The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Committee on Rules

BILL:	CS/CS/SB 1254
INTRODUCER:	Rules Committee; Health Policy Committee; and Senator Grimsley
SUBJECT:	Health Care Services
DATE:	April 2, 2014 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Stovall	HP	**Fav/CS**
2.	Looke	Phelps	RC	**Fav/CS**
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/CS/SB 1254 amends various sections of the Florida Statutes to delete unused, obsolete, and redundant rulemaking authority granted to the Agency for Health Care Administration (AHCA) and the Department of Elder Affairs (DOEA) and make other technical and conforming changes.

The bill also:

- Changes "certification" to "licensure" for organ, eye, and tissue procurement organizations and amends the procurement groups specified in statute. The AHCA must substantially base their procurement organizations licensure program on the standards and guidelines of the specified organizations;[1]
- Moves Medicaid recipients under the age of 21 who are not receiving waiver services but who are authorized by the Agency for Persons with Disabilities or the Department of Children and Families to reside in a group home facility from the mandatory enrollment group to the voluntary group for statewide Medicaid managed care; and,
- Clarifies the definition of "provider service network" (PSN), and requires the AHCA to terminate its contract with a PSN that no longer meets that definition if that PSN is the only PSN under contract as a managed care plan in that region under the statewide Medicaid managed care program. The AHCA must terminate the PSN's contract, issue another notice

[1] In addition to state and federal laws.

of invitation to negotiate, and procure and contract with another PSN within 12 months after the first PSN ceases to meet the definition of a PSN.
- Allows all hospitals, rather than only specialty-licensed children's hospitals, that are authorized to provide pediatric cardiac catheterization and pediatric open-heart surgery to provide cardiovascular services to adults that the hospital treated as children for congenital heart disease.
- Reduces the frequency for a home health agency (HHA) to report certain information to the AHCA from quarterly to semiannually and requires the reports to be submitted electronically.
- Exempts from the reporting requirements HHAs that share a controlling interest with a licensee that bills Medicaid or Medicare so long as the HHA is not a Medicaid or Medicare provider itself.

II. Present Situation:

The AHCA has a number of regulatory responsibilities, among these being the licensure of health care facilities including abortion clinics, nursing homes and clinical laboratories.

In recent years, many of the facilities licensed by the AHCA have come under increasing regulatory control of federal law relating to Medicaid and Medicare, and state laws providing greater specificity than previously provided. At the same time, frequent changes to many of these overlapping legal environments have made it difficult for the AHCA to maintain rules consistent with current law. Some of this difficulty has related to unnecessary rulemaking mandates, particularly relating to statutes that provide sufficient specificity to enforce without resort to rulemaking.

Rulemaking is required by the Administrative Procedures Act (APA) whenever an agency has express authority to make rules, and must resort to rulemaking in order to implement, interpret or prescribe law, policy or requirements including mandatory forms.[2] Rulemaking is not discretionary under the APA.[3]

In 2009 and again in 2013, the Joint Administrative Procedures Committee held hearings focusing on 2007 legislation that, on its face, requires the AHCA to make rules that have yet to be finally adopted. In some cases, that legislation and similar legislation contemplated rulemaking that was either unnecessary under the APA or already promulgated under previously enacted law.

Medicaid Statewide Managed Medical Care Program

In 2011, the Legislature passed HB 7107, creating the Statewide Medicaid Managed Care Program as ch. 409, part IV, F.S. The law required AHCA to create an integrated managed care program for Medicaid enrollees that incorporates all of the minimum benefits, for the delivery of primary and acute care as well as long-term care services. The Agency for Health Care

[2] Section 120.52(16), F.S., defines "rule" to mean "each agency statement of general applicability that implements, interprets, or prescribes law or policy or describes the procedure or practice requirements of an agency and includes any form which imposes any requirement or solicits any information not specifically required by statute…"
[3] Section 120.54(1)(a), F.S.

Administration sought and received federal authorization through two different Medicaid waivers.

In most regions, the law prescribed the minimum and the maximum number of contract awards. The law also directed that at least one plan per region be a PSN, if a responsive PSN bid was received. If no responsive bids were received from a PSN, the AHCA was to contract with one less than the maximum number of plans permitted for the region and to conduct a re-procurement within 12 months of the initial procurement in order to secure a PSN.

