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 966
INTRODUCER:	Health Policy Committee and Senator Bean
SUBJECT:	Health Care
DATE:	March 14, 2013 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Stovall	HP	**Fav/CS**
2.			AP	
3.				
4.				
5.				
6.				

Please see Section VIII. for Additional Information:

A. COMMITTEE SUBSTITUTE.....	X	Statement of Substantial Changes
B. AMENDMENTS.....		Technical amendments were recommended
		Amendments were recommended
		Significant amendments were recommended

I. Summary:

CS/SB 966 amends various sections of the Florida Statutes to:

- Update those sections with the most current names for CARF International and the Joint Commission and add the American Osteopathic Association/Healthcare Facilities Accreditation Program to those organizations specifically recognized as accrediting organizations.
- Designate the Florida Hospital Sanford-Burnham Translational Research Institute for Metabolism and Diabetes (Institute) as a resource for research in the prevention and treatment of diabetes.
- Strike language requiring drug-testing laboratories to submit a monthly report to the Agency for Health Care Administration (AHCA).
- Allow hospitals, ambulatory surgical centers, and mobile surgical facilities to pay inspection fees at times other than the time of inspection.
- Repeal s. 395.1046, F.S., which grants the AHCA duplicative authority to investigate complaints related to access to emergency services and care;
- Strike obsolete language regarding the AHCA's list of primary and comprehensive stroke centers.

- Exempt all state operated hospitals, rather than only hospitals run by the Department of Corrections (DOC), from the annual assessments on net operating revenues for inpatient and outpatient services to fund public medical assistance required by s. 395.701, F.S.
- Repeal the Public Medical Assistance Trust Fund (PMATF) assessment on healthcare entities which was found to be unconstitutional.
- Exempt state operated hospitals from filing the Florida Hospital Uniform Reporting System (FHURS) report.
- Exempt state operated hospitals from an assessment used to fund the data collection and analysis activities of the AHCA.
- Create the Standardized Credentials Collection and Verification Program for physicians.
- Exclude the transfer of prescription drugs from a hospital's supplier to a prescription drug repackager from the definition of the term wholesale distribution.
- Require any person located outside of the state that repackages and delivers prescription drugs into Florida obtain a prescription drug repackager permit.
- Require that the pedigree paper for prescription drugs transferred to and from a repackager contain the specified information.

This bill substantially amends sections 112.0455, 154.11, 394.741, 395.0161, 395.3038, 395.701, 395.7016, 397.403, 400.925, 400.9935, 402.7306, 408.061, 408.20, 409.966, 409.967, 430.80, 440.102, 440.13, 499.003, 499.01, 499.01212, 627.645, 627.668, 627.669, 627.736, 641.495, and 766.1015, F.S., creates sections 385.2035 and 456.0125, F.S., and repeals sections 395.1046 and 395.7015, F.S.

II. Present Situation:

Accrediting Organizations

In 2012, the Legislature enacted 2012-66, L.O.F., which substantially amended the definition of "accrediting organizations" in s. 395.002, F.S. Prior to the passage of 2012-66, L.O.F., the statutes defined "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. Currently, the definition includes any national accreditation organizations that are approved by the Centers for Medicare and Medicaid Services and whose standards incorporate comparable licensure regulations required by the state.

The Joint Commission

The Joint Commission is a non-profit organization that accredits and certifies more than 20,000 health care organizations and programs in the United States.[1] The Joint Commission was established in 1951 as the Joint Commission on Accreditation of Hospitals. In 1987, the organization changed its name to the Joint Commission on Accreditation of Healthcare Organizations in order to reflect an expanded scope of activities. In 2007, the Joint Commission on Accreditation of Healthcare Organizations shorted its name to the Joint Commission in order

[1] About the Joint Commission, found at: http://www.jointcommission.org/about_us/about_the_joint_commission_main.aspx, last visited on Mar. 4, 2013.

to refresh its brand identity.[2] Currently, the Florida Statutes refer to the Joint Commission on Accreditation of Healthcare Organizations.

