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 Health Policy

BILL:	CS/SB 1254
INTRODUCER:	Health Policy Committee and Senator Grimsley
SUBJECT:	Health Care Services
DATE:	March 25, 2014
REVISED:	

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

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 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.

[1] In addition to state and federal laws.

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 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

[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.
[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)

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 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]

---

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).

[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).

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]

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.

Sections 2 - 4 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.

Sections 5 - 8 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 9, 21, and 22 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 10-11 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 12-13 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

[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).

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 14-15 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 16 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 17 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 18 and 20 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 19 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 23 amends s. 440.102, F.S., to clarify the AHCA's rulemaking responsibilities pertaining to drug-free workplace laboratories.

Section 24 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 25 and 26 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 27 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, 400.021, 400.0712, 400.23, 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 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.