

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 Judiciary Committee

BILL: CS/CS/SB 162

INTRODUCER: Governmental Oversight and Accountability Committee, Health Regulation Committee, and Senator Ring

SUBJECT: Electronic Health Records

DATE: April 15, 2009

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Stovall</u>	<u>Wilson</u>	<u>HR</u>	Fav/CS
2.	<u>McKay</u>	<u>Wilson</u>	<u>GO</u>	Fav/CS
3.	<u>Sumner</u>	<u>Maclure</u>	<u>JU</u>	Favorable
4.	_____	_____	<u>HA</u>	_____
5.	_____	_____	_____	_____
6.	_____	_____	_____	_____

Please see Section VIII. for Additional Information:

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

I. Summary:

This bill creates the “Florida Electronic Health Records Exchange Act.” It provides for definitions of terms related to electronic health records and the exchange of health information. The bill requires the Agency for Health Care Administration (Agency or AHCA) to develop a universal patient authorization form for the use or release of a patient’s identifiable health record and provides immunity from liability for release of an identifiable health record in reliance on the information provided on the authorization form.

The bill authorizes the emergency release of an identifiable health record without patient consent or the consent of a patient’s representative. It permits licensed hospitals, ambulatory surgical centers, and mobile surgical facilities to release patient records without the consent of the patient or his or her legal representative to health care practitioners and providers currently involved in the care or treatment of the patient for use only in connection with the treatment of the patient. It permits clinical laboratories to disclose a patient’s test results, without the patient’s consent, to a health care practitioner or provider who did not request that the test be performed but who is involved in the care or treatment of the patient.

The bill also authorizes the Agency to operate a certified electronic health records system loan program, subject to a specific state appropriation and the receipt of federal funding or public or private donations.

This bill substantially amends the following sections of the Florida Statutes: 395.3025, 409.916, and 483.181. The bill creates sections 408.051 and 408.0512, F.S.

II. Present Situation:

The Agency is responsible for developing and implementing a strategy for the adoption and use of electronic health records, including the development of an electronic health information network for the sharing of electronic health records among health care facilities, health care providers, and health insurers.¹

Federal Impetus

On April 27, 2004, President George W. Bush issued an Executive Order² to encourage the development of a nationwide interoperable health information technology infrastructure. The Executive Order directed the Secretary of Health and Human Services to establish within the Office of the Secretary the position of National Health Information Technology Coordinator. The Office of the National Coordinator for Health Information Technology (ONCHIT) is tasked with developing, maintaining, and implementing a strategic plan to guide the nationwide implementation of interoperable health information technology in both the public and private health care sectors in order to reduce medical errors, improve quality, and produce greater value for health care expenditures. Also in 2004, President Bush set the goal for most Americans to have access to an interoperable electronic medical record by the year 2014.

The federal government created a program aimed at increasing the adoption of electronic health records (EHR) among physician practices. The five-year project, which began in the spring of 2008, provides annual bonuses to physician groups using nationally certified EHR systems to meet clinically qualified measures. During the five-year project, it is estimated that 3.6 million consumers will be directly affected as their primary care physicians adopt certified EHRs in their practices.³ Six counties in the Jacksonville area have been selected to participate in the second phase of the demonstration project.⁴

The American Recovery and Reinvestment Act of 2009⁵ (the stimulus law) provides \$19 billion nationally to develop, implement, and promote a health information technology infrastructure,

¹ Section 408.062(5), F.S.

² *Executive Order: Incentives for the Use of Health Information Technology and Establishing the Position of the National Health Information Technology Coordinator*, available at: <<http://georgewbush-whitehouse.archives.gov/news/releases/2004/04/20040427-4.html>> (Last visited on April 9, 2009).

³ U.S. Department of Health and Human Services, "HHS Announces Project to Help 3.6 Million Consumers Reap Benefits of Electronic Health Records," October 30, 2007 available at: <<http://www.hhs.gov/news/press/2007pres/10/pr20071030a.html>> (Last visited on April 9, 2009).