CARF International

What is now known as CARF International was founded in 1966 as the Commission on Accreditation of Rehabilitation Facilities when the National Association of Sheltered Workshops and Homebound Programs and the Association of Rehabilitation Centers agreed to pool their interests.[3] The CARF International is a nonprofit accreditor of health and human services providers in multiple areas including aging services, behavioral health, and medical rehabilitation. The CARF family of organizations currently accredits close to 50,000 programs in countries across the globe.[4] Currently, the Florida Statutes still refer to CARF - the Commission on Accreditation of Rehabilitation Facilities or something similar.

The American Osteopathic Association / Healthcare Facilities Accreditation Program

The Healthcare Facilities Accreditation Program (HFAP) is a program that is authorized by the Centers for Medicare and Medicaid Services (CMS) to survey hospitals for compliance with the Medicare Conditions of Participation. HFAP has maintained its authority to survey hospitals for compliance with the Medicare Conditions of Participation and Coverage since 1965 and meets or exceeds the standards required by CMS/Medicare to provide accreditation to hospitals, ambulatory care/surgical facilities, mental health facilities, physical rehabilitation facilities, clinical laboratories and critical access hospitals. The HFAP also provides certification reviews for Primary Stroke Centers.[5] The HFAP facility accreditation process consists of five basic steps including application, survey, reporting deficiencies, creating a plan of corrections/correct action response, and accreditation.[6]

Forensic Toxicology Laboratory Monthly Statistical Report

Florida law requires licensed forensic toxicology laboratories to submit monthly statistical reports[7] to the AHCA. These reports include information including the lab's name, license number, address, the total number of specimens received for testing, the total number of specimens received but not tested, and the total number of confirmed positive reports for various listed drugs. A laboratory that fails to submit the monthly report is subject to administrative action under 59A-24.006(12)(a), F.A.C.

The Florida Hospital Sanford-Burnham Translational Research Institute for Metabolism and Diabetes

The Institute focuses on translational research and has established advanced technology resources and formed clinical and pharmaceutical research partnerships to drive their discoveries

[2] The Joint Commission History, found at: http://www.jointcommission.org/assets/1/6/Joint_Commission_History.pdf, last visited on Mar. 4, 2013
[3] History of CARF International, found at: http://www.carf.org/About/History/, last visited on Mar. 4, 2013.
[4] CARF International, found at: http://www.carf.org/About/WhoWeAre/, last visited on Mar. 4, 2013.
[5] HFAP Overview, found at http://www.hfap.org/about/overview.aspx, last visited on Mar. 14, 2013.
[6] Accreditation by HFAP, found at http://www.hfap.org/WhyHfap/workingwithhfap.aspx, last visited on Mar. 14, 2013.
[7] The report form can be found at http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Laboratory_Licensure/docs/tox%20monthly%20report%20form.pdf, last visited on Mar. 14, 2013.

toward patient application.[8] The Institute was designated as a resource for research in the prevention and treatment of diabetes in the 2012 Appropriations Act[9] but has not been permanently designated as such in the Florida Statutes. According to Sanford-Burnham and Florida Hospital, such a designation will provide a competitive advantage for the Institute over research facilities in other states when applying for federal grants.[10]

Complaint Investigation for Access to Emergency Services and Care

Section 395.1046, F.S., requires the AHCA to investigate any complaint against a hospital for violation of provisions relating to access to emergency services and care which the AHCA deems to be legally sufficient. The section also specifies that the AHCA must prepare an investigative report with findings and recommendations concerning the existence of probable cause and that the complaint and all information obtained by the AHCA during the investigation are exempt from public records laws for specified periods of time. The section does not define the terms legally sufficient or probable cause. Presently, the AHCA is also granted authority to investigate all complaints against a hospital by s. 408.811, F.S.