Ongoing litigation[4] arising from the procurement of managed care organizations as part of the implementation of statewide managed care has identified several ambiguities in the current statutes. These issues include whether any group of providers constitutes "an affiliated provider group" and whether the AHCA has a continuing responsibility to maintain a contract with at least one PSN in every region.

Under Medicaid managed care, all persons meeting applicable eligibility requirements of Title XIX of the Social Security Act must be enrolled in a managed care plan. Medicaid recipients who (a) have other creditable care coverage, excluding Medicare; (b) reside in residential commitment facilities operated through the Department of Juvenile Justice, group care facilities operated by the DCF, and treatment facilities funded through DCF Substance Abuse and Mental Health Program; (c) are eligible for refugee assistance; or, (d) are residents of a developmental disability center, may voluntarily enroll in the program. If they elect not to enroll, they will be served through the Medicaid fee for service system.

Organ Donations in Florida

Over 3,500 people in Florida are registered and waiting for organ transplants, and thousands more wait for tissue donations.[5] The most common types of organ transplants include the kidneys, liver, heart, lungs and pancreas, but many other organs and tissues can be transplanted or used for various other medical procedures.[6] Nationwide, nearly 6,000 people die each year waiting for an organ donation.[7]

Four major organ and tissue procurement agencies operate in Florida to facilitate the process of organ donation. These agencies are certified by the U.S. Centers for Medicare and Medicaid Services (CMS) and operate in Florida to increase the number of registered donors and coordinate the donation process when organs become available.[8] Each agency serves a different

[4] *Care Access PSN, LLC, vs. State of Florida, Agency for Health Care Administration and Prestige Health Choice, LLC, DOAH Case No. 13 4113BID, AHCA ITN 027 12/13 (*Agency for Health Care Administration Final Order, Jan. 2014) *available at* https://www.doah.state.fl.us/FLAID/HCA/2014/HCA_AHCA%20ITN%20027-12-13_02102014_095654.pdf (last visited Mar. 26, 2014.)
[5] See Donate Life Florida, 2009, *FAQs About Donation*, available at: http://www.donatelifeflorida.org/content/about/facts/faq/#faq_22 (last visited Mar. 26, 2013).
[6] Id.
[7] Id.
[8] See Donate The Gift of Life, *Organ Procurement Organizations*, available at http://organdonor.gov/materialsresources/materialsopolist.html (last visited Mar. 26, 2014).

region of the state.[9] In addition to federal certification of organ procurement organizations, the AHCA also certifies these organ procurement organizations and other eye and tissue organizations.[10]

The Organ Procurement and Transplantation Network (OPTN) is the unified network established by the United States Congress in 1984. The OPTN is a public-private partnership of professionals involved in the donation and transplantation system. The main goals of the OPTN are to increase the effectiveness and efficiency of organ sharing, increase the equity of the national system of organ allocation, and to increase the supply of donated organs.[11]

The Association of Organ Procurement Organizations (AOPO) is the national representative of the 58 federally-designated organ procurement organizations. The AOPO's main goal is to help member OPOs maximize the availability of organs and tissues for transplantation and enhance the quality, effectiveness and integrity of the donation process. The AOPO also works closely with the OPTN and has two seats on the OPTN Board of Directors.[12]

The Eye Bank Association of America (EBAA) is the oldest transplant association in the United States. The EBAA is also a nationally-recognized accrediting body for eye banks and the EBAA Medical Advisory Board develops standards to ensure consistently acceptable levels of quality, proficiency, and ethics in dealing with ocular tissue for transplantation and defines the minimum standards of practice in the recovery, preservation, storage, and distribution of eye tissue for transplantation and research, as determined by the ophthalmological medical community. The EBAA Medical Standards are reviewed semi-annually and are endorsed by the American Academy of Ophthalmology (AAO).[13]

Specialty-Licensed Children's Hospitals

Presently, s. 395.003, F.S., states that a specialty hospital may not provide any service or regularly serve any population group beyond those that are specified in its license with an exception made for specialty-licensed children's hospitals to allow them to treat certain adult patients with cardiovascular issues that the hospital treated as children. The AHCA licenses all hospital types in the state of Florida either as a Class I general acute care hospital or as a Class II specialty hospital. The options for a class II specialty hospital are a women's hospital or a children's hospital. To offer services to the population as a whole, a hospital must be licensed as a class I general acute care hospital. A hospital must also obtain a Certificate of Need (CON) from the AHCA before offering specialized types of services, including routine adult cardiac surgery.

