HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/CS/HB 1419 Health Care Facilities
SPONSOR(S): Health & Human Services Committee; Health & Human Services Quality Subcommittee; Brodeur
TIED BILLS: **IDEN./SIM. BILLS:** CS/SB 1884

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health & Human Services Quality Subcommittee	14 Y, 0 N, As CS	Guzzo	Calamas
2) Health & Human Services Committee	12 Y, 6 N, As CS	Guzzo	Gormley

SUMMARY ANALYSIS

The bill amends the Health Care Licensing Procedures Act (Act) and the various authorizing statutes of entities regulated by the Agency for Health Care Administration (AHCA) to reduce, streamline, and clarify regulations for those providers. The bill makes the following changes to current law:

- Repeals obsolete or duplicative provisions in licensing and related statutes, including expired reports and regulations and provisions that exist in other sections of law;
- Resolves conflicts among and between provisions in the Act and various authorizing statutes for individual provider types;
- Makes various revisions to update terminology and conforms current law to prior legislative changes;
- Amends the Health Care Clinic Act to provide additional exemptions;
- Amends various licensure provisions, including those related to bankruptcy notifications, licensure renewal notices, billing complaints, accrediting organizations, licensure application document submissions, staffing in geriatric outpatient clinics, medical records, property statements, AHCA inspection staff, litigation notices, and health care clinic licensure exemptions;
- Clarifies that all new hospice inpatient facilities are subject to certificate of need (CON) review and enables CON applicants to submit an audit of their parent corporation in an audit of the applicant does not exist;
- Revises the definition of “remuneration” to allow home health agencies to distribute certain novelty items with a value of up to $15 that are intended solely for promotional and advertising purposes;
- Revises the definition of “hospice” to include limited liability companies;
- Requires hospital housekeeping and sanitations staff to wear masks and gloves while cleaning patient rooms and disinfect environmental surfaces in patient rooms in accordance with the time instructions on the label of the disinfectant used;
- Requires Medicaid to post prior authorization and step edit criteria, protocol, and updates to the list of drugs that are subject to prior authorization;
- Designates the Florida Hospital/Sanford-Burnham Translational Research Institute for Metabolism and Diabetes as a resource for diabetes research in prevention and treatment;
- Clarifies what constitutes a kickback in a clinical laboratory by prohibiting placement of a specimen collector in a physician’s office; and
- Declares that all hospitals shall be deemed to be a part of a managed care plan’s network in its application for participation or expansion in the Medicaid program prior to the implementation of the statewide Medicaid Managed Care Program, and provides a payment rate for those providers.

The bill does not appear to have a significant impact on state or local government.

The bill has an effective date of July 1, 2012.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

The Agency for Health Care Administration (AHCA) regulates over 41,000 health care providers under various regulatory programs. Regulated providers include:

- Laboratories authorized to perform testing under the Drug-Free Workplace Act (ss. 112.0455, 440.102, F.S.).
- Birth centers (Ch. 383, F.S.).
- Abortion clinics (Ch. 390, F.S.).
- Crisis stabilization units (Pts. I and IV of Ch. 394, F.S.).
- Short-term residential treatment facilities (Pt. I and IV of Ch. 394, F.S.).
- Residential treatment facilities (Pt. IV of Ch. 394, F.S.).
- Residential treatment centers for children and adolescents (Pt. IV of Ch. 394, F.S.).
- Hospitals (Part I of Ch. 395, F.S.).
- Ambulatory surgical centers (Pt. I of Ch. 395, F.S.).
- Mobile surgical facilities (Pt. I of Ch. 395, F.S.).
- Health care risk managers (Pt. I of Ch. 395, F.S.).
- Nursing homes (Pt. II of Ch. 400, F.S.).
- Assisted living facilities (Pt. I of Ch. 429, F.S.).
- Home health agencies (Pt. III of Ch. 400, F.S.).
- Nurse registries (Pt. III of Ch. 400, F.S.).
- Companion services or homemaker services providers (Pt. III of Ch. 400, F.S.).
- Adult day care centers (Pt. III of Ch. 429, F.S.).
- Hospices (Pt. IV of Ch. 400, F.S.).
- Adult family-care homes (Pt. II of Ch. 429, F.S.).
- Homes for special services (Pt. V of Ch. 400, F.S.).
- Transitional living facilities (Pt. V of Ch. 400, F.S.).
- Prescribed pediatric extended care centers (Pt. VI of Ch. 400, F.S.).
- Home medical equipment providers (Pt. VII of Ch. 400, F.S.).
- Intermediate care facilities for persons with developmental disabilities (Pt. VIII of Ch. 400, F.S.).
- Health care services pools (Pt. IX of Ch. 400, F.S.).
- Health care clinics (Pt. X of Ch. 400, F.S.).
- Clinical laboratories (Pt. I of Ch. 483, F.S.).
- Multi-phasic health testing centers (Pt. II of Ch. 483, F.S.).
- Organ, tissue, and eye procurement organizations (Pt. V of Ch. 765, F.S.).

Health Care Licensing Procedures Act

Providers are regulated under the Health Care Licensing Procedures Act (Act) in part II of chapter 408, F.S. The Act provides uniform licensing procedures and standards applicable to most AHCA-regulated entities. The Act contains basic licensing standards for 29 provider types in areas such as licensure application requirements, ownership disclosure, staff background screening, inspections, administrative sanctions, license renewal notices, and bankruptcy and eviction notices.

In addition to the Act, each provider type has an authorizing statute which includes unique provisions for licensure beyond the uniform criteria. Pursuant to s. 408.832, F.S., in the case of conflict between the Act and an individual authorizing statute, the Act prevails. There are several references in authorizing statutes that conflict with or duplicate provisions in the Act, 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. Chapter 2009-223, L.O.F., made changes to part II of chapter 408, F.S., which supersede components of the specific licensing statutes.

This bill repeals obsolete or duplicative provisions in licensing and related statutes, including expired reports and regulations and provisions that exist in other sections of law like the Act. The bill also makes changes to the Act to reduce, streamline, or clarify regulations for all providers regulated by AHCA.

The bill changes individual licensing statutes to reflect updates to the uniform standards in the Act. The bill makes corresponding changes to provider licensing statutes to reflect the changes made to the Act to eliminate conflicts and obsolete language.

Certificates of Need

A certificate of need (CON) is a written statement issued by AHCA providing evidence of community need for a new, converted, expanded, or otherwise significantly modified health care facility, health service, or hospice.[1] Section 408.037, F.S., requires the applicants for CON to be audited. According to AHCA, the applicant is frequently a sub-entity of a larger corporation and usually has no operations yet.[2] Therefore, the applicant has to go through the expense of getting a separate audit on the sub-entity company to meet the filing requirement.[3]

The bill modifies s. 408.037, F.S., to allow audited financial statements of an applicant's parent corporation in exchange for the audited financial statements of an applicant when such statements do not exist.

License Renewal Notices

Section 408.806, F.S., requires AHCA to notify licensees by mail or electronically when it is time to renew their licenses. AHCA mails renewal notices to over 30,000 providers every two years. While the statute does not specify the manner of mailing notices, AHCA sends them by certified mail to verify receipt by the providers. The cost of certified mail is approximately $56,000 annually. According to AHCA, some certified mail is returned, as providers do not pick it up or the post office is unable to obtain necessary signatures for delivery. AHCA has also encountered situations in which licensees did not timely renew their licenses and claimed that their lack of receipt of a renewal reminder was a reason for that failure.

The bill clarifies that renewal notices are courtesy reminders only and do not excuse the licensees from the requirement to file timely licensure applications. The revised language gives AHCA clear flexibility to use or not use certified mail to send courtesy renewal reminders.

Background Screening

Persons screened under the Agency for Health Care Administration (AHCA) must be rescreened every five years.[4] In 2010, authority was given to AHCA to establish by rule a staggered schedule for the rescreening of all persons who have a controlling interest in, is employed by, or contracts with a licensee on July 31, 2010.[5] All such persons must be rescreened by July 31, 2015.[6]

The bill delays until July 31, 2013, the start of the staggered period for rescreens of persons who have a controlling interest in, is employed by, or contracts with a licensee on July 31, 2010. The bill adds the schedule to statute eliminating the need for a rule.

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[1] S. 408.032(2), F.S.
[2] AHCA, *Staff Analysis and Economic Impact, House Bill Number 1419* (January 20, 2012).
[3] Id.
[4] S. 408.809(2), F.S.
[5] Ch. 2010-114, L.O.F.
[6] *Id.*

Classification and Fines for Violations

Section 408.813, F.S., includes criteria for the classification of deficiencies for all providers licensed by AHCA. Some authorizing statutes also contain criteria for the classification of deficiencies, some of which do not match the provisions contained in the Act. The provisions in the Act legally supersede conflicting provisions in the authorizing statutes. However, the dual provisions may be confusing, and some conflicts still exist. Additionally, authorizing statutes are inconsistent related to fines for unclassified deficiencies such as failure to maintain insurance or exceeding licensed bed capacity.

The bill modifies the classification of licensure violations related to home health agencies, intermediate care facilities for the developmentally disabled and adult family care homes to refer to the scope and severity in s. 408.813, F.S. Fine amounts for violations are unchanged. For intermediate care facilities for the developmentally disabled, the amount of fines for Class I, II, and III violations are unchanged, but a new Class IV is added for consistency with s. 408.813, F.S., with a fine not to exceed $500. The addition of the Class IV violation creates a lower category for minor violations by those facilities. This resolves conflicting or confusing differences between the Act and the authorizing statutes, and resolves inconsistencies between these three authorizing statutes.