Standardized Credentials Collection and Verification Program for Physicians

Currently, the Division of Medical Quality Assurance (MQA or division) within the DOH presently licenses and regulates medical doctors (ch. 458, F.S.) and osteopathic physicians (ch. 459, F.S.). Proof of state licensure as a physician is one of several credentials health care entities evaluate when deciding whether to grant staff appointments, reappointments, clinical privileges, etc., or enter into other contractual relationships with physicians. The division verifies licensure and disciplinary history, but does not credential physicians. Section 456.077, F.S., provides that citations may be issued when authorized by rule of the board[11] or the DOH. Rules are promulgated by the board or the DOH through the rule making process to identify violations that may be resolved by citation, including fines or other penalties to be imposed.

A similar credentialing program was created by legislative mandate in 1998.[12] The development of the program, which became known and the CoreSTAT Credentialing program, began in 1998 and was repealed and no longer required practitioners to report core credentials data on July 1, 2002.[13] The CoreSTAT program was created as an internal MQA program, and a work unit was established to manage the program. Contracted vendors were also solicited to implement the statutory requirements. Over the four years it operated, the total cost of the CoreSTAT Credentialing program was $14,712,566 and the total revenues collected for the program was $173,815. The CoreSTAT program was funded by the MQA Trust Fund.[14]

[8] About the Diabetes and Obesity Center, found at: http://www.sanfordburnham.org/research/diabetes/Pages/doc.aspx, last visited on Mar. 4, 2013.
[9] 2012-118, L.O.F.
[10] According to telephone conversations with Elizabeth Gianini, representing Sanford-Burnham, and Amy Christian, representing Florida Hospital, on Mar. 4, 2013.
[11] The term "board" is defined in s. 456.001(1), F.S.
[12] 98-226, L.O.F.
[13] Changes to CoreSTAT, found at: http://www.doh.state.fl.us/mqa/corestat/index.htm, last visited on Mar. 14, 2013.
[14] Department of Health bill analysis for amendment 373656 for SB 966, dated Mar. 13, 2013, on file with the Senate Health Policy Committee.

Prescription Drug Repackaging

The Department of Business and Professional Regulation's (DBPR) Division of Drugs, Devices and Cosmetics regulates and permits prescription drug repackaging in the state of Florida. The term repackaging when applied to prescription drugs includes repacking or otherwise changing the container, wrapper or labeling to further the distribution of the drug, device, or cosmetic.[15] Some examples of repackaging include:

- Altering a packaging component that is or may be in direct contact with the drug, device, or cosmetic. For example, repackaging from bottles of 1,000 to bottles of 100.
- Altering a manufacturer's package for sale under a label different from the manufacturer. For example, a kit that contains an injectable vaccine from manufacturer A; a syringe from manufacturer B; alcohol from manufacturer C; and sterile gauze from manufacturer D packaged together and marketed as an immunization kit under a label of manufacturer Z.
- Altering a package of multiple-units, which the manufacturer intended to be distributed as one unit, for sale or transfer to a person engaged in the further distribution of the product.[16]

Prescription drug repackagers that are located in Florida[17] must be permitted by the DBPR. In order to obtain a permit an applicant must have an FDA establishment registration number, pass an onsite inspection (unless the applicant holds a Prescription Drug Manufacturer permit), and pay a fee of $1,500 for a two year permit and a one-time $150 pre-permit inspection fee.[18] Prescription drug repackagers must comply with all the requirements of, and rules and regulations promulgated under, part I of ch. 499, F.S., that apply to wholesale distributors as well as all appropriate state and federal good manufacturing procedures.[19]

III. Effect of Proposed Changes:

Sections 2, 4, 11-14, 17-19, 21, and 26-31 amend ss. 154.11, 394.741, 397.403, 400.925, 400.9935, 402.7306, 409.966, 409.967, 430.80, 440.13, 627.645, 627.668, 627.669, 627.736, 641.495, and 766.1015, F.S., respectively, to update those sections with the most current names for CARF International and the Joint Commission, add the American Osteopathic Association/Healthcare Facilities Accreditation Program to those organizations specifically recognized as accrediting organizations (except for s. 409.967, F.S.), and to make other technical revisions.