⁴ U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, "Electronic Health Records (EHR) Demonstration Summary" <http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/EHR_DemoSummary.pdf> (Last visited on April 9, 2009).

⁵ Public Law 111-5.

including nationwide electronic health records, by 2014. Under the stimulus law, physicians and other health professionals are eligible for health information technology (health IT) incentive payments via Medicare or Medicaid through 2016, but in 2015 penalties for non-adopters begin. Medicare-participating physicians who adopt a certified electronic health records system could receive up to \$44,000 over a period of up to five years and certain physicians treating Medicaid patients are eligible for up to \$64,000 in support. The stimulus law provides for \$2 billion for discretionary health IT grants and loans to become available in 2010.⁶ The stimulus law also mandates changes in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) related to health data privacy and security and reinvigorates the ONCHIT to adopt national standards for electronic health records.

Title XIII, Section 3014 of the stimulus law authorizes the ONCHIT to award competitive grants to states and Indian Tribes for the development of loan programs to facilitate the widespread adoption of certified electronic health records technology. The law provides for loan programs for health care providers to purchase certified electronic health records technology, train personnel in the use of such technology, and improve the secure electronic exchange of health information. To be eligible, grantees [the state] would be required to:

- Submit an application;
- Establish a qualified health information technology loan fund;
- Submit a strategic plan, updated annually, describing the intended uses of the funds and providing assurances that loans will only be given to health care providers that submit required reports on quality measures and use the certified electronic records technology supported by the loan for the electronic exchange of health information to improve the quality of care; and
- Provide matching funds of at least \$1 for every \$5 of federal funding.

Under the stimulus law, loans would be repayable over a period of up to 10 years, and awards would not be permitted before January 1, 2010.

The stimulus law provides that the term “certified electronic health records technology” means a qualified electronic health record that is certified pursuant to section 3001(c)(5) as meeting standards adopted under section 3004 that are applicable to the type of record involved (as determined by the Secretary, such as an ambulatory electronic health record for office-based physicians or an inpatient hospital electronic health record for hospitals).⁷ The Certification Commission for Healthcare Information Technology or CCHIT is an independent, voluntary, private-sector initiative whose mission is to accelerate the adoption of health information technology by creating an efficient, credible, and sustainable certification program. It is currently the only recognized certification body for electronic health records and has established a testing program for determining which EHRs meet its certification standards.⁸

⁶ Public Law 111-5, Title XIII, Part II, Section 3014.

⁷ Public Law 111-5, Title XIII, Part I, Section 3000.

⁸ Health and Human Services, Centers for Medicare and Medicaid Services, Electronic Health Records Demonstration Project: *What does CCHIT certification mean?* (last updated 9/24/2008) found at <http://questions.cms.hhs.gov/cgi-bin/cmshhs.cfg/php/enduser/std_adp.php?p_faqid=9061&p_created=1207313988&p_sid=fosWtwsj&p_accessibility=0&p_re_direct=&p_lva=&p_sp=cF9zcmNoPSZwX3NvcnRfYnk9JnBfZ3JpZHNvcnQ9JnBfcm93X2NudD03OCw3OCZwX3Byb2Rz>

Florida's Efforts

In Florida, the development of a statewide health information exchange began on May 4, 2004, when Governor Jeb Bush created the Governor's Health Information Infrastructure Advisory Board (Board) by executive order.⁹ The executive order required the Board to advise and support the Agency as it develops and implements a strategy for the adoption and use of electronic health records and creates a plan to promote the development and implementation of a Florida health information infrastructure. Complementing the Governor's Executive Order was the passage of the 2004 Affordable Health Care for Floridians Act, which directed the agency to "develop and implement a strategy for the adoption and use of electronic health records."¹⁰

The Board issued an interim report to Governor Bush in 2005 that called for, among other recommendations, the immediate development of the Florida Health Information Network (FHIN) in order to encourage the adoption of electronic health records.¹¹ The vision for the FHIN is outlined in the Board's white paper, "Florida Health Information Network, Architectural Considerations for State Infrastructure."¹² The model outlined by the Board relies heavily on the regional health information organization (RHIO) as the vehicle for statewide health information exchange. The FHIN acts as the conductor of health information among health care providers and has two main components: regional health information exchange (through RHIOs) and a statewide infrastructure that will connect the RHIOs to enable statewide health information exchange.¹³ The report also recognized two main obstacles facing the development of the FHIN: the low number of healthcare providers who have adopted electronic health record systems, and the lack of an infrastructure to share health information effectively.

