

- A pediatric cardiology or perinatology clinic facility or anesthesia clinical facility that is not otherwise exempt under another paragraph, that is a publicly traded corporation or that is wholly owned by a publicly traded corporation;
- An entity that is owned or controlled, directly or indirectly, by a publicly traded entity with $100 million or more in total annual revenues derived from providing health care services by licensed health care practitioners who are employed with or contracted by the entity;
- An entity that is owned by a corporation that has $250 million or more in total annual sales of health care services provided by licensed health care practitioners if at least one of the owners of the entity is a health care practitioner who is licensed in this state, is responsible for supervising the business activities, and is legally responsible for the entity's compliance with state law; and
- An entity that employs 50 or more health care practitioners who are licensed under the allopathic or osteopathic practice act, if the billing for medical services is under a single corporate tax identification number. The bill requires the application for exemption to contain information that identifies the entity that owns the practice, a complete list and contact information of all the officers and directors, identifying information for each health care practitioner who is licensed in Florid and employed by the entity, the entity's corporate tax identification number, a listing of the health care services to be provided by the entity; and a certified statement prepared by an independent certified public accountant which states that neither the entity or the entity's clinics have received payment for health care services under personal injury protection (PIP) insurance for the preceding year. The AHCA is authorized to deny or revoke an exemption from licensure if the entity has received payment under a PIP policy.

Section 30 amends s. 400.991, F.S., to repeal the option for an applicant for a health care clinic license to submit a $500,000 surety bond in lieu of proof of financial ability to operate. Another cross-reference is added to reflect an existing provision concerning proof of financial ability to operate for an applicant for a health care clinic license.

Section 31 amends s. 408.033, F.S., to authorize annual health care assessments that must be paid by licensed health care facilities to be paid concurrently with applicable licensure fees.

Section 32 amends s. 408.034, F.S., to correct a reference to the AHCA's authority to issue licenses to intermediate care facilities for developmentally disabled persons under part VIII of ch. 400, F.S., without the facility first obtaining a certificate of need as required by s. 408.036(1)(a), F.S.

Section 33 amends s. 408.036, F.S., to eliminate a cross-reference to an exception to the certificate-of-need requirements for a hospice. No exceptions are currently provided in s. 408.043, F.S.

Section 34 amends s. 408.037, F.S., to authorize an application for a certificate of need to include the audited financial statements of the applicant's parent corporation if the applicant does not have audited financial statements.

Section 35 amends s. 408.043, F.S., to remove the term "primarily" to clarify that a certificate of need is required to establish or expand an inpatient hospice facility unless the facility is licensed as a health care facility, such as a hospital or skilled nursing facility.

Section 35 amends s. 408.061, F.S., to remove an inappropriate reference to an administrative rule that describes data reporting.

Section 37 amends s. 408.07, F.S., to conform the definition of a rural hospital to the provisions related to licensure of rural hospitals in s. 395.602, F.S., as amended in this bill.

Section 38 amends s. 408.10, F.S., to eliminate the requirement for the AHCA to investigate consumer complaints related to health care facilities' billing practices and publish related reports.

Section 39, effective May 1, 2012, amends s. 408.7056, F.S., to limit the applicability of the subscriber assistance program to health plans that meet the requirements of 45 C.F.R. 147.140, which addresses grandfathered health plans under the federal Patient Protection and Affordable Care Act. The bill also retains the ability for prepaid clinics and the Florida Healthy Kids health plan to utilize the Subscriber Assistance Program to resolve subscriber disputes regarding managed care plan grievances.

Section 40 repeals s. 408.802(11), F.S., related to the general licensure provisions, to delete reference to private review agents. The regulation of private review agents was repealed by the Legislature in 2009.

Section 41 amends s. 408.804, F.S., related to the general licensing provisions. The act of, or causing another to alter, deface, or falsify a license certificate is a misdemeanor of the second degree. A licensee or provider who displays an altered, defaced, or falsified license certificate is subject to an administrative fine of $1,000 for each day of illegal display, and a license or application for a license is subject to revocation or denial.

Section 42 amends s. 408.806, F.S., related to general licensing provisions, to require the AHCA to send a courtesy notice to the licensee 90 days before renewal. However, if the licensee does not receive the notice, it does not excuse the licensee's responsibility to timely submit the

renewal application and fee. Submission of the renewal application, application fee, and any applicable late fees is required to renew the license.

Section 43 amends s. 408.8065, F.S., to modify the description of the financial statements that a home health agency, home medical equipment provide, or health care clinic must submit for initial licensure to "projected" financial statements instead of "pro forma" financial statements.