Section 1 amends s. 112.0455, F.S., to strike language requiring drug-testing laboratories to submit a monthly report with statistical information regarding the testing of employees and job applicants to the AHCA and detailing what information must be included in the report.

[15] Prescription Drug Repackager, found at: http://www.myfloridalicense.com/dbpr/ddc/PrescriptionDrugRepackager.html, last visited on Mar. 14, 2013.
[16] Supra, n. 14
[17] s. 499.01(b), F.S.
[18] Supra, n. 14
[19] s. 499.01(b)(1) and (2), F.S.

Section 3 creates s. 385.2035, F.S., to designate the Florida Hospital Sanford-Burnham Translational Research Institute for Metabolism and Diabetes as a resource for research in the prevention and treatment of diabetes.

Section 5 amends s. 395.0161, F.S., to allow hospitals, ambulatory surgical centers, and mobile surgical facilities to pay inspection fees at times other than the time of inspection.

Section 6 repeals s. 395.1046, F.S., which grants the AHCA duplicative authority to investigate complaints related to access to emergency services and care which it finds to be legally sufficient. This section also details the AHCA's duties when investigating such complaints and details what information, under what circumstances, and for how long information related to the complaint and investigation is exempt from public records.

Section 7 amends s. 395.3038, F.S., to update those sections with the most current names for CARF International and the Joint Commission, add the American Osteopathic Association/Healthcare Facilities Accreditation Program to those organizations specifically recognized as accrediting organizations, and to strike obsolete language regarding the AHCA's list of primary and comprehensive stroke centers.

Section 8 amends s. 395.701, F.S., to exempt all state operated hospitals, rather than only hospitals run by the DOC, from the annual assessments on net operating revenues for inpatient and outpatient services, required by s. 395.701, F.S., which fund public medical assistance.

Section 9 repeals s. 395.7015, F.S., which levies the PMATF assessment on healthcare entities. The PMATF was found to be unconstitutional by Florida 1st District Court of Appeal in 2003 but the language remains in the Florida Statutes.[20]

Section 10 amends s. 395.7016, F.S., to conform this section to changes made by section 9 of the bill.

Section 15 amends s. 408.061, F.S., to exempt state operated hospitals from filing the FHURS report which the AHCA uses to assess the amount required for the annual assessments on net operating revenues for inpatient and outpatient services required. State operated hospitals are made exempt from that assessment by section 8 of the bill.

Section 16 amends s. 408.20, F.S., to exempt state operated hospitals, rather than only hospitals run by the Department of Children and Families, the DOH, and the DOC, from an assessment used to fund the data collection and analysis activities of the AHCA.

Section 20 amends s. 440.102, F.S., to strike language requiring drug-testing laboratories to submit a monthly report to conform this section to changes made in section 1 of the bill. This section also strikes language requiring laboratories that analyze initial drug testing specimens comply with certain requirements to conform to changes made to the statutes in 2009.[21]

[20] A full summary of the case law finding the PMATF unconstitutional is on file with the Senate Health Policy Committee.
[21] Ch. 2009-127, L.O.F., removed the requirement for initial drug-free workplace testing to be performed by a licensed forensic toxicology laboratory from s. 440.102(5)(d), F.S.

Section 22 creates s. 456.0125, F.S., which establishes the Standardized Credentials Collection and Verification Program for physicians. This section:

- Establishes legislative intent to establish a repository for physician core credentials data[22] to ensure that such data is collected only once, unless a correction, update, or modification is required and that the credentials collection and verification entity,[23] the DOH, health care entities, and physicians work cooperatively to ensure the integrity and accuracy of the program;
- Mandates that all physicians, certain insurance companies,[24] health maintenance organizations as defined in s. 641.19, F.S., entities licenses under ch. 395, F.S.,[25] and accredited medical schools in the state must participate in the program;
- Defines terms;
- Requires physicians to report all core credentials data to the credentials collection and verification entity (CCVE) under contract with the DOH and sets penalties for failing to do so.[26]
- Requires physicians to update their core credentials data within 45 days after any corrections, updates, or modifications are made to the data.
- Requires, by January 1, 2014, the DOH to contract with one CCVE that must be fully accredited or certified[27] by a national accrediting organization[28] and allows the DOH to terminate the contract if the CCVE fails to maintain accreditation, or provide data authorized by a physician. The CCVE must also maintain liability insurance.
- Requires the CCVE to maintain a complete current file of all core credentials data on each physician and must develop standardized forms for physicians to report and authorize the release of their credentials.
- Allows the CCVE to release any confidential or exempt data to a health care entity, if authorized by the physician.
- Mandates that health care entities receive all physician core credentials data from the CCVE, including corrections, updates, and modifications.
- Restricts healthcare entities from requesting core credentials from physicians.
- States that the section does not restrict health care entities from approving or denying an application for hospital staff membership, clinical privileges, or participation in managed care networks and that a health care entity may rely upon the data it receives from the CCVE to meet primary source requirements of national accrediting organizations.
- Allows the DOH to adopt rules to develop and implement the program.

[22] As defined in paragraph (2)(b) of section 22 of the bill and as modified by DOH rule.
[23] As defined in paragraph (2)(d) of section 22 of the bill.
[24] Insurance companies that operate in accordance with ch. 624, F.S., that offer health insurance coverage under part VI of ch. 627, F.S.
[25] Including hospitals, ambulatory surgical centers, and mobile surgical facilities, and trauma centers.
[26] Failure to report initial core credentials data and updated data is grounds for disciplinary action under the physician's licensing chapter. If a licensee or person applying for initial licensure fails to report the DOH or the board may refuse to issue a license or issue a citation pursuant to s. 456.077, F.S., and asses a fine.
[27] As defined in paragraph (2)(a) of section 22 of the bill.
[28] As defined in paragraph (2)(g) of section 22 of the bill.

Section 23 amends s. 499.003, F.S., to exempt the transfer of prescription drugs from a hospital's supplier to a prescription drug repackager from the definition of the term wholesale distribution and make conforming changes.

Section 24 amends s. 499.01, F.S., to require any person located outside of the state who repackages and delivers prescription drugs into Florida pursuant to the provisions in section 23 of the bill to obtain a prescription drug repackager permit.

Section 25 amends s. 499.01212, F.S., to require that the pedigree paper for prescription drugs transferred to a repackager pursuant to section 23 of the bill include:

- A statement that the distributor purchased the prescription drug directly from the manufacturer;
- The manufacturer's national drug code identifier;
- The name and address of the distributor and purchaser of the prescription drug;
- The name of the drug as it appears on the label; and
- The quantity, dosage form, and strength of the drug.

This section also requires the pedigree paper for prescription drugs transferred from a repackager to a hospital or health care entity pursuant to section 23 of the bill include:

- A statement that the distributor purchased the prescription drug directly from the manufacturer;
- The lot numbers of the prescription drugs;
- The name and address of the repackager;
- The repackager's signature;
- The date of receipt; and
- The name and address of the person authorized by law to purchase prescription drugs for the purpose of administering or dispensing the drugs.

Section 32 provides an effective date of July 1, 2013.

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:

CS/SB 966 will have an indeterminate positive fiscal impact on various private health care organizations and practitioners.

Many of the bill's provisions, such as reducing various reports certain hospitals and forensic toxicology laboratories must file, will reduce the overall regulatory burden on Florida's health care system.

Creating the Standardized Credentials Collection and Verification Program will streamline the process of finding and obtaining physician's credentials which will likely have a positive fiscal impact on physicians who will only be required to submit their information one time. However, the program language makes no mention of any fees the CCVE will be allowed to charged to physicians and health care facilities for submitting and obtaining credentials.

