

**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.)

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Prepared By: The Professional Staff of the Health Regulation Committee

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BILL: SB 1884

INTRODUCER: Senator Garcia

SUBJECT: Health Regulation by the Agency for Health Care Administration

DATE: January 30, 2012      REVISED: \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Stovall	HR	<b>Pre-meeting</b>
2.	_____	_____	_____	_____
3.	_____	_____	_____	_____
4.	_____	_____	_____	_____
5.	_____	_____	_____	_____
6.	_____	_____	_____	_____

**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:

- Revises provisions affecting nursing homes as follows:
  - 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 a \$1,000 fine per day if a nursing home fails to impose a moratorium on new admissions when the facility has not complied with the minimum staffing requirements;
  - Eliminates the requirement for a newly hired nursing home surveyor to observe a facility's operations as a part of basic training;
  - Eliminates the requirement that an "incident" be reported within 1-day and only requires reporting if the investigation, which must be completed within 15 days, indicates the incident qualifies as an adverse incident;
  - Establishes in statute minimum staffing requirements for a nursing home that serves persons under 21 years of age;
  - Eliminates the reporting of staffing ratios, staff turnover, and staff stability; and
  - Eliminates the monthly reporting of any notice of claims or liability claims filed against the facility;

- 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 for the following:
  - Pediatric cardiology or perinatology clinic facilities and
  - Certain publicly traded entities;
- 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;
- 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;
- 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; 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, 400.0234, 400.0255, 400.063, 400.071, 400.0712, 400.111, 400.1183, 400.141, 400.142, 400.147, 400.19, 400.23, 400.275, 400.462, 400.464, 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, 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, 400.145, 408.802(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.<sup>1</sup>

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<sup>1</sup> Agency for Health Care Administration 2012 *Bill Analysis for SB 1884*, on file with the Senate Health Regulation Committee.

## 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.

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.

Nursing homes are required to report adverse incidents to the AHCA within 1 day (initial report) and 15 days (final report) after the incident. In addition, federal requirements for participation in Medicaid or Medicare require facilities to report abuse, neglect, and exploitation immediately (initial report) and within 5 days (full report). An adverse incident is 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 the 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 for which the resident has not given his or her informed consent, including failure to honor advanced directives;
- 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; or
- An event that is reported to law enforcement or its personnel for investigation.

In addition, an adverse incident includes resident elopement, if the elopement places the resident at risk of harm or injury.<sup>2</sup>

Nursing homes are required to report staff-to-resident ratios. Under s. 400.141(1)(o)1, F.S., nursing homes must submit semiannually to the AHCA or more frequently if requested by the AHCA, information regarding facility staff-to-resident ratios, staff turnover, and staff stability. Nursing home staffing levels also reported as part of Medicaid cost reports and reviewed during inspection where payroll records are also examined.

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<sup>2</sup> Section 400.147(5), F.S.

Nursing homes must comply with nursing staff-to-resident staffing ratios. Under s. 400.141(1)(o), F.S., if a nursing home fails to comply with minimum staffing requirements for two consecutive days, the facility must cease new admissions until the staffing ratio has been achieved for six consecutive days. Failure to self-impose this moratorium on admissions, results in a class II deficiency cited by the AHCA. All other citations for a class II deficiency represent current, ongoing non-compliance that the AHCA determines has compromised the resident's ability to maintain or reach his or her highest practicable physical, mental, and psychosocial well-being. The AHCA indicates that use of the class II deficiency for a failure to cease admissions is an inconsistent use of a "class II" level for all other violations.<sup>3</sup>

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.<sup>4</sup>

The AHCA employs surveyors to inspect nursing homes. Newly hired nursing home surveyors must spend 2 days in a nursing home as part of basic training in a non-regulatory role. Federal regulations prescribe an extensive training process for nursing home inspection staff. Staff must pass the federal Surveyor Minimum Qualifications Test (SMQT). Federal regulations prohibit an AHCA staff person who formerly worked in a nursing home from inspecting a nursing home within 2 years of employment with that home; state law requires a 5-year lapse.

### **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.

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<sup>3</sup> *Supra*, fn 1.

<sup>4</sup> *Id.*

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
- Medical supplies, restricted to drugs and biologicals prescribed by a physician.<sup>5</sup>

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

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<sup>5</sup> Section 400.462(14), F.S.