In addition, the bill establishes uniform sanction authority for unclassified deficiencies of up to $500 per violation. Examples of unclassified deficiencies include failure to maintain insurance and other administrative requirements, exceeding licensed capacity, or violating a moratorium. Without fine authority, AHCA would be required to initiate revocation action for violations against those providers that do not have general fine authority. These violations may not warrant such a severe sanction.

Billing Complaint Authority

The Act provides authority to review billing complaints across all programs and gives the impression that AHCA can take licensure action regarding billing practices. Section 408.10(2), F.S., requires AHCA to investigate consumer complaints regarding billing practices and determine if the facility has engaged in billing practices which are unreasonable and unfair to the consumer. However, the Act does not provide specific standards for billing practices which AHCA can use to cite violations and discipline a provider's license. Nor does the Act define what activities would be unreasonable and unfair. Several providers' authorizing statutes do include billing standards, including nursing homes and assisted living facilities.[7] However, other authorizing statutes are silent on billing standards, including hospitals, labs, crisis stabilization units and residential treatment facilities.

For calendar year 2011, AHCA received 436 complaints that alleged billing-related issues.[8] Of those, 126 were for providers that have billing standards in their licensure statutes. The remaining 310 were related to billing issues for which no regulatory authority existed for billing matters. When the agency receives a billing complaint regarding one of the providers which does not have statutory billing standards, it is the agency's policy to review the complaint and encourage the parties to work together to resolve the problem. However, the provider is not cited or disciplined due to lack of authority.

The bill repeals AHCA's independent authority related to billing complaints in the Act. However, a review for regulatory compliance will continue to be conducted when a complaint is received for one of the providers over which AHCA has well-defined statutory billing authority. This review could possibly result in citations and discipline.

License Display

Section 408.804, F.S., makes it unlawful to provide or offer services that require licensure without first obtaining a license. This section of law also makes licenses valid only for entities and locations for which they are issued. Licensees are required to display licenses in a conspicuous place readily visible to the clients. The Act does not currently address falsification or ill-usage of license documents.

[7] S. 400.23, F.S., (Nursing Homes) and s. 429.19, F.S., (Assisted Living Facilities).
[8] AHCA, *Staff Analysis and Economic Impact, House Bill Number 1419* (January 20, 2012).

The bill makes it a second degree misdemeanor to knowingly alter, deface, or falsify a license and is punishable by up to 60 days in jail and a fine of up to $500. The bill makes it an administrative violation for a licensee to display an altered, defaced, or falsified license. Such violations are subject to licensure revocation and a fine of up to $1,000 per day.

Maternal and Infant Health Care

Section 383.325, F.S., requires birth centers to maintain as public information, records of all inspection reports which have been filed with, or issued by, any governmental agency. Copies of such reports must be retained in the records of the facility for at least five years. Facilities are required to furnish a copy of the last inspection report to patients and potential patients of the facility. All of these requirements are also contained in s. 408.811, F.S.

Section 408.806(8), F.S., allows AHCA to provide electronic access to information or documents, such as inspection report results, as an alternative to sending documents as required by authorizing statutes. Upon review by AHCA, the reports are posted on the inspections reports website.[9]

The bill repeals s. 383.325, F.S., relating to inspection report requirements for birth centers. The section is duplicative of the inspection report requirements contained in part II of chapter 408, F.S.

Diabetes Research

The bill creates s. 385.2031, F.S., designating the Florida Hospital/Sanford-Burnham Translational Research Institute for Metabolism and Diabetes as a resource for diabetes research in prevention and treatment.

Hospitals

Accreditation Organizations

Currently, Florida law allows AHCA to consider and use hospital accreditation by certain accrediting organizations for various purposes, including accepting accreditation surveys in lieu of AHCA surveys, requiring accreditation for designation as certain specialty hospitals, and setting standards for quality improvement programs. Section 395.002, F.S., defines “accrediting organizations” as the Joint Commission on Accreditation of Healthcare Organizations, the American Osteopathic Association, the Commission on Accreditation of Rehabilitation Facilities, and the Accreditation Association for Ambulatory Health Care, Inc.

The bill broadens the definition of “accrediting organizations” to include any nationally recognized accrediting organization whose standards incorporate comparable licensure requirements as determined by AHCA. This gives AHCA and providers greater flexibility to accept additional accrediting organizations and reconsider existing organizations based on current statutory and rule-based standards.

Private Utilization Review

A private review agent is a person or entity that performs utilization review services for third party payers on a contractual basis for outpatient or inpatient services.[10] Prior to 2009, s. 395.0199, F.S., required private review agents to be registered by AHCA to conduct utilization reviews for third-party payers concerning the medical necessity or appropriateness in the allocation of health care services offered by hospitals.[11] This process required the private review agents to make an initial denial

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[9] Agency for Health Care Administration, Public Records Search, *available at:* http://apps.ahca.myflorida.com/dm_web/(S(fgto15qkcyqp4dcaauvgfjho))/default.aspx (last viewed February 1, 2012).
[10] S. 395.002(24), F.S.
[11] S. 395.002(31), F.S.

determination if the services being furnished were found to be inappropriate, not medically necessary, or not reasonable.[12] In 2009, the Legislature repealed this requirement.[13]

The bill deletes obsolete definitions in s. 395.002, F.S., referring to "private review agent", "utilization review" and "initial denial determination".

Complaint Investigation Procedures

Complaint investigation procedures for hospitals exist in the hospital authorizing statutes as well as in the Act. Section 395.1046, F.S., provides special procedures for hospital complaints regarding emergency access issues. AHCA may investigate emergency access complaints even if the complaint is withdrawn. When the investigation is complete, AHCA shall prepare an investigative report that makes a probable cause determination. AHCA reports that the federal process for emergency access complaints dictates that these complaints should not be handled any differently from other types of complaints.

The bill repeals s. 395.1046, F.S., which eliminates the special procedures for investigating hospital emergency access complaints and would allow AHCA to employ existing hospital complaint investigation procedures used for all other types of complaints.

Infection Control

Section 395.1055(1), F.S., requires AHCA to adopt rules requiring hospitals to meet certain minimum standards of patient care and safety. The rules must include:

- Infection control, housekeeping, sanitary conditions, and medical record procedures that will adequately protect patients; and
- Conforming of licensed facility beds to minimum space, equipment, and furnishings standards as specified by DOH.

AHCA Rule 59A-3.250, F.A.C., was promulgated in 1995 to comply with the provisions of s. 395.1055, F.S.

Hospitals use chemical disinfectants to control infection in their facilities. The Environmental Protection Agency (EPA) has been testing hospital sterilants, disinfectants, and tuberculocides since 1991 to ensure that products meet stringent efficacy standards.[14] If disinfectants meet these standards, they are given a registration number that appears on the product label, along with other required statements.[15] One of the label requirements is the recommended contact time for the disinfectant to be effective. The labels of most registered disinfectants specify a contact time of 10 minutes. However, EPA will approve a shortened contact time if a product manufacturer submits confirmatory efficacy data.[16]

The bill amends s. 395.1055(1)(b), F.S., to require AHCA to adopt rules requiring hospital sanitation and housekeeping staff to:

- Wear gloves and masks while cleaning patient rooms; and
- Disinfect environmental surfaces in patient rooms in accordance with the time instructions on the label of the disinfectant used by the hospital and document compliance.

The bill provides authority for AHCA to impose an administrative fine for each day that a violation of these provisions occurs.

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[12] S. 395.002(14), F.S.
[13] Ch. 2009-223, L.O.F.
[14] *See*, Antimicrobial Testing Program, U.S. Environmental Protection Agency, *available at* http://www.epa.gov/oppad001/antimicrobial-testing-program.html (last viewed January 26, 2012).
[15] I*d.*
[16] *Id.*

The bill also amends s. 395.1055(1)(e), F.S., providing that licensed facility beds conform to minimum space, equipment, and furnishings standards as specified by AHCA, the Florida Building Code, and the Florida Fire Prevention Code, instead of DOH.

Licensure Inspection

Section 395.0161(3), F.S., requires hospital license applicants to pay a fee at the time of inspection. The fee cannot be less than $8 per bed, and cannot be more than $12 per bed, with a minimum fee of $400 per facility.

The bill removes the requirement for the fees to be paid at the time of inspection, allowing for a single collection of fees when the license is renewed, rather than separate billing after each inspection.

Patient Records

Section 395.3025, F.S., provides that hospital patient records are considered confidential and must not be disclosed without the consent of the patient or the patient's legal representative. Also contained in s. 395.3025, F.S., is a provision allowing AHCA to obtain patient records upon subpoena issued pursuant to s. 456.071, F.S., for the purpose of an investigation. This provision is inconsistent with s. 456.071, F.S., which provides authority for DOH to issue subpoenas to obtain patient records for investigative purposes.

The bill amends s. 395.3025(4), F.S., to reference the DOH instead of AHCA, because AHCA regulates facilities under chapter 395, F.S., not DOH.

Trauma Centers

The regulation of trauma centers in Florida is established under chapter 395, F.S. Trauma centers treat individuals who have incurred a single or multiple injuries because of blunt or penetrating means or burns, and who require immediate medical intervention or treatment.

Pursuant to s. 395.402, F.S., Florida is divided into 19 "trauma service areas." A trauma service area is determined based on population density and an ability to respond to a specified number of patients in a trauma center environment. For purposes of medical response time, the trauma service area should have at least one Level I or Level II trauma center, and DOH is required to allocate, by rule, the number of trauma centers for each trauma service area. There cannot be more than 44 trauma centers in the state.

