

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 Appropriations Subcommittee on Health and Human Services

BILL: CS/SB 804

INTRODUCER: Health Policy Committee and Senator Brandes

SUBJECT: Electronic Health Records

DATE: April 17, 2017

REVISED: _____

| | ANALYST | STAFF DIRECTOR | REFERENCE | ACTION |
|----|---------------|-----------------|------------|--------------------|
| 1. | <u>Looke</u> | <u>Stovall</u> | <u>HP</u> | Fav/CS |
| 2. | <u>Jones</u> | <u>Miller</u> | <u>TR</u> | Favorable |
| 3. | <u>Forbes</u> | <u>Williams</u> | <u>AHS</u> | Pre-meeting |
| 4. | _____ | _____ | <u>AP</u> | _____ |

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 804 allows a patient, or the patient's health care surrogate or proxy, to donate the patient's electronic health records (EHR) and qualified electronic health records (QEHR)¹ to an approved² medical or dental school; college; university; hospital; or repository that collects, stores, and shares de-identified electronic health records with the public. The health records may be used for the purposes of educating or developing diagnoses, treatment choices, policies, health care system designs, and innovations in order to improve health outcomes and reduce health care costs.

To implement the provisions of this bill, the Agency for Health Care Administration will incur costs of \$438,000 annually and the Department of Highway Safety and Motor Vehicles will incur insignificant new costs.

The effective date of the bill is July 1, 2017.

¹ As defined in s. 408.051, F.S.

² By the Department of Health (DOH).

II. Present Situation:

The Florida Electronic Health Records Exchange Act

Section 408.051, F.S., establishes the Florida Health Records Exchange Act. The act requires a healthcare provider that receives an authorization form containing a request for the release of an identifiable health record to accept the form as a valid authorization to release the record.³ Any release of health information after the receipt of an authorization form completed and submitted as prescribed by the Agency for Health Care Administration (AHCA) creates a rebuttable presumption that the release was appropriate.⁴ For the purposes of the act, the term:

- “Electronic health record” means a record of a person’s medical treatment which is created by a licensed health care provider and stored in an interoperable and accessible digital format;⁵ and
- “Qualified electronic health record” means an electronic record of health-related information concerning an individual which includes patient demographic and clinical health information, such as medical history and problem lists, and which has the capacity to provide clinical decision support, to support physician order entry, to capture and query information relevant to health care quality, and to exchange electronic health information with, and integrate such information from, other sources.⁶

In addition to the provisions contained within the Florida Electronic Health Records Exchange Act, s. 408.062(5), F.S., requires the AHCA to develop and implement 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.

The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule and the Authorization for Release of Protected Health Information

The HIPAA privacy rule is a federal rule that restricts the use and disclosure of individuals’ health information — called “protected health information”⁷ (PHI) by organizations subject to the Privacy Rule — called “covered entities,”⁸ as well as standards for individuals’ privacy rights to understand and control how their health information is used.⁹ In general, HIPAA grants an individual the right to access his or her own PHI. Included within this right is the right to:

- Ask to see and get a copy the individual’s own health records from most doctors, hospitals, and other health care providers;

³ Section 408.051(4)(c), F.S.

⁴ Section 408.051(4)(e), F.S.; however, pursuant to s. 408.051(4)(d), F.S., the use of the form adopted by the AHCA is not required to authorize release of protected health information.

⁵ Section 408.051(2)(a), F.S.

⁶ Section 408.051(2)(b), F.S.

⁷ Protected health information is all individually identifiable health information held or transmitted by a covered entity or its business associate, in any form or media, whether electronic, paper, or oral.

⁸ In general, covered entities are health plans, health care clearinghouses, and to any health care provider who transmits health information in electronic form in connection with transactions for which the Secretary of HHS has adopted standards under HIPAA.

⁹ U.S. Department of Health and Human Services, Health Information Privacy, *Summary of HIPAA Privacy Rule*, <https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/> (last visited Mar. 8, 2017)

- Get either a paper or electronic copy, if the records are kept electronically, of the health records; and
- Have a copy of the records sent to someone else.¹⁰

HIPAA and De-Identified Health Information

For the purposes of HIPAA, protected health information is information, including demographic information, which relates to:

- The individual's past, present, or future physical or mental health or condition;
- The provision of health care to the individual; or
- The past, present, or future payment for the provision of health care to the individual, and that identifies the individual or for which there is a reasonable basis to believe can be used to identify the individual. Protected health information includes many common identifiers (e.g., name, address, birth date, Social Security Number) when they can be associated with the health information listed above.