[9] Id.; LifeLink of Florida serves west Florida, LifeQuest Organ Recovery Services serves north Florida, TransLife Organ and Tissue Donation Services serves east Florida, and LifeAlliance Organ Recovery Services serves south Florida.
[10] See AHCA's authority for certifying organ, eye, and tissue banks can be found in s. 765.542, F.S., and a list of organ, eye and tissue banks, *FloridaHealthFinder* at www.floridahealthfinder.gov (last visited on Mar. 26, 2013).
[11] See http://optn.transplant.hrsa.gov/optn/, (last visited on Mar. 26, 2013). Also see http://www.aopo.org/about-aopo, for the OPTN's policies (last visited Mar. 26, 2014).
[12] See http://www.aopo.org/about-aopo (last visited on Mar. 26, 2014).
[13] See http://www.restoresight.org/about-us/ (last visited on Mar. 26, 2014).

In addition to the three hospitals in Florida that qualify as specialty-licensed children's hospitals,[14] some Class I general acute care hospitals offer specialty services for children but are not technically considered specialty-licensed children's hospitals. One example of such an embedded children's hospital is the Palm Beach Children's Hospital located within St. Mary's Medical Center in West Palm Beach Florida. Currently, St. Mary's Hospital is authorized to perform pediatric cardiac surgeries, including pediatric open heart surgery and pediatric cardiac catheterization. However, since St. Mary's Medical Center does not have a CON for routine adult cardiac surgery and since the present exception in s. 395.003, F.S., only applies to specialty-licensed children's hospitals, St. Mary's Medical Center may not continue to treat children for the same congenital heart conditions once they reach adulthood without obtaining a waiver from the AHCA for each instance.

Home Health Agencies

A Home Health Agency (HHA) is an organization that provides home health services and staffing services.[15] Home health services provided by an HHA include health and medical services and medical equipment provided to an individual in his or her home, such as nursing care, physical and occupational therapy, and home health aide services.[16] Home health agencies are regulated by the AHCA pursuant to ch. 400, part III, F.S.

In 2008 the Florida Legislature passed ch. 2008-246, L.O.F., with anti-fraud measures including the requirement for an HHA quarterly report to be submitted to the AHCA within 15 days following the end of each quarter. The Legislature passed ch. 2008-246, L.O.F., to combat an increase in Medicaid fraud in HHAs during the early to mid 2000s. In Fiscal Year 2004-2005, the AHCA's Bureau of Medicare Program Integrity (MPI) opened 47 investigations of HHAs for Medicaid fraud, 72 in Fiscal Year 2005-2006, and 144 in Fiscal Year 2006-2007.[17] Between 2004 and 2007, 19 HHAs were terminated from the Medicaid program in Miami-Dade County alone.[18]

Section 400.474(6)(f), F.S., enacted in ch. 2008-246, L.O.F., requires HHAs to report data as it existed on the last day of the quarter for four items that are markers for possible fraudulent activity. These items include:

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

[14] All Children's Hospital in Saint Petersburg, Miami Children's Hospital in Miami, and Nemours Children's Hospital in Orlando. See AHCA bill analysis for SB 1264, dated Mar. 15, 2013, on file with the Senate Health Policy Committee.
[15] S. 400.462(12), F.S.
[16] S. 400.462(14)(a)-(c), F.S.
[17] Staff analysis of SB 1374 (2008), dated Mar. 7, 2008, on file with the Senate Health Policy Committee.
[18] Id.