Section 395.401, F.S., requires local and regional trauma agencies to develop and submit plans for local and regional trauma service systems to DOH. The plans must include:

- The organizational structure of the trauma system;
- Pre-hospital care management guidelines for triage and transportation of trauma cases;
- Flow patterns of trauma cases and transportation system design and resources; and
- The number and location of needed trauma centers based on local needs, population, and location of resources.

Section 395.4025, F.S., provides a scheduled application process and specific trauma center selection criteria. Standards for designation are based on national guidelines established by the American College of Surgeons. Standards for designation as a pediatric center are developed in conjunction with Children's Medical Services.

The bill amends s. 395.102 and s. 395.402, F.S., removing the direction to DOH to determine the number and location of trauma centers. The bill also removes the requirement that there be no more than 44 trauma centers in the state.

The bill amends s. 395.401, F.S., by removing the requirement for plans submitted by local and regional trauma agencies to include the information on the number and location of needed trauma centers.

The bill amends s. 395.4025, F.S., by removing the requirement for a hospital to certify that its intent to operate as a trauma center is consistent with the trauma services plan of the local regional trauma agency. The bill provides that the instructions for submitting information to DOH for approval as a trauma center must explain the specific documentation necessary for DOH to determine a hospital's compliance with the clinical standards and capabilities of a trauma center. The bill also removes the ability for DOH to grant time extensions up to 18 months to trauma center applicants. The bill requires DOH to approve applications that meet clinical standards for trauma centers.

Statutory Revisions

The bill makes the following changes to update correct statutory cross references, and remove obsolete, or duplicative statutory provisions:

- Amends s. 394.4787, F.S., to update a cross reference relating to the definition of "specialty psychiatric hospitals";
- Amends s. 395.0193, F.S., to update a reference to the correct authority of DOH instead of AHCA relating to medical staff peer review;
- Amends s. 395.1023, F.S. to clarify that referrals regarding child abuse or neglect are referred to DCF by correcting a cross reference to Department;
- Amends s. 395.3036, F.S., to update a cross reference relating to public lessors and private lessees;
- Amends s. 395.3037, F.S., to repeal duplicative definitions of DOH and AHCA; and
- Amends s. 395.602, F.S., deleting an obsolete provision relating to the definition of "rural hospital"

Nursing Homes

Licensure

An application for nursing home licensure must include the following:

- A signed affidavit disclosing financial or ownership interest of a nursing home controlling interest in the last five years in any health or residential facility which has closed, filed bankruptcy, has a receiver appointed or an injunction placed against it, or been denied, suspended, or revoked by a regulatory agency.[17]
- A plan for quality assurance and risk management.[18]
- The total number of beds including those certified for Medicare and Medicaid. This information is also required by s. 408.806(1)(d), F.S.
- Copies of any civil verdicts or judgments involving the applicant rendered within the last 10 years.

The bill amends s. 400.071(1)(b), F.S., to remove the requirement for prospective licensees to routinely submit a signed affidavit disclosing financial or ownership interest at the time of licensure and provides AHCA the authority to request the documents if needed.

The bill amends s. 400.071(5), F.S., to remove the requirement for prospective licensees to submit with their applications a plan for quality assurance and for conducting risk management. The plans for quality assurance and risk management are reviewed by AHCA as part of its licensure inspection process.[19]

[17] SS. 400.071(1)(b), and 400.111, F.S.
[18] S. 400.071(5), F.S.
[19] S. 400.147(11), F.S.

The bill amends s. 400.071(1)(c), F.S., to remove to duplicative language requiring prospective licensees to submit the total number of beds including those certified for Medicare and Medicaid at the time of licensure. This information is also required under s. 408.806(1)(d), F.S.

The bill amends s. 400.071(1)(e), F.S., to remove the requirement for applicants to submit with their applications copies of civil verdicts or judgments involving the applicant rendered within the last 10 years and provides AHCA the authority to request the documents if needed.

The bill also amends s. 400.0712, F.S., relating to inactive licensure of nursing homes, to remove duplicative language. Inactive licenses may be issued by AHCA to nursing homes for all or a portion of its beds, pursuant to part II of chapter 400, F.S., and s. 400.0712(1), F.S.

Administrator Licensure

Nursing home administrators are licensed by the Department of Health (DOH) and the Board of Nursing Home Administrators (board), pursuant to s. 468.1695, F.S., and DOH Rule 64B10-11, F.A.C. Applicants must either:[20]

- Hold a baccalaureate degree from an accredited college or university with a major in health care administration or have credit in at least 60 semester hours in subjects, as prescribed by rule of the board;[21] and
- Complete a college-affiliated or university-affiliated internship or a 1,000-hour nursing home administrator-in-training program approved by the board.

Or:

- Hold a baccalaureate degree from an accredited college or university; and
  - Complete a 2,000-hour nursing home administrator-in-training program approved by the board; or
  - Have one year of management experience in performing executive duties and skills, including the staffing, budgeting, and directing of resident care, dietary, and bookkeeping departments within a skilled nursing facility, hospital, hospice, assisted living facility with a minimum of 60 licensed beds, or geriatric residential treatment program.

Nursing home administrator applicants are examined by DOH once the board certifies that they have completed the application form and remitted an examination fee. The examination is given two times each year and includes questions on the various subjects of nursing home administration.[22] The board approves the nursing home administrators examination developed and administered by the National Association of Boards of Examiners of Nursing Home Administrators. In addition to the national examination, each applicant must also take an examination on the laws and regulations of the State of Florida which governs the practice of nursing home administrators.[23]

The bill amends s. 468.1695(2), F.S., to revise the education requirements for nursing home administrators to include applicants with a health services administration or equivalent major.

Geriatric Outpatient Clinics

[20] S. 468.1695(2), F.S.; Rule 64B10-11.002, F.A.C.
[21] Florida Department of Health Rule 64B10-11.007, F.A.C., requires courses from the following subject areas to fulfill the 60 semester hours: General administration and management of health care facilities (minimum 6 hours); Accounting and financial management (minimum 6 hours); Personnel management and labor relations (minimum 3 hours); Computer applications (minimum 3 hours); Long-term health care administration (minimum 3 hours); Health care planning and delivery systems (minimum 3 hours); Aging (minimum 3 hours); Governmental standards and regulation of long-term health care (minimum 3 hours); Legal aspects of health care administration (minimum 3 hours); and patient care management (minimum 3 hours).
[22] S. 468.1695(1), F.S.
[23] Rule 64B10-11.002, F.A.C.

Currently, nursing homes may establish a geriatric outpatient clinic as authorized in s. 400.021, F.S., to provide outpatient health care to persons 60 years of age or older. The clinic can be staffed by a registered nurse or a physician's assistant.

The bill expands the health care professionals that may staff a geriatric outpatient clinic in a nursing home to include licensed practical nurses under the direct supervision of a registered nurse, advanced registered nurse practitioner, physician assistant, or physician.

Administration and Management

Section 400.021(16), F.S., defines "resident care plan" as a written plan developed, maintained, and reviewed not less than quarterly by a registered nurse, which includes a comprehensive assessment of the needs of an individual resident. The resident care plan is required to be signed by the director of nursing or another registered nurse employed by the facility.

Section 400.141(1)(j), F.S., requires licensees to maintain full patient records. AHCA Rule 59A-4.118, F.A.C., establishes certain requirements regarding the credentials of nursing home records personnel. Specifically, the rule requires nursing homes to employ or contract with a person who is eligible for certification as a registered record administrator or an accredited record technician by the American Health Information Management Association or is a graduate of a school of medical record science that is accredited jointly by the Council on Medical Education of the American Medical Association and the American Health Information Management Association. AHCA Rule 59A-4.118, F.A.C., was promulgated in 1994 and the credentialing organizations referred to in the rule presently do not exist as listed. There is also no authorizing statute that requires nursing homes to contract with a medical records consultant.

Section 400.141(1)(v), F.S., requires facilities to assess all residents for eligibility for pneumococcal polysaccharide vaccination (PPV) and vaccinate residents when indicated within 60 days after the effective date of this act. PPV is an infection that is caused by a bacterium and can result in infections of the middle ear, sinus infections, lung infections (pneumonia), blood stream infections, and meningitis.[24] The United States Food and Drug Administration (FDA) recently approved another pneumococcal vaccine, known as pneumococcal conjugate (PCV) or Prevnar 13.[25] PCV prevents invasive disease caused by 13 different serotypes of the bacterium streptococcus pneumonia.[26] The bacterium can cause infections of the blood, middle ear, and the covering of the brain and spinal cord, as well as pneumonia.[27]

The bill removes the requirement that the director of nursing or other administrative nurse sign the resident care plan.

The bill amends s. 440.141(1)(j), F.S., to include federal language regarding maintenance of medical records consistent with federal medical records regulations contained in Title 42, Code of Federal Regulations. Specifically, the federal regulations require nursing homes to maintain medical records in accordance with accepted professional standards and practices that are complete, accurately documented, readily accessible, and systematically organized.[28] The addition of these federal standards will require the repeal of AHCA Rule 59A-4.118, F.A.C., related to the credentials of medical records personnel.

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[24] *See* Vaccines & Immunizations, Pneumococcal Disease Q&A, Department of Health and Human Services, Centers for Disease Control and Prevention, available at http://www.cdc.gov/vaccines/vpd-vac/pneumo/dis-faqs.htm (last viewed January 9, 2012).
[25] United States Food and Drug Administration, Center for Biologics Evaluation and Research. Pneumococcal 13-Valent Conjugate Vaccine approval letter, February 24, 2010. Retrieved February 18, 2012, available at http://www.fda.gov/BiologicsBlood Vaccines/Vaccines/ApprovedProducts/ucm201741.htm (last visited February 18, 2012).
[26] United States Food and Drug Administration, News Release: *FDA Approves Pneumococcal Disease Vaccine with Broader Protection*, February 24, 2010, available at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm201758.htm (last visited February 18, 2012).
[27] *Id.*
[28] 42 C.F.R. 483.75.