Over the course of three years, the Board and the Agency worked together to implement recommendations related to advancing the adoption and utilization of electronic health records and establishing RHIOs and regional health information exchanges.¹⁴ The Board ceased to operate on June 30, 2007, upon expiration of the executive order.

The board published its final report to Governor Charlie Crist on July 6, 2007.¹⁵ The report said that the foundation for a statewide network is in place and recommended the following actions to Governor Crist to implement the FHIN:

[PSZwX2NhdHM9JnBfcHY9NC45ODgmcF9jdj0mcF9zZWFyY2hfdHlwZT1hbnN3ZXJzLnNIYXJjaF9ubCZwX3BhZ2U9MQ**&p_li=&p_topview=1](http://www.fdhc.state.fl.us/dhit/Board/executive_order.pdf)> (Last visited on April 9, 2009).

⁹ Executive Order Number 04-93 (2004), available at http://www.fdhc.state.fl.us/dhit/Board/executive_order.pdf (Last visited April 9, 2009).

¹⁰ Chapter 2004-297, Laws of Fla.; s. 408.062(5), F.S.

¹¹ Governor's Health Information Infrastructure Advisory Board, "First Interim Report to Governor Jeb Bush," http://ahca.myflorida.com/dhit/Board/interim_rept_gov.pdf (Last visited April 9, 2009).

¹² Governor's Health Information Infrastructure Advisory Board, "Florida Health Information Network, Architectural Considerations for State Infrastructure," Version 6.2, April 19, 2007.

¹³ Florida Health Policy Center, "Florida's Health Information Network: What will it cost to develop?," February 2007, <<http://www.floridahealthpolicycenter.org/research/pdfs/FHIN%20brief.pdf>> (Last visited April 9, 2009).

¹⁴ Florida Center for Health Information and Policy Analysis, "Privacy and Security Solutions for Interoperable Health Information Exchange, Florida Implementation and Impact Report," December 3, 2007, 4.

¹⁵ Governor's Health Information Infrastructure Advisory Board, "Final Report of the Governor's Health Information Infrastructure Advisory Board," July 6, 2007, <<http://ahca.myflorida.com/dhit/Board/Brdmtg63007.pdf>> (Last visited April 9, 2008).

- Promote and support the continuing development of the state's local health information exchanges.
- Establish a new advisory board as soon as possible to guide the direction and development of the FHIN.
- Require action on specific steps to assist in developing the network from Florida Medicaid, the Department of Health, and the Department of Management Services, and possibly other state agencies.
- Insist on a "bias in favor of action" on this initiative by members of the administration, placing an emphasis on data exchange operations over the occasional government tendency to conduct further studies before taking substantive action.

In January 2008, the Agency's Secretary, Andrew Agwunobi, appointed a 14-member Health Information Exchange Coordinating Committee. The committee is organized "to advise and support the agency in developing and implementing a strategy to establish a privacy-protected, secure and integrated statewide network for the exchange of electronic health records among authorized physicians."¹⁶

Florida Health Information Network Grants Program

The Florida Health Information Network grants program was initiated in FY 2005-06 with an appropriation of \$1.5 million. The Agency began soliciting applications under that grant program in late 2005 from not-for-profit organizations and units of state or local governments. The Agency received \$2 million in each subsequent fiscal year, until FY 2008-09, to continue the grants program. No funds were appropriated in FY 2008-09 for this grants program. Applications for planning grants could not exceed \$150,000, implementation grants could not exceed \$500,000, and training grants could not exceed \$200,000. Grant funding required a 50/50 match of funds from the applicant.