However, information that is not individually identifiable to a particular patient is not considered PHI and, therefore is not covered by HIPAA. For example, a health plan report that only noted the average age of health plan members was 45 years would not be PHI because that information, although developed by aggregating information from individual plan member records, does not identify any individual plan members and there is no reasonable basis to believe that it could be used to identify an individual.¹¹

Potential Rationale for Donation of Electronic Health Records

In addition to pure research related to specific medical conditions, recently, new technologies have been developed that are able to scan large amounts of data and apply the results to individual medical decisions. For example, IBM has begun using its computing system, Watson, within the healthcare field. IBM states that Watson's applications extend over many health fields including genomics, drug discovery, health patient engagement, oncology, and care management.¹² Watson is able to store significant amounts of data, analyze it, and find patterns and meaning within the data much quicker and more efficiently than any human. The abilities of Watson, and other computing systems like it, will be further enhanced by the availability of large amounts of data with which to work. Donating EHR and QEHR could help these future technologies become more effective in providing better overall outcomes within the healthcare system.

¹⁰ Message from Jocelyn Samuels, Director, Office of Civil Rights, U.S. Department of Health and Human Services, *Right to Access* (September 28, 2015) <https://www.hhs.gov/sites/default/files/righttoaccessmemo.pdf>, (last visited Mar. 3, 2017).

¹¹ U.S. Department of Health and Human Services, Health Information Privacy, *Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule* <https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html#protected> (last visited Mar. 8, 2017).

¹² See IBM Watson Health, <https://www.ibm.com/watson/health/> (last visited Mar. 8, 2017).

Organ Donation Encouragement Program

Following direction from the Legislature¹³, the Department of Highway Safety and Motor Vehicles (DHSMV) and AHCA implemented a system to encourage potential donors of anatomical gifts (organ donors) through the process of issuing and renewing driver licenses or identification cards. The DHSMV includes “Organ Donor” notations on identification cards, driver licenses, and driver records to indicate an individual’s intent to be a donor. Donor registration cards are distributed by the DHSMV, with necessary supplies and forms provided by AHCA. The DHSMV is responsible for providing the necessary recordkeeping system. Additionally, the DHSMV is required to maintain an integrated link on its website referring individuals conducting business on the site to the donor registry.¹⁴ Approximately 98 percent of people who enroll in Florida’s registry do so while obtaining or renewing a driver license.¹⁵

III. Effect of Proposed Changes:

The bill amends ch. 765, F.S., relating to health care advance directives, to allow a patient, or the patient’s health care surrogate or proxy, to donate the patient’s Electronic Health Records (HER) and Qualified Electronic Health Records (QEHR)¹⁶ to an approved¹⁷ medical or dental school, college, university, hospital, or repository that collects, stores, and shares de-identified electronic health records with the public. The bill authorizes the donation of EHR and QEHR after the patient’s death.

Donations of EHR and QEHR by the Patient

Section 2 creates s. 765.114, F.S., to specify that a person may donate all or part of his or her EHR or QEHR by:

- Signing an EHR donor card;
- Indicating an intent to donate on his or her driver license or identification card issued by the DHSMV;
- Expressing the wish to donate in a living will or other advance directive;
- Expressing the wish to donate in a will;¹⁸ or
- Expressing a wish to donate in another document that has been signed by the donor (or his or her designee) and two witnesses.

This section provides a standard form that may be used to indicate the wish to donate EHR and QEHR.

De-identified EHR may be given to one or more donees that are accredited medical or dental schools, colleges, universities, hospitals, or repositories for the purpose of educating or

¹³ See Section 765.521, F.S.,

¹⁴ Section 765.521(2), F.S.

¹⁵ Donate Life Florida 2015 *Annual Report*, available at https://www.donateliflorida.org/files/53_file.pdf at p. 12.

¹⁶ The bill references the definitions of EHR and QEHR in s. 408.051, F.S. (See Present Situation for definitions of these terms).

¹⁷ By the DOH.

¹⁸ The bill specifies that, when a wish to donate is expressed in a will, the donation becomes effective upon the death of the testator without entering probate and that the donation is considered valid if made in good faith even if the will is found to be invalid for testamentary purposes.

developing diagnoses, treatment choices, policies, health care system designs, and innovations to improve health outcomes and reduce health care costs. Donees must be approved by the DOH and may be specified by name. The bill specifies that identified information may be donated with the written consent of the donor.