The bill removes obsolete language requiring facilities to vaccinate residents within 60 days after the effective date of the act which made this law. The bill retains language that requires new residents to be assessed for vaccination within five working days after admission and if needed, vaccinated within 60 days. The bill also allows for the use of an additional vaccination to be provided in accordance with the requirements above. Nursing homes will be required to assess all residents within 5 working days after admission for eligibility of pneumococcal vaccination or revaccination, which can be either a PPV or a PCV and if needed, vaccinate the resident within 60 days.

Nursing homes are required to maintain records of all grievances, and to report to the agency, upon licensure renewal, various data regarding those grievances.[29] The bill retains the requirement for nursing homes to maintain all grievance records, but removes the requirement that nursing homes report the grievance information at the time of relicensure. The bill requires nursing homes to maintain a report, subject to inspection by AHCA, of the total number of grievances handled.

Resident Transfer and Discharge

The landlord tenant laws under part II of chapter 83, F.S., apply generally to the rental of a dwelling unit.[30] Nursing home facilities are governed by the specific transfer and discharge requirements contained in s. 400.0255, F.S, which apply to transfers and discharges that are initiated by the nursing home facility. Facilities are required to provide at least 30 days advance notice of a proposed transfer or discharge to the resident.[31] The notice must be in writing and must contain all information required by state and federal law, rules, or regulations applicable to Medicaid or Medicare cases.[32] Residents are entitled to a fair hearing to challenge a facility's proposed transfer or discharge.[33] The Department of Children and Family Services' Office of Appeals Hearings is tasked with conducting the hearings. A hearing decision must be rendered within 90 days after receipt of request for the hearing.[34]

The bill adds language to clarify that nursing home residents are excluded from the landlord tenant laws found under part II of chapter 83, F.S. The transfer and discharge procedures under s. 400.0255, F.S., govern all transfers and discharges for residents of all facilities licensed under part II of chapter 400, F.S.

Staffing Requirements

Nursing homes must comply with staff-to-resident ratios requirements. Under s. 400.141(1)(o), F.S., nursing homes are required to semiannually submit to AHCA information regarding facility staff-to-resident ratios, staff turnover, and staff stability, including information regarding certified nursing assistants, licensed nurses, the director of nursing, and the facility administrator. The ratio must be reported as an average of the most recent calendar quarter. Staff turnover must be reported for the most recent 12-month period. The formula for determining staff stability is the total number of employees that have been employed for more than 12 months, divided by the total number of employees employed at the end of the most recent calendar quarter, and expressed as a percentage.

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 AHCA. All other citations for a Class II deficiency represent current ongoing non-compliance that AHCA determines has compromised a resident's ability to maintain or reach his or her highest practicable physical, mental, and psychosocial well-being. Use of the Class II deficiency for a failure to cease admissions is an inconsistent use of a "Class II" deficiency in comparison to all other violations. No nursing homes were cited for this violation in 2010.

[29] S. 400.1183(2), F.S.
[30] S. 83.41, F.S.
[31] S. 400.0255(7), F.S.
[32] S. 400.0255(8), F.S.
[33] S. 400.0255(10)(a), F.S.
[34] S. 400.0255(15), F.S.

The bill removes the requirements under s. 400.141(1)(o), F.S., for reporting staff-to-resident ratio information semiannually to AHCA.

The bill modifies the penalty for nursing homes that fail to self-impose an admissions moratorium for insufficient staffing to a fine of $1,000 instead of a Class II deficiency.

General Staffing Requirements

Section 400.23(3)(a), F.S., establishes general nursing home staffing standards. Until 2001, s. 400.23(3)(a) did not require a minimum number of licensed nurses or certified nursing assistants. When Rule 59A-4.1295, F.A.C., was adopted in 1997, it was in compliance with s. 400.23(3)(a), F.S., because there were no minimum staffing standards required in the statute at that time. However, the minimum staffing requirements in s. 400.23(3)(a), F.S., have changed since the Rule language above was adopted.

In 2001, s. 400.23(3)(a), F.S., was amended to include a minimum staffing standard, which is still in effect today. Currently, s. 400.23(3)(a), F.S., establishes general nursing home staffing standards and requires at least 3.6 hours of licensed nursing and CNA direct care per resident per day. Minimums of 2.5 hours of direct care by a CNA and 1 hour of direct care by a licensed nurse are required. The minimum staffing requirements for pediatric nursing homes in Rule 59A-4.1295, F.A.C., are inconsistent with those required for general nursing homes in s. 400.23(3)(a), F.S. The rule limits CNA care to no more than 1.5 hours per day for both fragile and skilled patients, while the statute allows a minimum of 2.5 hours of CNA care per day.

Pediatric Staffing Requirements

Section 400.23(5), F.S., requires AHCA, in collaboration with the Division of Children's Medical Services within the Department of Health (DOH), to adopt rules for minimum standards of care for persons under 21 years of age who reside in nursing home facilities. In 1997, Rule 59A-4.1295, F.A.C., was adopted to provide these additional standards of care for pediatric nursing homes which consist of the following:

- For residents who require **skilled care**, each nursing home must provide an average of 3.5 hours of nursing care per patient per day. A maximum of 1.5 hours may be provided by a certified nursing assistant (CNA), and no less than 1 hour of care must be provided by a licensed nurse.
- For residents who are **fragile,** each nursing home must provide an average of 5 hours of direct care per patient per day. A maximum of 1.5 hours of care may be provided by a CNA, and no less than 1.7 hours of care must be provided by a licensed nurse.

The bill codifies in law the current AHCA rule on pediatric staffing requirements for nursing homes that serve individuals less than 21 years of age. Further, the bill provides that these rules are to apply in lieu of the standards contained in s. 400.23(3)(a), F.S. The staffing requirements are as follows:

- For individuals under age 21 who require **skilled** care, each nursing home facility must provide a minimum combined average of licensed nurses, respiratory therapists, respiratory care practitioners and CNAs of 3.9 hours of direct care per resident per day. The 3.9 hours must consist of:
    - No less than 1 hour licensed nursing care; and
    - No more than 1.5 hours of CNA care;

- For individuals under age 21 who are **fragile**, each nursing home must include a minimum combined average of licensed nurses, respiratory therapists, respiratory care practitioners and CNAs of 5.0 hours of direct care per resident per day. The 5 hours must consist of:
    - No less than 1.7 hours of licensed nursing care; and

- No more than 1.5 hours of CNA care.

The bill requires one registered nurse to be on duty 24 hours per day for both skilled nursing and medically fragile facilities.

Do Not Resuscitate Orders

Section 400.142, F.S., requires AHCA to develop rules relating to implementation of do not resuscitate orders (DNRs) for nursing home residents. Criteria for DNRs are found in s. 401.45, F.S., which allows for emergency pre-hospital treatment to be provided by any licensee and provides that resuscitation may be withheld from a patient by an emergency medical technician (EMT) or paramedic if evidence of a DNR is presented.[35] Section 401.45, F.S., also provides rule-making authority to DOH to implement this section and requires DOH, in consultation with the Department of Elderly Affairs and AHCA, to develop a standardized DNR identification system with devices that signify, when carried or worn, that the patient has been issued an order not to administer cardiopulmonary resuscitation by a physician.[36]

DOH developed rule 64J-2.018, F.A.C., which became effective October, 1 2008, while AHCA has yet to promulgate any rules relating to the implementation of DNRs. Rule 64J-2.018, F.A.C., provides the following:[37]

- An EMT or paramedic must withhold or withdraw cardiopulmonary resuscitation if presented with an original or completed copy of DH Form 1896 (Florida DNR Form).
- The DNR Order form must be printed on yellow paper and have the words "DO NOT RESUSCITATE ORDER" printed in black.
- A patient identification device is a miniature version of DH Form 1896 and is a voluntary device intended to provide convenient and portable DNR order form.
- The DNR order form and patient identification device must be signed by the patient's physician.
- An EMT or paramedic must verify the identity of the patient in possession of the DNR order form or patient identification device by means of the patient's driver license or a witness in the presence of the patient.
- During transport, the EMT must ensure that a copy of the DNR order form or the patient identification device accompanies the live patient.
- A DNR may be revoked at any time by the patient.

The bill removes the requirement for AHCA to promulgate rules related to the implementation of DNRs for nursing home residents. This requirement appears to be duplicative of DOH rulemaking authority in s. 401.45(5), F.S.

Inspections and Surveys

AHCA employs surveyors to inspect nursing homes. Pursuant to s. 400.275, F.S., newly hired nursing home surveyors must spend two 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. Federal regulations prohibit an AHCA staff person who formerly worked in a nursing home from inspecting a nursing home within two years of employment with that home; state law requires a five year lapse.

The bill removes the requirement for new AHCA nursing home inspection staff to spend two days in a nursing home as part of basic training and aligns staff requirements with federal regulations. AHCA nursing home staff must still be fully qualified under federal requirements for the Surveyor Minimum Qualifications Test.

[35] Section 401.45, F.S.
[36] *Id.*
[37] Florida Department of Health Rule 64J-2.018, F.A.C.