The AHCA is required to impose a fine of $200 per day, up to $5,000 per reporting period, if the report is not submitted within the first 15 days following the close of the quarter. From January 1, 2009, through December 31, 2012, there were a total of 1,407 fines imposed.[19] For the 2012-2013 state fiscal year, fines of $932,750 were imposed by final order. Also, the number of HHAs that fail to submit the reports each quarter has decreased. For the quarter ending December 31, 2012, 42 of the 2,250 licensed HHAs failed to submit their reports.[20]

The data from each quarter's reports is shared with the federal Centers for Medicare and Medicaid Services' (CMS), MPI, Miami Satellite Division; the Medicare Fraud Investigations Manager at SafeGuard Services, LLC; the CMS contractor; and the AHCA's MPI office. Their investigators use multiple sources of information to identify fraudulent activities.[21]

The AHCA also uses the data on the number of patients on the last day of the quarter as an indicator of the number of patients when a home health agency is closing. In addition, the data on numbers of patients is used as an indicator that the home health agency may not be operational, along with other information. Failing to provide at least one service directly for a period of 60 days is grounds to deny or revoke a license under s. 400.474(1)(2)(e), F.S. The AHCA already collects the number of patients admitted over a 12-month period, from each home health agency on the biennial license renewal application as required by s. 400.471(2)(c), F.S.[22]

III. Effect of Proposed Changes:

Section 1 amends s. 390.012, F.S., relating to the disposal of fetal remains, to repeal the requirement that the AHCA adopt rules to require that abortion clinics be in compliance with s. 390.0111, F.S., relating to termination of pregnancies. This rule requirement is not necessary since abortion clinics must already comply with that section of law.

Section 2 amends s. 395.003, F.S., to allow all hospitals, rather than only specialty-licensed children's hospitals, that are authorized to provide pediatric cardiac catheterization and pediatric open-heart surgery to provide cardiovascular services to adults that the hospital treated as children for congenital heart disease. This change will allow St. Mary's Medical Center in West Palm Beach to continue to offer cardiac services to adult patients that were by the Medical Center treated for congenital cardiac disorders as children without obtaining a waiver from the AHCA.

Sections 3 - 5 amend ss. 400.021, 400.0712, and 400.23, F.S., relating to the regulation of nursing homes, to repeal specific mandatory rule requirements and replace them with general authority allowing the AHCA to adopt rules to implement part II of ch. 400, F.S.

Section 6 amends 400.474, F.S., to reduce the frequency of reports that HHAs are required to submit to the AHCA from quarterly to every six months, adjusting the remuneration amount required to be reported from $25,000 to $50,000 to account for the extended reporting period, and to require that the reports be submitted electronically. The bill also exempts from the

[19]AHCA analysis of HB 4031 (SB 1094), dated Mar. 14, 2013, on file with the Senate Health Policy Committee.
[20] Id.
[21]Supra n. 19
[22]Supra n. 19

reporting requirements HHAs that share a controlling interest with a licensee that bills Medicaid or Medicare so long as the HHA is not a Medicaid or Medicare provider itself.

Sections 7 - 10 amend ss. 400.487, 400.497, 400.506, and 400.509, F.S., relating to home health agencies, to repeal specific mandatory rule requirements and replace them with general authority allowing the AHCA to adopt rules to implement part III of ch. 400, F.S.

Sections 11, 23, and 24 amend ss. 400.6095, 429.255, and 429.73, F.S., respectively, to repeal the requirement to adopt rules to implement do not resuscitate orders pursuant to s. 401.45, F.S., in hospice, assisted living facilities and adult family-care homes. These grants of rulemaking authority are unnecessary since the statute is self-executing.

Sections 12-13 amend s. 400.914, F.S., and create s. 400.9141, F.S., respectively, to substitute mandatory rulemaking with discretionary rulemaking authority as needed to administer part VI of ch. 400, F.S., relating to prescribed pediatric extended care centers. Section 400.9141, F.S., is created with language moved from s. 400.914, F.S., to make the conditions self-executing.

Sections 14-15 amend ss. 400.934 and 400.935, F.S., relating to home medical equipment providers, to repeal certain specific mandatory rule requirements and replace them with general authority allowing the AHCA to adopt rules to administer part VII of ch. 400, F.S. In addition s. 400.934, F.S., requires the comprehensive emergency management plan of a home medical equipment provider to include criteria for a patient's equipment and supply list to accompany a patient who is transported from his or her home.

Sections 16-17 amend ss. 400.962 and 400.967, F.S., relating to intermediate care facilities for developmentally disabled persons, to repeal specific mandatory rule requirements and replace them with general authority allowing the AHCA to adopt rules to administer part VIII of ch. 400, F.S.