Section 44 amends s. 408.809, F.S., to provide, in law, a schedule for background rescreening for persons who are required to be screened by July 31, 2015. The schedule is based on the recency of the individual's last screening. Authority for the AHCA to adopt rules to establish the reschedule is repealed. The bill also adds the Department of Elderly Affairs to the list of agencies that require background screening to ensure that all persons working for health care providers licensed by the AHCA are eligible for employment using the same screening criteria.

Section 45 amends s. 408.810, F.S., related to general licensing provisions, to include the requirement for a controlling interest to notify the AHCA within 10 days after a court action to initiate bankruptcy, foreclosure, or eviction proceedings concerning the provider in which the controlling interest is a petitioner or defendant.

Section 46 amends s. 408.813, F.S., related to general licensing provisions, to authorize the AHCA to impose an administrative fine, not to exceed $500 per violation, for violations that do not qualify within the classification scheme of class I – class IV violations. Unclassified violations might include: violating any term or condition of a license; violating any provision of the general licensing provisions, authorizing statutes, or applicable rules; exceeding licensed capacity without authorization; providing services beyond the scope of the license; or violating a moratorium.

Section 47 amends s. 409.912, F.S., to authorize the AHCA to post prior-authorization and step-edit criteria, protocols, and updates to the list of drugs that are subject to prior authorization on the AHCA's website within 21 days after the prior authorization, criteria, protocols, or updates are approved by the AHCA.

Section 48 amends s, 409.91195, F.S., to identify specific professional academies, societies, associations or other groups that will nominate members to the Medicaid Pharmaceutical and Therapeutics Committee (P&T). The bill requires nine professional organizations and one advocacy group to nominate professionals for appointment by the Governor's Office. The bill requires the committee to allow an unlimited number of speakers to present for three minutes each at the P&T meetings and authorizes members to ask questions of the persons providing public testimony. If the AHCA does not follow a recommendation by the P&T committee, the AHCA must notify the committee members in writing of its action at the next committee meeting following the reversal of its recommendation.

Section 49 effective upon becoming a law, the bill declares that each essential provider and each hospital that are necessary in order for a managed care plan to demonstrate an adequate network under the new statewide Medicaid managed care program are part of that managed care plan's network for purposes of the provider's or hospital's application for enrollment or expansion in

the Medicaid program. A managed care plan's payment to an essential provider must be made in accordance with s. 409.975, F.S.

Section 50 repeals s. 429.11(6), F.S., to remove duplicative language pertaining to the issuance of a provisional license for ALFs. Provisional licenses are provided for in the general licensing provisions under part II of ch. 408, F.S.

Section 51 amends s. 429.294, F.S., to remove a cross-reference to a section of law and substitute a different statute. However, the new statutory subsection does not currently exist and is not created in this bill.

Section 52 amends s. 429.71, F.S., to remove duplicative language concerning the classification of adult family care home violations that are also in the general licensing provisions under part II of ch. 408, F.S, and substitutes the term "violations" for "deficiencies."

Section 53 amends s. 429.915, F.S., to remove the requirement for a plan of correction as a part of issuing a conditional license for an adult day care facility since this is authorized in the general licensing provisions in part II of ch. 408, F.S.

Sections 54 and 55 amend ss. 430.80 and 430.81, F.S., to change a statutory cross-reference. However, since s. 400.141, F.S., is not amended in the committee substitute, existing language is correct.

Section 56 repeals s. 440.102(9)(d), F.S., to remove a monthly reporting requirement for a laboratory to notify the AHCA of statistical information regarding drug testing under workers' compensation provisions.

Section 57 amends s. 483.035, F.S., to authorize an advanced registered nurse practitioner to license and operate a clinical laboratory exclusively in connection with the diagnosis and treatment of his or her own patients.

Section 58 amends s. 483.051, F.S., to provide that the AHCA will license nonwaived clinical laboratories and to provide for the requirements for licensure, including submitting a copy of the application for or proof of a federal Clinical Laboratory Improvement Amendment (CLIA) certificate. The term "nonwaived clinical laboratories" is defined to mean any laboratories that perform any test that the CMS has determined does not qualify for a certificate of waiver. The bill repeals the requirement for alternate site testing locations to be registered when the clinical laboratory applies to renew its license.

Section 59 amends s. 483.245, F.S., relating to prohibiting rebates, to prohibit a licensed clinical laboratory from placing, directly or indirectly, through an independent staffing company or lease arrangement, or otherwise, a specimen collector or other personnel in any physician's office, unless the clinical lab and the physician's office are owned and operated by the same entity. The bill establishes a private action for any person aggrieved by a violation of this section. The person may bring a civil action for a declaratory judgment, injunctive relief, and actual damages.