Internal Risk Management and Quality Assurance Program

Sections 400.147(10) and 400.0233, F.S., require nursing homes to report civil notices of intent to litigate and civil complaints filed with clerks of courts by a resident or representative of a resident. This information has been used to produce the Semi-Annual Report on Nursing Homes required by s. 400.195, F.S. However, s. 400.195, F.S., was repealed in 2010.

Section 400.147(7), F.S., requires nursing homes to initiate an investigation and notify AHCA within one business day after the risk manager has received an incident report. The notification must be made in writing and be provided electronically, by facsimile device or overnight mail delivery.

The bill eliminates the requirement to report notices of intent to litigate and civil complaints. The bill also eliminates the requirement that nursing homes notify AHCA in writing when they initiate an investigation. However, providers must still initiate their own evaluation within one day. A full report is also still required to be sent to AHCA within 15 calendar days after the adverse incident occurs.

Respite Care

Section 400.141(1)(f), F.S., allows nursing homes to provide respite care for people needing short-term or temporary nursing home services. Only nursing homes with standard licensure status with no Class I or Class II deficiencies in the past two years or having Gold Seal status may provide respite services. AHCA is authorized to promulgate rules for the provision of respite services.

The bill amends s. 400.141, F.S., to expand the ability of nursing homes to provide respite services not exceeding 60 days per year and individual stays may not exceed 14 days. The bill allows all licensed nursing homes to provide respite services without limitations based on prior deficiencies. The bill provides additional criteria for the provision of respite services. For each patient, the nursing home must:

- Have an abbreviated plan of care for each respite patient, covering nutrition, medication, physician orders, nursing assessments and dietary preferences;
- Have a contract that covers the services to be provided;
- Ensure patient release to the proper person; and
- Assume the duties of the patient’s primary caregiver.

The bill provides that respite patients are exempt from discharge planning requirements, allowed to use his or her personal medication with a physician’s order, and covered by the resident rights as delineated in s. 400.022, F.S., except those related to transfer, choice of physician, bed reservation policies, and discharge challenges. The bill requires prospective respite patients to provide certain medical information to the nursing home and entitles the patient to retain his or her personal physician.

Notice of Bankruptcy and Eviction

Currently, nursing homes are required to notify AHCA of bankruptcy filing pursuant to s. 400.141(1)(r), F.S. However, nursing homes are not required to notify AHCA of eviction, and there is no statutory requirement for other types of facility providers to notify AHCA if served with an eviction notice or of bankruptcy filing.

The bill amends s. 408.810, F.S., to require providers’ controlling interests to notify AHCA within 10 days after a court action to initiate bankruptcy, foreclosure, or eviction proceedings. This applies to any such action to which the controlling interest is a petitioner or defendant.

Statutory Revisions

The bill makes the following changes to update correct statutory cross references, and remove obsolete, or duplicative statutory provisions:

- Amends s. 400.0255, F.S., updating an obsolete cross reference relating to fair hearings for Medicaid cases;
- Amends s. 400.063, F.S., removing an obsolete cross reference; and
- Amends s. 400.915, F.S., removing an obsolete cross reference in the licensing standards for Prescribed Pediatric Extended Care Centers.

Home Health Agencies

A home health agency is an organization that provides home health services and staffing services.[38] Home health agencies are regulated by AHCA pursuant to part III of chapter 400, F.S. Florida law regulates the business relationships of home health agencies, prohibiting "self-referral" situations, in which home health agencies provide monetary incentives for referrals. Section 400.474(6), F.S., provides AHCA the authority to deny, revoke, or suspend the license of a home health agency and impose a fine of $5,000 against a home health agency that gives remuneration to:

- Another home health agency with which it has formal or informal patient-referral transactions or arrangements for staffing services;
- A health services pool with which it has formal or informal patient-referral transactions or arrangements for staffing services;
- A physician without a medical director contract, and the home health agency has received a patient referral in the preceding 12 months from that physician;
- A physician, and the home health agency has more than one medical director contract in effect at one time, and the home health agency has received a patient referral in the preceding 12 months from that physician;
- A member of the physician's office staff, and the home health agency has received a patient referral in the preceding 12 months from that physician; or
- An immediate family member of the physician, and the home health agency has received a patient referral in the preceding 12 months from that physician.

Remuneration is defined as any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind.[39]

The bill amends s. 400.462(27), F.S., revising the definition of "remuneration" to allow home health agencies to distribute items with an individual value of up to $15 and which include, but are not limited to, plaques, certificates, trophies, or novelties that are intended solely for promotional, recognition, or advertising purposes.

Homemaker and Companion Organizations

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 services such as housekeeping, errands, shopping, and meal preparation. Companions or sitters keep people company and take them to recreational activities, shopping or appointments. Homemakers and companions cannot provide any hands-on personal care.[40] Personal care must be provided by home health aides and CNAs that work for licensed home health agencies and nurse registries.

There are currently 2,303 registered organizations providing homemaker and companion services.[41] Of that total, 503 are contractors of the Agency for Persons with Disabilities (APD) who provide companion

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[38] S. 400.462(12), F.S.
[39] S. 400.462(27), F.S.
[40] S. 400.462(7),(16), F.S.
[41] AHCA, *Staff Analysis and Economic Impact, House Bill Number 1419* (January 20, 2012).

services through the Developmental Disabilities Medicaid Waiver.[42] APD requires training and experience as well as background screening, while AHCA only requires background screening prior to registration.

The 1999 Florida Legislature exempted from home health agency and nurse registry licensure, the companion and sitter organizations that were registered by AHCA on January 1, 1999, and were authorized to provide personal services to developmentally disabled persons on January 1, 1999, and permitted the organizations to continue to provide services to any past, present and future clients who need personal care services.[43] Currently there are seven organizations that are exempt under this law.[44]

The bill amends s. 400.509, F.S., to exempt organizations that only provide companion services to developmentally disabled persons under contract with APD from registration by AHCA. The exemption is expected to result in estimated annual savings to providers of $123,486.[45]

Nurse Registries

A nurse registry is defined as any person that procures, offers, promises, or attempts to secure health-care-related contracts for registered nurses, licensed practical nurses, CNAs, home health aides, companions, or homemakers, who are compensated by fees as independent contractors to provide services to patients, or staffing services to facilities.[46] Nurse registries are regulated by AHCA pursuant to part III of chapter 400, F.S.

Section 400.506(15)(a), F.S., allows AHCA to deny, suspend, or revoke the license of a nurse registry and impose a fine of $5,000 against a nurse registry that:

- Provides services to residents in an assisted living facility (ALF) for which the nurse registry does not receive fair market value remuneration;
- Provides staffing to an ALF for which the nurse registry does not receive fair market value remuneration;
- Gives remuneration to a case manager, discharge planner, facility-based staff member, or third-party vendor who is involved in the discharge planning process of a hospital or facility licensed under chapter 395, F.S.; or
- Gives remuneration to a physician, member of the physician's staff, or an immediate family member of the physician, and the nurse registry received a patient referral in the last 12 months from that physician.

However, nurse registries can give remuneration in the manner described above if they do not bill the Florida Medicaid program or the federal Medicare program, or share a controlling interest with any entity licensed under part II of chapter 408, F.S.

The bill amends s. 400.506(15)(a), F.S., to broaden the exemption to nurse registry marketing restrictions, by exempting nurse registries that bill the Florida Medicaid program.

The bill also amends s. 400.506, F.S., to authorize an administrator of a nurse registry to manage up to five registries if all five registries 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.

Hospice Licensure

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[42] *Id.*
[43] S. 400.464(5)(b)4, F.S.
[44] AHCA, *Staff Analysis and Economic Impact, House Bill Number 1419* (January 20, 2012).
[45] AHCA, *Staff Analysis and Economic Impact, House Bill Number 1419* (January 20, 2012).
[46] S. 400.462(21), F.S.

Section 400.601(3), F.S., defines “hospice” as a centrally administered corporation providing a continuum of palliative and supportive care for a terminally ill patient and his or her family.

Section 408.810(8) F.S., requires any hospice initial or change of ownership applicant show anticipated provider revenue and expenditures, the basis for financing anticipated cash flow requirements and access to contingency financing. Section 400.606(1)(l), F.S., requires that an annual operating budget be submitted, which duplicates the financial information now required in the Act.

The hospice authorizing statutes and federal regulations require that hospices have inpatient beds for pain control, symptom management, and respite care. Inpatient beds may be in a hospital, skilled nursing facility or a freestanding inpatient facility operated by a hospice. Section 408.043, F.S., requires that there be a certificate of need for a hospice freestanding facility “primarily engaged in providing inpatient care and related services.” This provision is repeated in the Act.

The bill amends s. 400.601(3), F.S., to include limited liability companies in the definition of “hospice”.

The bill removes the requirement for hospice licensure applicants to submit a projected annual operating budget. Financial projections are already submitted as part of the proof of financial ability to operate as required in the Act; therefore, this removes duplicative requirements.

The bill amends both the Act and the hospice authorizing statutes related to certificates of need for inpatient hospice facilities. The bill eliminates the modifier “primarily” to provide that any provision of inpatient hospice care, in any facility not already licensed as a health care facility (like a hospital or nursing home), requires a certificate of need. In effect, the bill provides that no exemptions to this requirement exist.

Home Medical Equipment

Section 400.931(2), F.S., allows a bond be posted as an alternative to submitting proof of financial ability to operate for a home medical equipment provider. Section 408.8065, F.S., requires the submission of financial statements demonstrating the ability to fund start up costs, working capital, and contingency requirements.

The bill deletes the provisions of s. 400.931, F.S., related to the ability to submit a bond as an alternative to submitting proof of financial ability to operate. Due to 2009 legislative changes, financial oversight is now addressed in the Act. In addition, the bill requires out-of-state home medical equipment providers to be accredited to be licensed in Florida.