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.<sup>6</sup>

### **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 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.<sup>7</sup>

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.<sup>8</sup>

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<sup>9</sup> Currently there are seven organizations exempt under this law.<sup>10</sup>

### **Laboratory Licensure**

Clinical laboratory providers seeking to perform non-waived tests must be licensed by the AHCA and hold a valid federal CLIA certificate before any testing may be done.<sup>11</sup> 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.<sup>12</sup> 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

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<sup>6</sup> Section 400.462(21), F.S.

<sup>7</sup> Section 400.462(7) and, (16), F.S.

<sup>8</sup> *Supra*, fn 1.

<sup>9</sup> Section 400.464(5)(b)4., F.S.

<sup>10</sup> *Supra*, fn 1.

<sup>11</sup> See part III of ch. 483, F.S.

<sup>12</sup> Section 483.245, F.S.



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.<sup>13</sup> 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.<sup>14</sup> 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,<sup>15</sup> Miami Children's Hospital has 51 Level II and Level III NICU beds,<sup>16</sup> and Nemours Pediatric Partners at AtlantiCare in Jacksonville has 22 NICU beds.<sup>17</sup>

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.<sup>18</sup>

### **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.

<sup>13</sup> The Declaratory Statement and Final Order is available at:

<[http://ahca.myflorida.com/MCHO/Health\\_Facility\\_Regulation/Laboratory\\_Licensure/docs/FinalOrderDominion2008.pdf](http://ahca.myflorida.com/MCHO/Health_Facility_Regulation/Laboratory_Licensure/docs/FinalOrderDominion2008.pdf)> (Last visited on January 29, 2012).

<sup>14</sup> This letter is available at:

<[http://ahca.myflorida.com/MCHO/Health\\_Facility\\_Regulation/Laboratory\\_Licensure/kickback.shtml](http://ahca.myflorida.com/MCHO/Health_Facility_Regulation/Laboratory_Licensure/kickback.shtml)> (Last visited on January 29, 2012).

<sup>15</sup> See <<http://www.allkids.org/body.cfm?id=14>> (Last visited on January 28, 2012).

<sup>16</sup> See <<http://www.mch.com/page/EN/256/Medical-Services/Neonatology.aspx>> (Last visited on January 28, 2012).

<sup>17</sup> See <<http://www.nemours.org/filebox/healthpro/patientreferral/npppomonanicu.pdf>> (Last visited on January 28, 2012).

<sup>18</sup> National Institutes of Health <[http://www.nichd.nih.gov/health/topics/high\\_risk\\_pregnancy.cfm](http://www.nichd.nih.gov/health/topics/high_risk_pregnancy.cfm)> (Last visited on January 28, 2012).

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.<sup>19</sup>

### **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.

### **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.,

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<sup>19</sup> *Supra*, fn 1.

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<sup>20</sup>**

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.

**Section 3** amends s. 318.21, F.S., to allow 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.

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<sup>20</sup> 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](http://www.naic.org/documents/committees_b_uniform_health_carrier_ext_rev_model_act.pdf)> (Last visited on January 28, 2012).

**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. Note: Section 78 of this bill creates an undesignated section of law with the same provision.

**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.

**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 "AHCA" 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 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. 400.0234, F.S., to eliminate a cross-reference to s. 400.145, F.S., to conform to the repeal of that section in this bill.

**Section 20** amends s. 400.0255, F.S., to correct an obsolete cross-reference to a rule concerning fair hearings which a nursing home resident might request. This correction was requested by the Joint Administrative Procedures Committee.

**Section 21** amends s. 400.063, F.S., to eliminate a cross-reference in the procedures for resident protection and relocation accounts, since the section of law that is referenced has been repealed. The Division of Statutory Revision requested clarification of this provision.

**Section 22** amends s. 400.071, F.S., to repeal the requirement for certain information to be submitted when a nursing home applies for a license. The information eliminated in this section includes:

- Certain information related to the closure of other licensed facilities in which the nursing home licensure applicant held a controlling interest. The bill amends s. 400.111, F.S., to require this disclosure if requested by the AHCA;
- The number of beds and the number of Medicare- and Medicaid-certified beds. The general licensing provisions in s. 408.806(1)(d), F.S., require the disclosure of the total number of beds requested; and
- Copies of any civil verdicts or judgments involving the applicant rendered within the preceding 10 years which pertain to medical negligence, violation of residents' rights, or wrongful death. In addition, the provision requiring, as a condition of licensure, that the licensee agree to provide to the AHCA copies of any new verdicts or judgments is repealed. Under current law, the AHCA is required to maintain this information in the facility's licensure file and in a database which is available as a public record.