Also, provisions in the bill allow hospitals and health care entities to use out of state prescription drug repackagers and to send drugs directly from their supplier to the repackager. These provisions will likely have a positive fiscal impact by streamlining the prescription drug repackaging process and allow hospitals to maximize potential savings in drug pricing.

C. Government Sector Impact:

The DOH has indicated that it will require additional resources to implement the Standardized Credentials Collection and Verification Program.[29] A similar program (the CoreSTAT program) which the DOH operated from 1998 to 2002, cost the state $14,712,566 over that time period and only generated $173,815. However, the program implemented by CS/SB 966 will likely differ in cost from the CoreSTAT program. CS/SB 966 will likely cost less than the CoreSTAT program due to the requirement in CS/SB 966 that the DOH must contract with a CCVE (rather than creating the program in house) and due to advances in electronic filing and storage technology since 1998. Also, adding language to section 22 of the bill specifying how much the DOH will pay to the CCVE and the fees that the CCVE may charge could further reduce the cost to the DOH.

VI. Technical Deficiencies:

The language added to the flush-left text in section 25 of this bill creates requirements for what must be included in the pedigree paper when drugs are transferred from a prescription drug repackager to a hospital or health care entity pursuant to s. 499.003(54)(b)7, F.S. However, the

[29] Supra, n. 14

referenced section only pertains to prescription drugs transferred from a hospital or health care entity (or their distributor) to the prescription drug repackager, and not in the reverse. This language in the bill could be clarified by adding additional language so that it would read:

When a repackager further distributes prescription drugs to the hospital or other health care entity from which it received the drugs pursuant to s. 499.003(54)(b)7,…

VII. Related Issues:

The provisions created in section 22 of this bill require the DOH to contract with a CCVE to collect physician credentials data, but do not state who must pay for collecting such data or if the CCVE may collect any fees related to its activities. Adding these provisions in might reduce any potential fiscal impact to the DOH from this bill.

VIII. Additional Information:

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

CS by Health Policy on March 14, 2013:
The CS substantially amends SB 966 to:

- Add the American Osteopathic Association/Healthcare Facilities Accreditation Program to those organizations specifically recognized as accrediting organizations in ss. 154.11, 394.741, 395.3038, 397.403, 400.925, 400.9935, 402.7306, 409.966, 430.80, 440.13, 627.645, 627.668, 627.669, 627.736, 641.495, and 766.1015, F.S.;
- Strike language requiring drug-testing laboratories to submit a monthly report to the AHCA;
- Allow hospitals, ambulatory surgical centers, and mobile surgical facilities to pay inspection fees at times other than the time of inspection;
- Repeal s. 395.1046, F.S., which grants the AHCA duplicative authority to investigate complaints related to access to emergency services and care;
- Strike obsolete language regarding the AHCA's list of primary and comprehensive stroke centers;
- Exempt all state operated hospitals, rather than only hospitals run by the DOC, from the annual assessments on net operating revenues for inpatient and outpatient services to fund public medical assistance required by s. 395.701, F.S.;
- Repeal an annual assessment on healthcare entities which was found to be unconstitutional;
- Exempt state operated hospitals from filing the FHURS report which the AHCA uses to assess the amount required for the annual assessments on net operating revenues for inpatient and outpatient services required; State operated hospitals are made exempt from that assessment by section 8 of the bill;
- Exempt state operated hospitals from an assessment used to fund the data collection and analysis activities of the AHCA; and
- Create the Standardized Credentials Collection and Verification Program for physicians.
- Restricts healthcare entities from requesting core credentials from physicians.

- Exempt the transfer of prescription drugs from a hospital's supplier to a prescription drug repackager from the definition of the term wholesale distribution and make conforming changes.
- Require any person located outside of the state who repackages and delivers prescription drugs into Florida to obtain a prescription drug repackager permit.
- Require that the pedigree paper for prescription drugs transferred to a repackager and from a repackager contain the specified information.

B. Amendments:

None.