Health Care Clinics

Part X of chapter 400, F.S., contains the Health Care Clinic Act. This act was passed in 2003 to reduce fraud and abuse in the personal injury protection (PIP) insurance system. Florida’s Motor Vehicle No-Fault Law[47] requires motor vehicle owners to maintain $10,000 of PIP insurance. PIP benefits are available for certain express damages sustained in a motor vehicle accident, regardless of fault.

Pursuant to the Health Care Clinic Act, AHCA licenses entities that meet the definition of a “clinic”: “an entity at which health care services are provided to individuals and which tenders charges for reimbursement for such services…”.[48] Licensure applications must identify the owners, medical director, and medical providers employed by the clinic. Applicants must provide proof of compliance with applicable rules and financial ability to operate. A level two background screening is required of each applicant for clinic licensure, and certain criminal offenses bar licensure. Each clinic must have a medical director or clinic director who agrees in writing to accept legal responsibility pursuant to s. 400.9935, F.S., for the following activities on behalf of the clinic:

[47] Sections 627.730-627.7405, F.S., the Florida Motor Vehicle No-Fault Law, were repealed on October 1, 2007 pursuant to s. 19, ch. 2003-411 L.O.F. The No-Fault Law was revived and reenacted effective January 1, 2008 pursuant to ch. 2007-324 L.O.F.
[48] Section 400.9905(4), F.S.

- Ensuring that all practitioners providing health care services or supplies to patients maintain a current, active, and unencumbered Florida license;
- Reviewing patient referral contracts or agreements made by the clinic;
- Ensuring that all health care practitioners at the clinic have active appropriate certification or licensure for the level of care being provided;
- Serving as the clinic records owner;
- Ensuring compliance with the recordkeeping, office surgery, and adverse incident reporting requirements of chapter 456, F.S., the respective practice acts, and rules adopted under the Health Care Clinic Act; and
- Conducting systematic reviews of clinic billings to ensure billings are not fraudulent or unlawful. If an unlawful charge is discovered, immediate corrective action must be taken.

AHCA may deny, revoke, or suspend a health care clinic license and impose administrative fines of up to $5,000 per violation pursuant to s. 400.995, F.S.

Although all clinics must be licensed, s. 400.9905(4), F.S., contains a listing of entities that are not considered a “clinic” for purposes of licensure, including:

- Entities licensed or registered by the state under one or more specified practice acts and that only provide services within the scope of their license, and entities that own such entities, and entities under common ownership with such entities;
- Entities that are exempt from federal taxation under 26 U.S.C. sec. 501(c)(3) or sec. 501(c)(4);
- Community college and university clinics;
- Entities owned or operated by the federal or state government;
- Clinical facilities affiliated with an accredited medical school which provides certain training;
- Entities that provide only oncology or radiation therapy services by physicians and are owned by publicly-traded corporations;
- Clinical facilities affiliated with an accredited certain college of chiropractic which provides certain training;
- Entities that provide a certain amount of practitioner staffing or anesthesia services to hospitals;
- Orthotic or prosthetic facilities owned by publicly-traded corporations; and

The bill expands an existing exemption from health care clinic licensure for clinics that are wholly owned, directly or indirectly, by a publicly traded corporation to include pediatric cardiology, perinatology, or anesthesia clinics. The bill also creates exemptions from licensure for entities:

- Owned by a corporation generating more than $250 million in annual sales and which have at least one owner who is a health care practitioner;
- Owned directly or indirectly by a publically traded entity with $100 million or more in total annual revenues derived from providing health care services by employed or contracted licensed health care practitioners; and
- Entities that employ 50 or more licensed health care practitioners where the billing for medical services is under a single tax identification number.

Licensure for health care clinics includes mobile clinics and portable equipment providers. The bill provides that portable service providers, such as mobile ultrasound providers, are subject to health care clinic licensure even though they do not deliver care at the clinic’s location.

Section 400.991(4), F.S., allows a bond to be posted as an alternative to submitting proof of financial ability to operate for health care clinics. The bill deletes provisions in s. 400.991(4), F.S., related to the ability to submit a bond as an alternative to submitting proof of financial ability to operate. Due to 2009 legislative changes, financial oversight is now addressed in the Act.

Local Health Councils

Local health councils are established in s. 408.033, F.S., as public or private nonprofit agencies to provide certain health related services to the counties of a district. Funding for local health councils is provided in s. 408.033(2), F.S., which states the cost of local health councils is to be borne by assessments on selected health care facilities subject to facility licensure by AHCA. Currently there is no timetable in statute addressing when fees are to be paid.

The bill requires fees to be collected prospectively at the time of licensure renewal and prorated for the licensure period.

Assisted Living Facilities

Licensure

Section 429.11, F.S., provides that, in addition to the license categories available in part II of chapter 408, F.S., a provisional license may be issued to an individual who submits an initial or change of ownership application.

Section 429.915, F.S., allows AHCA to issue a conditional license to an individual who submits an application for license renewal or change of ownership and the applicant fails to meet all standards and requirements for licensure. The conditional license issued by AHCA must not be valid for longer than six months, and must be accompanied by an approved plan of correction.

The bill amends s. 429.11, F.S., eliminating the ALF provisional license.

The bill amends s. 429.915, F.S., removing the requirement that AHCA must issue an approved plan of correction upon issuing a conditional license.

Resident Referrals

Section 429.195, F.S., prohibits ALFs from contracting to pay or receive any commission, bonus, kickback, or rebate with any person for resident referrals. These actions are considered patient brokering and are punishable as a third degree felony as provided in s. 817.505, F.S.

The bill amends s. 429.195(3), F.S., providing that the following activities are not prohibited patient brokering by ALFs and are not punishable as third degree felonies:

- Employing or contracting for marketing services;
- Referral services which provide information, consultation, or referrals to consumers; or
- Referrals to an ALF by residents of the ALF.

Drug Free Workplace Act

Section 112.0455, F.S., contains the Drug Free Workplace Act (Act). The purpose of the Act is to:

- Promote the goal of drug-free workplaces within government through fair and reasonable testing methods for the protection of public employees and employers;
- Encourage employers to provide employees who have drug use problems with an opportunity to participate in an employee assistance program or an alcohol and drug rehabilitation program;
- Provide for confidentiality of testing results.

Section 112.0455(12), F.S., establishes drug testing standards for laboratories licensed under part II of chapter 408. Laboratories are required to submit a monthly report with statistical information regarding the testing of employees and job applicants to AHCA. The reports must include the following information:[49]

[49] Section 112.0455(12)(d), F.S.

- The methods of analyses conducted;
- Drugs tested for;
- The number of positive and negative results for both initial and confirmation tests; and
- Any other information deemed appropriate by AHCA.

Identical language requiring the same report to be submitted to AHCA can be found in s. 440.102(9)(d), F.S., as it relates to the drug free workplace program requirements of the workers' compensation program.

The bill removes the requirement for laboratories to submit a monthly report to AHCA from s. 112.0455, F.S., as well as s. 440.102, F.S. The laboratory reports are not used by AHCA, so the removal of this requirement would reduce regulation that requires unnecessary reporting and save providers approximately $11,300.[50]

Clinical Laboratories

<u>Advanced Registered Nurse Practitioners</u>

Part I of chapter 483, F.S., contains licensure requirements for, and regulation of, clinical laboratories operated by practitioners for exclusive use. Section 483.035(1), F.S., requires clinical laboratories licensed by one or more practitioners under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, or chapter 466 to be licensed under, and comply with the provisions of part I of chapter 483. It provides authority for AHCA to adopt rules for staffing, for personnel, including education and training of personnel, for proficiency testing, and for construction standards relating to the licensure and operation of the laboratory based upon the standards contained in the federal Clinical Laboratory Improvement Amendments (CLIAs) of 1988.

Currently, the above list does not include advanced registered nurse practitioners (ARNPs). A laboratory owned or operated by an ARNP is required to have a laboratory director qualified in accordance with part III of chapter 483, F.S., and the Department of Health (DOH) Rule 64B-3, F.A.C. Rule 64B3-5.007, F.A.C., requires any laboratory director to have specialty/subspecialty specific qualifications and be a licensed physician or dentist, or hold a doctoral degree and be licensed by DOH as a clinical laboratory director.

The bill adds ARNPs to the list of exclusive use laboratory providers in s. 483.035(1), F.S., which means CLIA staffing requirements apply to ARNPs instead of the current clinical laboratory director qualification requirements.

<u>CLIA Certificates</u>

Section 483.051, F.S., provides authority for AHCA to adopt rules to implement the provisions of part I of chapter 483, F.S. The rules must include, but are not limited to licensure qualifications. Section 483.051(1), F.S., requires AHCA to provide for biennial licensure of all clinical laboratories and prescribe the qualifications necessary for such licensure.

Currently, AHCA processes federal CLIA certificates for all laboratories, but only processes state licenses for non-waived (complex) clinical laboratories. The federal Centers for Medicare and Medicaid Services conduct a test to determine qualification for a certificate of waiver under the CLIAs.

The bill amends s. 483.051(1), F.S., clarifying that AHCA must provide for biennial licensure of all "non-waived" clinical laboratories and provides a definition for non-waived laboratories to make sure the distinction is clear.

<u>Prohibited Rebates</u>

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[50] AHCA, *Staff Analysis and Economic Impact, House Bill Number 1419* (January 20, 2012).