Section 60 amends s. 483.294, F.S., to conform the inspection frequency (biennially) for licensed multiphasic health testing centers with the general licensing provisions in part II of ch. 408, F.S.

Section 61 amends s. 499.003, F.S., to delete the requirement that contractors and subcontractor that receive prescription drugs from an entity that purchased the drugs under the 340B program (federal Public Health Services Act) maintain these drugs separate from any other prescription drugs in their possession.

Section 62, effective May 1, 2012, amends s. 627.602, F.S., relating to individual health insurance policies, to require such policies to comply with:

- Rules developed by the OIR to administer the provisions of the NAIC's Uniform Health Carrier External Review Model Act, dated April 2010; and
- The provisions of the ERISA, as implemented by 29 C.F.R. s. 2560.503-1, relating to internal grievances.

Health insurance policies that are subject to the Florida Subscriber Assistance Program are exempt from this requirement.

Section 63, effective May 1, 2012, creates s. 627.6513, F.S., to apply the following provisions to all group health insurance policies issued under part VII of ch. 627, F.S. (group, blanket, and franchise health insurance policies):

- Rules developed by the OIR to administer the provisions of the NAIC's Uniform Health Carrier External Review Model Act, dated April 2010; and
- The provisions of the ERISA, as implemented by 29 C.F.R. s. 2560.503-1, relating to internal grievances.

Group health insurance policies that are subject to the Florida Subscriber Assistance Program are exempt from this requirement.

Section 64, effective May 1, 2012, creates s. 641.312, F.S., to require the OIR to adopt rules to administer the provisions of the NAIC's Uniform Health Carrier External Review Model Act, dated April 2010. This provision does not apply to an HMO contract that is subject to the Florida Subscriber Assistance Program.

Section 65 amends s. 651.118, F.S., to change a cross-reference to s. 400.141, F.S. However, s. 400.141, F.S., is not amended in this committee substitute and the existing language is correct.

Section 66 creates an undesignated section of law directing the Division of Statutory Revision to provide the relevant substantive committees of the Senate and House of Representatives with assistance, if requested, in drafting legislation to correct the names of accrediting organizations in the Florida Statutes. This is to occur prior to the 2013 Regular Session of the Legislature.

Section 67 provides that except as otherwise expressly provided in the act, and except for this section which takes effect upon the act becoming a law, the law takes effect July 1, 2012.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill 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 this bill 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 bill 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:

Entities regulated by the AHCA may be favorably impacted due to the elimination of certain reporting and administrative requirements. Nursing homes and family caregivers may benefit from the authority for nursing homes to provide short-term respite services.

C. Government Sector Impact:

The bill does not have a fiscal impact on the AHCA.[23]

VI. Technical Deficiencies:

Sections 51, 54, 55, and 65 amend ss. 429.294, 430.80, 430.81, and 651.118, F.S., to change a cross-reference to s. 400.141, F.S. However, s. 400.141, F.S., is not amended in this committee substitute, so the current language is correct. These sections should be removed from the bill.

VII. Related Issues:

None.

[23] *Supra,* fn 1.

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 on January 31, 2011:

- Deletes several sections from the bill that were amending certain provisions relating to nursing homes, including ss. 400.0234, 400.0255, 400.063, 400.071, 400.0712, 400.111, 400.1183, 400.141, 400.142, 400.145, 400.147, 400.19, 400.23, 400.462, and 400.464, F.S.;
- Requires the AHCA to adopt rules to clarify clinical details for implementation of the provision allowing certain specialty-licensed children's hospitals to provide obstetrical services;
- Removes additional duplicative language regarding the issuance of a provisional license for ALFs and the classification of adult family care home violations;
- Provides a cross-reference to allowable fees for copying and providing resident records;
- Adds the Department of Elderly Affairs to the list of agencies to ensure that all persons working for health care providers licensed by the AHCA are eligible for employment using the same screening criteria;
- Retains the ability for prepaid clinics and the Florida Healthy Kids health plan to utilize the Subscriber Assistance Program;
- Deletes provisions relating to nursing homes and a provision that would allow companion and sitter organizations that have a developmental services provider certificate to provide personal services to persons with developmental disabilities, without additional licensure;
- Places a provision that was in an undesignated section of law into a specific statute; and
- Provides additional exemptions from licensure as a health care clinic.

B. Amendments:

None.