Additionally, a person may revoke or amend the terms of a donation of EHR by:

- The execution and delivery to the donee of a signed statement witnessed by at least two adults, one of whom is a disinterested witness;
- An oral statement made in the presence of two adult witnesses, one of whom is not a family member. The statement must be communicated to the donor's family, or to the donor's attorney, or to the donee and the donee must have actual notice of the revocation;
- An oral statement communicated during a terminal illness or injury to the primary physician who must communicate the revocation of the gift to the medical or dental school, college, university, hospital, or repository.
- A signed document found on or about the donor's person;
- A later-executed document of donation which amends or revokes a previous health records donation; or
- The destruction or cancellation, with the intent to revoke the donation, of the document, or portion of the document, that indicates the intent to donate.

Donation of EHR and QEHR by the Patient's Health Care Surrogate or Proxy

Section 1 amends s. 765.101, F.S., to allow a patient's health care surrogate or proxy to donate the patient's EHR and QEHR. This section amends the definition of "health care decision" in s. 765.101, F.S., to include the right of the health care surrogate or proxy to donate the principal's EHR and QEHR upon the principal's death and amends the suggested form of designation of a health care surrogate in s. 765.203, F.S., to include the authorization for the health care surrogate to donate the principal's EHR and QEHR. This section requires that information donated by a health care surrogate be de-identified.

Donation Encouragement Program

Section 3 creates s. 765.1141, F.S., to require the AHCA and the DHSMV to develop and implement a program to encourage and authorize persons to donate EHR and QEHR as part of the process of issuing and renewing identification cards and driver licenses. Donor cards distributed by the DHSMV must include the information and signatures necessary to authorize the donation of EHR and may include any additional information determined necessary by the DHSMV.

This section also requires the DHSMV to develop and implement a program to identify donors including notations on their identification cards or driver licenses to clearly indicate their intent to donate their EHR. The AHCA is required to provide necessary supplies and forms using appropriated funds or contributions from interested voluntary, nonprofit organizations, and the DHSMV is required to provide the necessary recordkeeping system using appropriated funds. The DHSMV is also required to maintain a link on its webpage referring visitors renewing identification cards and driver licenses to an electronic health records repository, if such repository is available.

This section exempts the DHSMV and the AHCA from liability in connection with the performance of any act regarding these programs, and requires the DHSMV, after consultation and concurrence with the AHCA, to adopt rules to implement the programs.

Section 4 amends s. 765.203, F.S., to expand the designation of health care surrogate to include the grant of authority to donate EHI.

The bill establishes an effective date of July 1, 2017.

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:

The bill may have a minor negative fiscal impact on health care facilities that are required to de-identify and electronically transfer records pursuant to a donation as detailed in the bill.

C. Government Sector Impact:

Under the provisions of the bill the AHCA and the DHSMV will incur new costs related to the implementation of the donation encouragement program.

The AHCA estimates costs will increase by \$447,318 annually.¹⁹ Of the \$438,432 recurring costs, the AHCA estimates an annual cost of \$300,000 for the production of supplies and forms. The remainder of the recurring costs (\$138,432) to the agency are associated with employing two full-time program staff to facilitate outreach with the DHSMV and to conduct training and education at each of the state's 67 county tax collector offices, and travel costs.

¹⁹ AHCA, *Senate Bill 804 Analysis* (Feb. 14, 2017) (on file with the Senate Committee on Health Policy).

The DHSMV will incur costs to develop and implement the EHR donor program. The bill requires the agency to:

- Identify donors and include notations on their identification cards or driver licenses;
- Provide the necessary recordkeeping system; and
- Maintain a link on the DHSMV webpage referring visitors to electronic health records repositories.

The DHSMV estimates programming and implementation costs to note such election on a driver license record or identification card record and to maintain a link on the DHSMV webpage is approximately \$16,522. Other costs associated with notating the driver license or identification card to indicate such election, staffing, and actual recordkeeping are unknown.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends sections 765.101 and 765.203 of the Florida Statutes.

This bill creates sections 765.114 and 765.1141 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 Committee on March 14, 2017:

The CS amends SB 804 to specify that identified EHR and QEHR may be donated with the written consent of the donor and to make other technical changes.

- B. **Amendments:**

None.