During FY 2008-09, the Agency funded nine projects that included seven implementation grants, one planning grant, and one training grant. For grants awarded from fiscal year 2007-08 funding, the Agency required that applicants for implementation grants propose certain operational metrics and also describe how project objectives would lead to or support sustainable health information exchange operations. The operational metrics were designed to provide comparable information about the number of providers using the system, the number of providers agreeing to share data or actually sharing data, the size of the health information exchange, and the number of transactions. Grantees were required to report the operational metrics quarterly to the Agency.

Additional Activity

Florida Medicaid is piloting an electronic health record system based on claims data that would enable health information exchange among practitioners participating in the Medicaid program. In November 2008, the Agency issued a Health Information Exchange Collaboration request for information that proposes a multi-payer health information exchange to include Florida

¹⁶ Agency for Health Care Administration, <<http://ahca.myflorida.com/dhit/Governance/HIECCIndex.shtml>> (Last visited April 9, 2008).

Medicaid. Currently the Florida Medicaid pharmacy claims data are used within the health information exchange operated by the Tampa Bay Regional Health Information Organization, and in 2007 the Agency provided hospitalization patient data to the Palm Beach County Community Health Alliance to study the feasibility of using the data within their health information exchange.

In November 2007, the Federal Communications Commission awarded \$9.6 million to the Big Bend Regional Healthcare Information Organization. The award provides funding for the construction of a gigabit optical fiber network over the Florida LambdaRail to connect nine rural hospitals in the Florida panhandle.

In 2007, the Legislature directed the Agency to collect information on the benefits of electronic prescribing and electronic prescribing software and to disseminate information through the Agency's website to facilitate and promote the adoption of electronic prescribing. The Agency published on its website its first annual report on the progress of electronic prescribing on February 1, 2008.

The 2008 Legislature appropriated \$100,000 for the deployment of an electronic health records system in outpatient clinics. The grant program was announced in July 2008 as the "Point of Care Model Electronic Health Records Demonstration." This grant was awarded to the Miami-Dade County Health Department.

Medical Records Privacy

The HIPAA established baseline health care privacy requirements for protected health information and established security requirements for electronic protected health information.¹⁷ A covered entity (for purposes of this analysis includes health care practitioners and providers) is permitted to use and disclose protected health information without an individual's authorization for, among other reasons, treatment. Treatment is defined as the provision, coordination, or management of health care and related services for an individual by one or more health care providers, including consultation between providers regarding a patient and referral of a patient by one provider to another.¹⁸ Similarly, a covered entity does not have to account to a patient for disclosures made for treatment to a patient.

In Florida, patients have a constitutional right to privacy under Article I, Section 23 of the State Constitution, and judicial decisions. Although Florida courts have recognized patients' rights to secure the confidentiality of their health information (medical records) under the right to privacy under the State Constitution, that right must be balanced with and yields to any compelling state interest. Several statutes authorize the release of patient records without consent of the person to whom they pertain. Specifically, s. 456.057, F.S., deals with the confidentiality of medical records created by specified health care practitioners, including medical physicians. Subsection (5) allows patient records, which are otherwise confidential, to be furnished without

¹⁷ United States Department of Health and Human Services, Office of Civil Rights, *Summary of the HIPPA Privacy Rule*, found at <<http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/privacysummary.pdf>> (Last visited on April 9, 2009)

¹⁸ 45 Code of Federal Regulations §164.501.

written authorization to other health care practitioners and providers involved in the care or treatment of the patient.

Section 395.3025, F.S., provides requirements for the confidentiality of patient records held by hospitals in Florida and outlines uses and disclosures of such records. Patient records that are otherwise confidential may be disclosed to licensed facility personnel and attending physicians for use in connection with the treatment of the patient without the consent of the person to whom they pertain. This provision does not appear to authorize the release of patient records to health care practitioners and providers outside of the licensed facility as needed for the care and treatment of the patient without obtaining consent of the patient.