Section 18 amends s. 400.980, F.S., relating to health care service pools, to repeal a mandate that the AHCA adopt rules for the registration of health care services pools.

Section 19 amends s. 409.912, F.S., relating to the cost-effective purchasing of health care in the Medicaid program, to repeal the requirement for the AHCA to adopt rules to administer subsection 409.912(43), F.S., related to provider lock in programs. The subsection expires on October 1, 2014.

Sections 20 and 22 amend ss. 409.962 and 409.974, F.S., respectively relating to the statewide Medicaid managed care program, to clarify under the definition of "provider service network" that a group of providers must be affiliated for the purpose of providing health care and to require that the AHCA terminate its contract with a PSN that no longer meets the definition in s. 409.962, F.S., and is the only PSN in that region. The AHCA must terminate the PSN's contract, issue another notice of invitation to negotiate, and procure and contract with another PSN within 12 months after the first PSN no longer meets the definition of a PSN.

Section 21 amends s. 409.972, F.S., to exempt from mandatory enrollment in Medicaid managed care Medicaid recipients under the age of 21 who are not receiving waiver services but who are

authorized by the Agency for Persons with Disabilities or the Department of Children and Families to reside in a group home facility, and instead make enrollment in Medicaid managed care voluntary.

Section 25 amends s. 440.102, F.S., to clarify the AHCA's rulemaking responsibilities pertaining to drug-free workplace laboratories.

Section 26 amends s. 483.245, F.S., to repeal the requirement that the AHCA adopt rules to assess administrative penalties for clinical laboratories that pay or receive kickbacks.

Sections 27 and 28 amend ss. 765.541 and 765.544, F.S., relating to organ and tissue procurement agencies, to repeal specific mandatory rule requirements and replace them with general authority allowing the AHCA to adopt rules to administer ss. 765.541 - 765.546, F.S. The bill also changes "certification" to "licensure" for organ, eye, and tissue procurement organizations and amends the procurement groups specified in statute. The AHCA must substantially base its procurement organizations licensure program on the standards and guidelines of the specified organizations.

The bill also makes technical, clarifying, and conforming changes as necessary throughout the sections of law amended by the bill.

Section 29 establishes an effective date of July 1, 2014.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 390.012, 395.003, 400.021, 400.0712, 400.23, 400.474, 400.487, 400.497, 400.506, 400.509, 400.6095, 400.914, 400.934, 400.935, 400.962, 400.967, 400.980, 409.912, 409.962, 409.972, 409.974, 429.255, 429.73, 440.102, 483.245, 765.541, and 765.544.

This bill creates section 400.9141 of the Florida Statutes.

IX. Additional Information:

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

CS/CS by Rules on April 2, 2014:
The CS amends CS/SB 1254 to:

- Allow all hospitals, rather than only specialty-licensed children's hospitals, that are authorized to provide pediatric cardiac catheterization and pediatric open-heart surgery to provide cardiovascular services to adults that the hospital treated as children for congenital heart disease; and
- Reduce the frequency of reports that HHAs are required to submit to the AHCA from quarterly to every six months and to require that the reports be submitted electronically. The CS also exempts from the reporting requirements HHAs that share a controlling interest with a licensee that bills Medicaid or Medicare so long as the HHA is not a Medicaid or Medicare provider itself.

CS by Health Policy on March 25, 2014:
The CS amends SB 1254 to:

- Reinstate some of the minimum standards the AHCA is required to adopt in rule to regulate home medical equipment providers;
- Change certification to licensure for organ, eye, and tissue procurement organizations and amend which groups are specified in statute. The AHCA must substantially base its procurement organizations licensure program on the standards and guidelines of the specified organizations as well as federal and state laws;
- Make technical changes to the rulemaking authority over nurse registries and drug-free workplace laboratories.

- Allow voluntary enrollment in Medicaid managed care for Medicaid recipients under the age of 21 who are not receiving waiver services but who are authorized by the Agency for Persons with Disabilities or the Department of Children and Families to reside in a group home facility; and,
- Clarify the definition of "provider service network" and require contract termination as a Medicaid managed care plan if a PSN no longer meets that definition and that a PSN is the only PSN in that region. The AHCA must re-procure another PSN within 12 months after the first PSN no longer meets the definition of a PSN.

B. Amendments:

None.