**Section 23** amends s. 400.0712, F.S., to make technical changes to move into another subsection the authority for a nursing home to request an inactive license for a portion of its beds and to provide a cross-reference to the general licensure provisions in part II of ch. 408, F.S.

**Section 24** amends s. 400.111, F.S., to require disclosure of certain information concerning other licenses that a controlling interest has held when requested by the AHCA, instead of requiring submission of this information as a part of all nursing home licensure applications.

**Section 25** amends s. 400.1183, F.S., to repeal the requirement for a nursing home to report to the AHCA upon relicensure information concerning grievances received by the facility. This information is reported at an aggregate level. Instead, the bill requires the nursing home to maintain a log that must be available to the AHCA during inspections.

**Section 26** amends s. 400.141, F.S., to authorize a nursing home with standard licensure status to provide respite care pursuant to standards set out in law without obtaining additional licensure. The requirements to provide respite care under these standards include, but are not limited to, a detailed contract, an abbreviated plan of care, the resident providing certain medical information to the facility, and the facility releasing the respite resident to his or her designated caregiver. A person receiving respite care may live in the facility for a total of 60 days within a 12-month period. If a single stay exceeds 14 consecutive days, the facility must comply with all assessment and care planning requirements applicable to nursing home residents. Certain residents' rights apply to the person receiving respite care.

The bill requires a nursing home to maintain clinical records on each resident in accordance with accepted professional standards and practices. Records must be complete, accurately documented, readily accessible, and systematically organized.

The bill eliminates the requirement for a licensed facility to disclose, within 30 days after the nursing home executes an agreement with a company to manage the nursing home, certain information related to the closure of other licensed facilities in which the management company held a controlling interest.

The bill eliminates the nursing home reporting requirements pertaining to average staffing ratios, staff turnover, and staff stability. Detailed records must be maintained by the facility, and these records are reviewed during inspections.

The penalty for a facility that does not comply with the requirement to impose a moratorium on accepting new admissions when the minimum staffing requirements for 2 consecutive days are not met is reduced to a \$1,000 fine. Currently, a nursing home's failure to impose the admissions moratorium is a class II deficiency, which is subject to a civil penalty of \$2,500 for an isolated deficiency, \$5,000 for a patterned deficiency, and \$7,500 for a widespread deficiency. In addition, the law authorizes the fine amount for a class II deficiency to be doubled in certain situations.

The bill repeals the requirement for a licensed nursing home to report to the AHCA information concerning a filing for bankruptcy, divestiture of assets, or corporate reorganization.

A provision concerning the AHCA's ability to impose a deficiency or take other action if a facility does not have enough staff to meet residents' needs is relocated within this section.

The bill authorizes a nursing home to charge a fee for copying resident records and provides that the fee may not exceed \$1 per page for the first 25 pages and 25 cents per page for each additional page.

**Section 27** amends s. 400.142, F.S., to remove references to rules adopted by the AHCA concerning do not resuscitate orders (DNR). Section 401.45, F.S., addresses procedures and authorization for withholding or withdrawing resuscitation from a patient when presented with a DNR.

**Section 28** repeals s. 400.145, F.S., relating to a nursing home providing copies of a resident's medical records to certain individuals. The federal Health Insurance Portability and Accountability Act (HIPAA) governs release of medical records. The provision concerning the amount that a facility may charge for copying residents' records is moved in this bill to s. 400.141, F.S.

**Section 29** amends s. 400.147, F.S., to remove the 1-day notification requirement to the AHCA when a risk manager in a nursing home receives an incident report. The requirement for the nursing home to complete the investigation and submit a report to the AHCA within 15 days if the incident is determined to be an adverse incident is deleted from subsection (8) and moved into subsection (7).

The bill also deletes duplicative language in subsection (8) concerning the AHCA's review of the adverse incident report to determine whether the incident potentially involved conduct by a health care professional. This requirement remains in subsection (7).