Section 395.3025(7)(a), F.S., provides that if the content of any record of patient treatment is provided under s. 395.3025, F.S., to a recipient other than the patient or the patient's representative, the recipient may use such information only for the purpose provided and may not further disclose any information to any other person or entity, unless expressly permitted by the written consent of the patient. A general authorization for the release of medical information is not sufficient for this purpose. The content of the patient treatment record is confidential and exempt from the provisions of s. 119.07(1), F.S., and s. 24(a), Art. I of the State Constitution.

Under s. 483.181, F.S., a clinical laboratory may examine human specimens at the request only of a licensed practitioner or other person authorized by law to use the findings of clinical laboratory examination. The clinical lab is restricted to reporting the results of a test directly to the licensed practitioner or other authorized person who requested it. A violation of this requirement subjects a clinical laboratory to an administrative fine, not to exceed \$1,000 per violation, and any person who violates this requirement may be subject to criminal penalty as a misdemeanor of the second degree.¹⁹

In 2006 and 2007, the Agency was awarded a contract by RTI International, Inc., to participate in a nationwide Health Information Security and Privacy Collaboration Project to analyze state laws relevant to information exchange. The Agency's Privacy and Security Project Legal Work Group, convened as a part of this study, identified several barriers to health information exchange in statutory law, including:

- Inconsistent language regarding the disclosure of patient records without consent in the hospital and physician patient records sections.²⁰
- Lack of authority for treating physicians to access lab results directly from the clinical lab under chapter 483, F.S.²¹

III. Effect of Proposed Changes:

Section 1. Amends s. 395.3025, F.S., to authorize licensed facilities (hospitals, ambulatory surgical centers, and mobile surgical facilities) to disclose patient medical records, without the consent of the patient or the patient's legal representative, to health care practitioners and providers that are currently involved in the care or treatment of the patient for use only in

¹⁹ Section 483.23, F.S.

²⁰ Sections 395.3025 and 456.057, F.S., respectively.

²¹ Section 483.181, F.S.

connection with the treatment of the patient when the practitioners or providers are not licensed facility personnel or attending physicians.

Section 2. Creates s. 408.051, F.S., the “Florida Electronic Health Records Exchange Act.” The following terms are defined: “electronic health record,” “qualified electronic health record,” “certified electronic health record technology,” “health record,” “identifiable health record,” “patient,” and “patient representative.”

A health care provider is authorized to release or access an identifiable health record of a patient without the patient’s consent for use in the treatment of that patient for an emergency medical condition when consent cannot be obtained from the patient or the patient representative due to the patient’s condition or the nature of the situation requiring immediate medical attention. Immunity from civil liability is provided when a health care provider accesses or releases the identifiable health record in good faith under this section.

The Agency is required to develop a form by July 1, 2010, in paper and electronic formats, to document patient authorization for the use or release of an identifiable health record. A health care provider must accept an authorization form requesting release of an identifiable health record as a valid authorization to release the record. Neither the provider nor the patient is required to use the form adopted and distributed by the Agency. The bill creates a rebuttable presumption that the release of an identifiable health record upon receipt of an authorization form completed and submitted in accordance with Agency instructions was appropriate and the health care provider does not violate any right of confidentiality and is immune from liability. In addition, the release or exchange of an identifiable health record upon receipt of an authorization form does not violate or waive any statutory or common law privilege.

The bill provides that a person who forges a signature on an authorization form, materially alters an authorization form without permission, or obtains an identifiable health record of another person under false pretenses may be liable to the patient or health care provider for compensatory damages caused by an unauthorized release, plus attorney’s fees and costs.

Section 3. Creates s. 408.0512, F.S., to require the Agency to operate an electronic health records system adoption loan program, subject to a specific state appropriation and the availability of funding through public or private entities or the federal stimulus law. The bill does not appear to specify what types of loans are to be made. The agency is required to adopt rules related to standard terms and conditions for use in the loan program. (See the comment under Other Constitutional Issues.)