Section 483.245, F.S., prohibits clinical laboratories from providing any commission, bonus, kickback, or rebate to any person or organization in return for patient referrals and requires AHCA to adopt rules that assess administrative penalties for such acts. Current law does not define what constitutes a rebate, commission, bonus, split-fee arrangement or kickback. However, AHCA defines the term "kickback" under Rule 59A-7.020(14), F.A.C., but the definition is broad and could be interpreted a number of different ways.

A collection station is a facility operated by a clinical laboratory where materials or specimens are withdrawn or collected from patients for subsequent delivery to another location for examination.[51] AHCA Rule 59A-7.024, F.A.C., authorizes clinical laboratories to maintain one or more collection stations provided they first obtain written approval from AHCA and they can only forward specimens to the clinical laboratory by which they are maintained.

In 2008, AHCA was petitioned for a declaratory statement related to the placing of specimen collectors in physician's offices without a lease agreement, and whether or not laboratories could provide free specimen cups when they also provide an on-site clinical laboratory test.[52] The declaratory statement was issued by AHCA on July 8, 2008, declaring that the placement of specimen collectors in a physician's office was a violation of this regulation, as was the provision of free specimen cups that offer physicians an instant test reading on-site.[53]

Further, AHCA provided a letter to providers in 2011 for clarification on other areas of the rule that could be broadly interpreted.[54] There is currently pending litigation related to AHCA's interpretation of what constitutes a kickback as defined under Rule 59A-7.020(14), F.A.C.[55]

The bill amends s. 483.245(1), F.S., providing that a clinical laboratory is prohibited from providing personnel to perform any functions or duties in a physician's office for any purpose, including for the collection of handling specimens, unless the clinical lab and the physician's office are owned and operated by the same entity. The bill requires AHCA to investigate all complaints of non-compliance and authorizes AHCA to impose a fine of $5,000 for each separate violation.

Multi-Phasic Health Testing Centers

Multi-phasic health testing centers (centers) are facilities which take human specimens for delivery to clinical laboratories for testing and may perform other basic human measurement functions. Centers are licensed and regulated under part II of chapter 483, F.S. Section 483.294, F.S., requires AHCA to inspect centers at least annually.

The bill amends the inspection schedule requiring AHCA to inspect centers biennially.

Brain and Spinal Cord Injury Trust Fund

Under current law, specified traffic fines may be used to provide an enhanced Medicaid rate to nursing homes that serve clients with brain and spinal cord injuries. According to AHCA, funds collected from these fines have not been sufficient to support a Medicaid nursing home supplemental rate for the estimated 100 adult ventilator-dependent patients.

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[51] S. 483.041(5), F.S.
[52] AHCA, *Staff Analysis and Economic Impact, House Bill Number 1419* (January 20, 2012).
[53] *In Re: Petition for Declaratory Statement of Dominion Diagnostics, LLC.,* Fraes No. 2008008228, available at http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Laboratory_Licensure/docs/FinalOrderDominion2008.pdf (last viewed February 1, 2012).
[54] Letter from AHCA, to Laboratory Director, (August 5, 2011), available at http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Laboratory_Licensure/kickback.shtml (last viewed February 1, 2012).
[55] AHCA, *Staff Analysis and Economic Impact, House Bill Number 1419* (January 20, 2012).

The bill redirects the revenue to the Brain and Spinal Cord Injury Trust Fund within DOH, to be used for Medicaid recipients who have sustained a brain or spinal cord injury and who are technologically and respiratory dependent.

Medicaid

Managed Care

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 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, 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.[56] A limited number of plans will be selected for each of the 11 regions. 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.[57]

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.[58]

Under current law, and prior to the implementation of statewide managed care, managed care plans participate in the Medicaid program by applying to the program on a county-by-county basis and meeting certain financial, organizational and provider network adequacy requirements.

The bill amends s. 409.9122, F.S., providing that all hospitals shall be deemed to be a part of a managed care plan's network in its application for participation or expansion in the Medicaid program prior to the implementation of the statewide Medicaid Managed Care Program, and provides that payments to such deemed hospitals must be in accordance with s. 409.975(1)(a), F.S.

Prescribed Drug Spending-Control Program

Section 499.003(54), F.S., defines "wholesale distribution" as distribution of prescription drugs to people other than consumers or patients. It expressly excludes certain activities, which effectively excludes these activities from wholesale drug distribution regulation.

One such excluded activity is the sale, purchase, trade or transfer of prescription drugs from or for entities able to purchase drugs at discount prices pursuant to the federal "340B" program. The 340B program limits the cost of certain drugs to certain federal grantees, federally-qualified health center

[56] S. 409.966, F.S.
[57] S. 409.974, F.S.
[58] S. 409.975(1)(a), F.S.

look-alikes and qualified disproportionate share hospitals.[59] To qualify for exclusion from state wholesale distribution regulation, s. 499.003(54)(a)4.d., F.S., requires such entities to maintain separate inventories for drugs purchased under the 340B program and other drugs.

The bill also amends s. 499.003(54)(a)4.d, F.S., to remove the requirement that participants of the 340B program maintain separate inventories for drugs purchased under the 340B program and other drugs.

Prior Authorization

Prior authorizations are currently used when a physician does not use the Medicaid preferred drug list when prescribing medication. A prior authorization is required to ensure there is an appropriate reason for Medicaid to pay for a drug not on the Medicaid preferred drug list. When a prior authorization is requested it is reviewed and tested for compliance with certain criteria.

Physicians are required to provide information to AHCA about the rationale and supporting medical evidence for the use of a drug. Currently, AHCA is authorized but not required to electronically post prior authorization criteria, protocol, and updates to the list of drugs that are subject to prior authorization without amending its rule or engaging in additional rulemaking.

The bill amends s. 409.912, F.S., to require AHCA to electronically post prior authorization and step edit criteria, protocol, and updates to the list of drugs that are subject to prior authorization on their website. In addition, the bill requires AHCA to post the information on their website within 21 days after the prior authorization and step edit information is approved by AHCA and removes the exemption from rulemaking for prior authorization. The bill provides a definition of the term “step edit” as an automatic review of certain medications subject to prior authorization.

According to AHCA, requiring AHCA to electronically post prior authorization criteria could allow physicians to inappropriately circumvent prior authorizations protocols, which could result in a cost increase to the program.[60]

Statutory Revisions

The bill deletes definitions for and references to private review agents and utilization review in s. 395.002, F.S., to conform to the repeal made in chapter 2009-223, L.O.F. The bill repeals unused or unnecessary definitions, including definitions for “department” and “agency”.

The bill makes technical corrections and repeals requested by the Division of Statutory Revision, such as repealing obsolete dates, amending cross-references, and updating the reference to an obsolete rule.

B. SECTION DIRECTORY:

Section 1: Amends s. 83.42, F.S., relating to exclusions from application of part.
Section 2: Amends s. 112.0455, F.S., relating to the Drug-Free Workplace Act.
Section 3: Amends s. 154.11, F.S., relating to powers of the board of trustees.
Section 4: Amends s. 318.21, F.S., relating to the disposition of civil penalties by county courts.
Section 5: Amends s. 383.011, F.S., relating to administration of maternal and child health programs.
Section 6: Repeals s. 383.325, F.S., relating to inspection reports.
Section 7: Creates s. 385.2031, F.S., relating to a resource for research in the prevention and treatment of diabetes.
Section 8: Amends s. 394.4787, F.S., relating to specialty psychiatric hospitals.

[59] *See*, Introduction to 340B Drug Pricing Program, U.S. Department of Health and Human Services, Health Resources and Services Administration, *available at* http://www.hrsa.gov/opa/introduction.htm (last viewed February 23, 2012).
[60] AHCA, *Staff Analysis and Economic Impact, House Bill Number 1419* (January 20, 2012).

Section 9: Amends s. 394.741, F.S., relating to accreditation requirements for providers of behavioral health care services.
Section 10: Amends s. 395.002, F.S., relating to accrediting organizations and specialty hospitals.
Section 11: Amends s. 395.003, F.S., relating to licensure; denial; suspension and revocation.
Section 12: Amends s. 395.0161, F.S., relating to licensure inspection.
Section 13: Amends s. 395.0193, F.S., relating to licensed facilities; peer review; disciplinary powers; and agency or partnership with physicians.
Section 14: Amends s. 395.1023, F.S., relating to child abuse and neglect cases.
Section 15: Amends s. 395.1041, F.S., relating to access to emergency services and care.
Section 16: Repeals s. 395.1046, F.S., relating to complaint investigation procedures.
Section 17: Amends s. 395.1055, F.S., relating to rules and enforcement.
Section 18: Amends s. 395.3025, F.S., relating to patient and personnel records; copies; and examination.
Section 19: Amends s. 395.3036, F.S., relating to confidentiality of records and meetings of corporations that lease public hospitals or other public health care facilities.
Section 20: Repeals s. 395.3037, F.S., relating to definitions of "department" and "agency".
Section 21: Amends s. 395.3038, F.S., relating to state licensed primary stroke centers and comprehensive stroke centers; notification of hospitals.
Section 22: Amends s. 395.602, F.S., relating to rural hospitals.
Section 23: Amends s. 400.021, F.S., relating to geriatric outpatient clinics.
Section 24: Amends s. 400.0239, F.S., relating to the quality of long-term care facility improvement trust fund.
Section 25: Amends s. 400.0255, F.S., relating to resident transfer or discharge; requirements and procedures; hearings.
Section 26: Amends s. 400.063, F.S., relating to resident protection.
Section 27: Amends s. 400.071, F.S., relating to application for license.
Section 28: Amends s. 400.0712, F.S., relating to application for inactive license.
Section 29: Amends s. 400.111, F.S., relating to disclosure of controlling interest.
Section 30: Amends s. 400.1183, F.S., relating to resident grievance procedures.
Section 31: Amends s. 400.141, F.S., relating to administration and management of nursing home facilities.
Section 32: Amends s. 400.142, F.S., relating to emergency medication kits; orders not to resuscitate.
Section 33: Amends s. 400.147, F.S., relating to internal risk management and quality assurance program.
Section 34: Repeals s. 400.148, F.S., relating to the Medicaid "Up-or-Out" Quality of Care Contract Management Program.
Section 35: Amends s. 400.19, F.S., relating to right of entry and inspection.
Section 36: Amends s. 400.191, F.S., relating to availability, distribution, and posting of reports and records.
Section 37: Amends s. 400.23, F.S., relating to rules; evaluation and deficiencies; licensure status.
Section 38: Amends s. 400.275, F.S., relating to agency duties.
Section 39: Amends s. 400.462, F.S., relating to home health agency remuneration.
Section 40: Amends s. 400.484, F.S., relating to right of inspection; violations and fines.
Section 41: Amends s. 400.506, F.S., relating to licensure of nurse registries; requirements; penalties.
Section 42: Amends s. 400.509, F.S., relating to registration of particular service providers exempt from licensure.
Section 43: Amends s. 400.601, F.S., relating to definitions.
Section 44: Amends s. 400.606, F.S., relating to license application, renewal, conditional license or permits and certificates of need.
Section 45: Amends s. 400.915, F.S., relating to construction and renovation requirements.
Section 46: Amends s. 400.925, F.S., relating to accrediting organizations.
Section 47: Amends s. 400.931, F.S., relating to application for licensure.
Section 48: Amends s. 400.967, F.S., relating to rules and classification of violations.
Section 49: Amends s. 400.9905, F.S., relating to clinics and portable health service or equipment providers.
Section 50: Amends s. 400.991, F.S., relating to license requirements; background screening; prohibitions.