This section repeals the requirement for a licensed nursing home to report to the AHCA, monthly, any notice of claims against the facility for violation of a resident's rights or for

negligence. This information has been required to be submitted since 2001. Currently, this information is published in the aggregate on the AHCA's website.<sup>21</sup>

**Section 30** amends s. 400.19, F.S., to authorize the AHCA to certify correction of a class III or class IV deficiency related to resident rights or resident care based on written documentation from the facility.

**Section 31** amends s. 400.23, F.S., to establish in statute minimum staffing requirements for a nursing home that serves persons under 21 years of age. For persons who require skilled care, the minimum combined average is 3.9 hours of direct care per resident per day, provided by licensed nurses, respiratory therapists, respiratory care practitioners, and certified nursing assistants. For persons who are medically fragile, the minimum combined average is 5 hours.

**Section 32** 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 33** amends s. 400.462, F.S., to revise the definition of remuneration as it applies to home health agencies and nurse registries to authorize them to provide items with an individual value of up to \$15 to referring entities without penalty. Examples of such items which are included in the bill are plaques, certificates, trophies, or novelty items that are intended solely for presentation or are customarily given away solely for promotional, recognition, or advertising purposes.

**Section 34** amends s. 400.464, F.S., to remove the date of January 1, 1999, which was a grandfathering provision exempting certain persons from licensure as a home health agency. The effect of removing this date is to allow a companion and sitter organization that is registered or will become registered as a developmental disabilities provider to provide personal care to developmentally disabled clients, as well as to those who are not developmentally disabled, without being licensed as a home health agency or nurse registry. Current law prohibits companions or sitters from providing personal care. Personal care must be provided by a home health aide, certified nursing assistant, or other licensed health care professional by a home health agency or nurse registry.

**Section 35** 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.

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<sup>21</sup> See: [http://www.fdhc.state.fl.us/MCHQ/Long\\_Term\\_Care/FDAU/docs/LiabilityClaims/ALF\\_Chart.pdf](http://www.fdhc.state.fl.us/MCHQ/Long_Term_Care/FDAU/docs/LiabilityClaims/ALF_Chart.pdf) (Last visited on January 17, 2012).



**Section 36** amends s. 400.484, F.S., relating to violations in nursing homes. 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 37** 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 38** 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 39** 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 40** 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 41** 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 42** 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 43** 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 44** 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.*

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; and
- 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.

**Section 45** 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 46** 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 47** 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 48** 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 49** 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 50** 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 51** amends s. 408.061, F.S., to remove an inappropriate reference to an administrative rule that describes data reporting.

**Section 52** 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 53** 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 54**, 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.

**Section 55** 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 56** 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 57** 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 58** 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 59** 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.

**Section 60** 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 61** 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 62** 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 63** 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 64** amends s. 429.294, F.S., to remove a cross-reference to a section of law that is repealed in this bill concerning the availability of facility records.

**Section 65** 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 66 and 67** amend ss. 430.80 and 430.81, F.S., to conform statutory cross-references with other changes made in the bill.

**Section 68** 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 69** 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 70** 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 71** 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 72** 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 73** 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 74**, 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 75**, 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 76**, 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 77** amends s. 651.118, F.S., to conform a cross-reference to changes made to s. 400.141, F.S., in section 26 of the bill.

**Section 78** designates the Florida Hospital/Sanford-Burnham Translational Research Institute as a State of Florida Resource for research in diabetes diagnosis, prevention, and treatment.

**Section 79**, 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 80** 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 81** 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.<sup>22</sup>

#### **VI. Technical Deficiencies:**

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 78 of this bill creates an undesignated section of law with the same provision.

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<sup>22</sup> *Supra*, fn 1.

**VII. Related Issues:**

The AHCA recommends an amendment to line 2350 to retain the ability for prepaid health clinics and the Florida Healthy Kids health plans to utilize the Subscriber Assistance Program to resolve subscriber disputes regarding managed care plan grievances.

Certain programs regulated by or operating under the Department of Elderly Affairs require background screening for licensure or employment. However, the Department of Elderly Affairs is omitted from the list of agencies (see lines 2465 – 2475) for which background screening by those listed agencies will suffice for an applicant for a certificate of authority or provisional certificate of authority to operate a continuing care retirement community under certain situations.

**VIII. Additional Information:**

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

None.

- B. **Amendments:**

None.