

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: SB 804

INTRODUCER: Senator Brandes

SUBJECT: Electronic Health Records

DATE: March 13, 2017

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Stovall	HP	Pre-meeting
2.			TR	
3.			AHS	
4.			AP	

I. Summary:

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.

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:

¹ As defined in s. 408.051, F.S.

² By the Department of Health (DOH).

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.

- “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;
- 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

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)

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).

- 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 (of Jeopardy fame), 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 to work with. Donating EHR and QEHR could help these future technologies become more effective in providing better overall outcomes within the healthcare system.

III. Effect of Proposed Changes:

SB 804 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 EHR and QEHR¹³ to an approved¹⁴ 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

The bill specifies that a person may donate all or part of his or her EHR or QEHR by:

- Signing an EHR donor card;

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).

¹³ The bill references the definitions of EHR and QEHR in s. 408.051, F.S. (See Present Situation for definitions of these terms).

¹⁴ By the DOH.

- Indicating an intent to donate on his or her driver license or identification card issued by the Department of Highway Safety and Motor Vehicles (DHSMV);
- Expressing the wish to donate in a living will or other advance directive;
- Expressing the wish to donate in a will;¹⁵ or
- Expressing a wish to donate in another document that has been signed by the donor (or his or her designee) and two witnesses.
 - The bill 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 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.

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, 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 to the donee;
- 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;
- 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

The bill also allows a patient's health care surrogate or proxy to donate the patient's EHR and QEHR. The bill 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. The bill requires that information donated by a health care surrogate be de-identified.

Donation Encouragement Program

The bill requires 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

¹⁵ 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.

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.

The bill 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.¹⁶ The AHCA is required to provide necessary supplies and forms and the DHSMV is required to provide the necessary recordkeeping system. 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.

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

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:

SB 804 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:

SB 804 may have a negative fiscal impact on the AHCA and the DHSMV related to the implementation of the implementation of the donation encouragement program.

¹⁶ The DHSMV currently implements a similar program for organ donation. See s. 765.521, F.S.

VI. Technical Deficiencies:

Subsection (1) of s. 765.114, F.S., allows a person to donate “all or part of his or her electronic health records and qualified electronic health records,” however, subsection (2) refers to “the de-identified electronic health records” that may be given to donees. Between these two subsections, it is unclear whether EHR and QEHR donated directly by a patient is required to be de-identified. The bill should be amended to clarify whether a person may directly donate identified health information.

Additionally, portions of the bill designate specific terms that are not used consistently throughout the bill. For example, lines 69-71 allow a person to donate all or part of his or her EHR or QEHR, but lines 132-133 only grant the donor the authority to amend or revoke a donation of EHR. Additionally, lines 48-58 allow “the health care surrogate or proxy,” to donate the EHR or QEHR of the principal, however, lines 126-31 only refer to donations by “the health care surrogate” when requiring such EHR or QEHR be de-identified. The bill should be amended to ensure that terms are used consistently throughout the entirety of the bill.

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 Changes:**

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.