Section 4. Amends s. 409.916(1), F.S., by providing that AHCA must deposit into the Grants and Donations Trust Fund those funds received from private donations for the purpose of funding a certified electronic health record technology loan fund.

Section 5. Amends s. 483.181, F.S., to authorize a clinical laboratory to release, without patient consent, test results that have been ordered by a practitioner to other health care practitioners and providers involved in the care or treatment of the patient for use in connection with the treatment of that patient.

Section 6. Provides that the act takes effect upon becoming a law.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. Other Constitutional Issues:

The rulemaking authority granted to the agency under this bill in section 3 of the bill may be too broad and run afoul of s. 3, Art. II of the Florida Constitution, the non-delegation doctrine. Under this doctrine, the Legislature may not delegate the power to enact a law or the right to exercise unrestricted discretion in applying the law. “[S]tatutes granting power to the executive branch ‘must clearly announce adequate standards to guide ... in the execution of the powers delegated. The statute must so clearly define the power delegated that the [executive] is precluded from acting from whim, showing favoritism, or exercising unbridled discretion.’”²² Section 3 of this bill allows for federal stimulus funds to be used for an electronic health records system adoption loan program. The state (the Agency) must apply for these funds, submit a strategic plan, and provide assurances that it will establish a loan fund in accordance with the stimulus law. The stimulus law sets forth certain requirements, restrictions, and authorizations for the use of the loan fund. These provisions could be used to provide more discrete standards for the Agency’s rulemaking authority with respect to the loan program in this bill.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The bill provides for a loan program to assist physicians to obtain and implement electronic health records systems pending the receipt of federal stimulus funding.

²² See *Bush v. Schiavo*, 885 So. 2d 321, 332 (Fla. 2004), quoting *Lewis v. Bank of Pasco County*, 346 So. 2d 53, 55-56 (Fla. 1976).

A universal authorization form will be available for a patient to authorize the release of his or her identifiable health record. A universal form may expedite access to and release of this information to facilitate the delivery of health care services.

C. Government Sector Impact:

The Agency must adopt rules for the universal authorization form and loan program. In addition to the amount appropriated for the loan program itself, the Agency estimates a fiscal impact of \$252,468 the first year and \$160,348 recurring for development and implementation of the electronic medical records systems adoption loan program. This includes \$80,000 for an OPS position the first year and two FTEs (one professional and one administrative assistant) beginning in the first year.²³

VI. Technical Deficiencies:

None.

VII. Related Issues:

It is unclear exactly what the purpose of the loan program is. A previous version of this bill provided guidance as to what loan funds were to be spent on, but section 3 of the bill is now standardless, allowing AHCA to set up a loan program, but not specifying the purpose of the loan program.

It is unclear whether the authorization form mentioned on line 203 and on line 228 refers to the authorization form adopted and distributed by the Agency.

VIII. 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 Governmental Oversight and Accountability on March 31, 2009:

The committee substitute:

- Replaces definitions of “electronic health records system” and “health information exchange” with definitions of “qualified electronic health record” and “certified electronic health record technology.”
- Amends the definition of “patient representative” to include an attorney for the patient’s surviving spouse, parent, or adult child, or the attorney for the parent or guardian of a surviving minor child.
- Provides that donations to the electronic health records system adoption loan program may be received from public or private entities, and that AHCA must deposit such funds in the Grants and Donations Trust Fund.

CS by Health Regulation on March 11, 2009:

The committee substitute eliminates the matching grants program for health information

²³ Agency 2009 Bill Analysis & Economic Impact Statement for SB 162.

organizations, the Florida Health Information Exchange Advisory Council, and the requirement for OPPAGA to evaluate and report on the grants program. New concepts in the committee substitute include the requirement for the Agency to develop a universal authorization form and provisions authorizing the release of identifiable health records without consent in emergency situations to treat a patient. The loan program for the adoption of electronic health records systems is substantially changed to provide the framework for the receipt of federal stimulus funds, which would allow additional types of health care providers to access these loans.

B. Amendments:

None.