Section 51: Amends s. 400.9935, F.S., relating to clinic responsibilities.
Section 52: Amends s. 408.033, F.S., relating to local and state health planning.
Section 53: Amends s. 408.034, F.S., relating to duties and responsibilities of the agency.
Section 54: Amends s. 408.036, F.S., relating to projects subject to review; exemptions.
Section 55: Amends s. 408.037, F.S., relating to application content.
Section 56: Amends s. 408.043, F.S., relating to special provisions.
Section 57: Amends s. 408.05, F.S., relating to the Florida Center for Health Information and Policy Analysis.
Section 58: Amends s. 408.061, F.S., relating to data collection; uniform systems of financial reporting; information relating to physician charges; confidential information; immunity.
Section 59: Amends s. 408.07, F.S., relating to rural hospitals.
Section 60: Amends s. 408.10, F.S., relating to consumer complaints.
Section 61: Amends s. 408.802, F.S., relating to applicability.
Section 62: Amends s. 408.804, F.S., relating to license required; display.
Section 63: Amends s. 408.806, F.S., relating to license application process.
Section 64: Amends s. 408.8065, F.S., relating to additional licensure requirements for home health agencies; home medical equipment providers, and health care clinics.
Section 65: Amends s. 408.809, F.S., relating to background screening; prohibited offenses.
Section 66: Amends s. 408.810, F.S., relating to minimum licensure requirements.
Section 67: Amends s. 408.813, F.S., relating to administrative fines; violations.
Section 68: Amends s. 409.912, F.S., relating to cost-effective purchasing of health care.
Section 69: Amends s. 409.9122, F.S., relating to mandatory Medicaid managed care enrollment;
Section 70: Amends s. 429.11, F.S., relating to initial application for license.
Section 71: Amends s. 429.71, F.S., relating to classification of violations.
Section 72: Amends s. 429.195, F.S., relating to rebates prohibited; penalties.
Section 73: Amends s. 429.915, F.S., relating to conditional licensure.
Section 74: Amends s. 430.80, F.S., relating to implementation of a teaching nursing home pilot project.
Section 75: Amends s. 430.81, F.S., relating to implementation of a teaching agency for home and community-based care.
Section 76: Amends s. 440.102, F.S., relating to drug-free workplace program requirements.
Section 77: Amends s. 440.13, F.S., relating to medical services and supplies; penalty for violations; limitations.
Section 78: Amends s. 468.1695, F.S., relating to licensure by examination.
Section 79: Amends s. 483.035, F.S., relating to clinical laboratories operated by practitioners for exclusive use; licensure and regulation.
Section 80: Amends s. 483.051, F.S., relating to powers and duties of the agency.
Section 81: Amends s. 483.23, F.S., relating to offenses; criminal penalties.
Section 82: Amends s. 483.245, F.S., relating to rebates prohibited; penalties.
Section 83: Amends s. 483.294, F.S., relating to inspection of centers.
Section 84: Amends s. 499.003, F.S., relating to wholesale distribution.
Section 85: Amends s. 627.645, F.S., relating to denial of health insurance claims restricted.
Section 86: Amends s. 627.668, F.S., relating to optional coverage for mental and nervous disorders required; exception.
Section 87: Amends s. 627.669, F.S., relating to optional coverage required for substance abuse impaired persons; exception.
Section 88: Amends s. 627.736, F.S., relating to required personal injury protection benefits; exclusions; priority; claims.
Section 89: Amends s. 641.495, F.S., relating to requirements for issuance and maintenance of certificate.
Section 90: Amends s. 651.118, F.S., relating to the Agency for Health Care Administration.
Section 91: Amends s. 766.1015, F.S., relating to civil immunity for members of or consultants to certain boards, committees, or other entities.
Section 92: Amends s. 817.505, F.S., relating to patient brokering prohibited; exceptions; penalties.
Section 93: Provides an effective date of July 1, 2012.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill is expected to result in combined annual savings of approximately $2,113,476 for providers and applicants.[61]

The following provisions are expected to save providers an estimated $1,413,476 annually:

- Removing the requirement for nursing homes to employ or contract with a medical records consultant – saving $335,000;
- Removing the requirement for toxicology and Drug-free Work Place laboratories to submit monthly statistical reports to the Agency for Health Care Administration (AHCA) – saving $11,300;
- Allowing nurse registries to share an administrator for up to five nurse registries with common controlling interests – saving $943,690; and
- Removing the requirement for companion organizations that are also contractors of the Agency for Persons with Disabilities to be registered with AHCA – saving $123,486.

Modifying certificate of need requirements to allow audited financial statements of an applicant's parent corporation is expected to result in savings of $700,000 annually for applicants.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   Not applicable. This bill does not appear to affect county or municipal governments.

2. Other:

   None.

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[61] AHCA, *Staff Analysis and Economic Impact, House Bill Number 1419* (January 20, 2012).

B. RULE-MAKING AUTHORITY:

The bill provides sufficient rule-making authority to AHCA to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On February 23, 2012, the Health and Human Services Committee adopted a strike-all amendment to HB 1419 and an amendment to the strike-all amendment.

The strike-all amendment:

- Requires DOH to establish an interagency agreement with DCF for management of the WIC program.
- Broadens the definition of "accrediting organizations".
- Updates the name of The Joint Commission and the Rehabilitation Accreditation Commission.
- Removes "or both" from the definition of "specialty hospital" relating to the range of medical services offered by general hospitals, but restricted to a defined age or gender group of the population.
- Retains the current statutory definition of "urgent care center".
- Removes provisions from the bill relating to high risk obstetrical services.
- Allow nursing homes to use both of the FDA-approved pneumococcal vaccines, PPV and PCV.
- Retains s. 400.145, F.S., relating to resident records, which was repealed by the original bill, and removes section 65 to conform to that change.
- Restores current law that requires adverse incident reports to be submitted to AHCA within 15 calendar days after the incident occurs.
- Codifies current rule requirements into law relating to staffing for pediatric nursing home residents.
- Restores current law to prevent registered companion and sitter organizations that are also developmental disability providers from providing personal care without being licensed as a home health agency or nurse registry.
- Broadens the exemption to nurse registry marketing restrictions, by exempting nurse registries that bill the Florida Medicaid program.
- Removes an incorrect cross reference as it relates to the inclusion of limited liability companies in the definition of "hospice".
- Removes section 54 from the bill, relating to the Subscriber Assistance Program.
- Retains current law relating to the composition of the Medicaid Pharmaceutical and Therapeutics Committee.
- Provides that, until the time of recipient enrollment in statewide managed care, all hospitals shall be deemed to be a part of a managed care plan's network in its application for participation or expansion in the Medicaid program prior to the implementation of the statewide Medicaid Managed Care Program, and provides a payment rate for those providers.
- Revises the education standards for nursing home administrators to allow applicants with a major equivalent to health services administration.
- Authorizes AHCA to issue a notice to cease and desist from certain acts and allows them to charge an administrative penalty not to exceed $5,000 per act.
- Revises language relating to clinical lab specimen collectors and removes the civil action provision.
- Removes requirement for providers to maintain separate drug inventories for prescription drugs in the 340B program.
- Removes language requiring legislative staff to prepare draft legislation to correct the names of accrediting organizations (because the names of these accrediting organizations are changed by the strike-all).

The amendment to the amendment:

- Deletes the requirement that a local and regional trauma agency assess number and location of centers based on local need.
- Deletes DOH authority to allocate by rule the number of trauma centers in each area, and the maximum number of trauma centers in the state.
- Amends the process for trauma center designation from a fixed schedule to an open process triggered by a letter of intent.
- Requires DOH to approve hospital applications for trauma center designation that meet clinical standards and capabilities.