SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: Health Care Committee

BILL:	SB 1408
INTRODUCER:	Health Care Committee
SUBJECT:	Health Records
DATE:	February 23, 2006
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Munroe	Wilson	HE	**Favorable**
2.				
3.				
4.				
5.				
6.				

I. Summary:

The bill amends provisions governing the confidentiality of certain health records to define the term "records custodian" and to recognize a third party custodian of medical and pharmaceutical records. The bill requires the records custodian and any health care practitioner's employer who is a records owner to be subject to the same statutory confidentiality and disclosure requirements for the records as the licensed or regulated health care practitioner who created the records.

The bill specifies that, in lieu of certain existing requirements for "written prescriptions of medicinal drugs," an "electronically generated and transmitted prescription" must contain the name of the prescribing practitioner, the name and strength of the drug prescribed, the quantity of the drug prescribed in numerical format, and the direction for use of the drug. Such a prescription must be dated and signed by the prescribing practitioner only on the day issued, which signature may be in an electronic format.

The bill also provides a mechanism for prescribers using electronic prescribing to prevent the generic substitution of a prescribed brand name drug product when the brand name drug is deemed medically necessary.

This bill substantially amends ss. 456.057, 456.42, and 465.025, F.S.

II. Present Situation:

Confidentiality of and Access to Patient Records

Chapter 456, F.S., specifies the general regulatory provisions for health care professions within the Department of Health (DOH). Section 456.057, F.S., deals with the confidentiality of, and

patient's access to, medical records created by specified health care practitioners. "Records owner" is defined to mean any health care practitioner who generates a medical record after making a physical or mental examination of, or administering treatment or dispensing legend drugs to, any person; any health care practitioner to whom records are transferred by a previous records owner; or any health care practitioner's employer, provided the employment contract or agreement between the employer and the health care practitioner designates the employer as the records owner.

For purposes of s. 456.057, F.S., the terms "records owner," "health care practitioner," and "health care practitioner's employer" do not include any of the following persons or entities: certified nursing assistants; pharmacists and pharmacies; dental hygienists; nursing home administrators; respiratory therapists; athletic trainers; electrologists; clinical laboratory personnel; medical physicists; opticians and optical establishments; and persons or entities practicing under s. 627.736(7), F.S., relating to personal injury protection claims. These persons or entities are not authorized to acquire or own medical records, but are authorized under the confidentiality and disclosure requirements of s. 456.057, F.S., to maintain those documents required by the part or chapter under which they are licensed or regulated.

Confidentiality of and Access to Pharmacy Records

Chapter 465, F.S., provides for the regulation of pharmacy and pharmacies. Section 465.017, F.S., provides that, except upon written authorization of the patient, a pharmacist is authorized to release patient prescription records only to the patient, the patient's legal representatives, and the patient's spouse if the patient is incapacitated, to DOH, or upon the issuance of a subpoena. Section 465.017, F.S., also specifies certain other exceptions for the release of records maintained in a pharmacy relating to the filling of prescriptions and dispensing of drugs. Pharmacists are subject to discipline for using or releasing a patient's records, except as authorized by ch. 465, F.S., and ch. 456, F.S.

Section 456.057, F.S., provides that, except upon a patient's written authorization, and exceptions which are specified by statute, both medical records and the medical condition of a patient may not be discussed with any person other than the patient, the patient's legal representative or other health care practitioners and providers involved in the care or treatment of the patient. Section 456.057, F.S., expressly excludes pharmacists and pharmacies from the definition of "health care practitioner" for purposes of the section. Section 456.057, F.S., provides that pharmacists and pharmacies are not authorized to acquire or own medical records, but are authorized under the confidentiality and disclosure requirements of that section to maintain those documents required by the part or chapter under which they are licensed or regulated.

Requirements for Written Prescriptions

Section 456.42, F.S., requires a written prescription for a medicinal drug issued by a health care practitioner licensed by law to prescribe such drug to be *legibly printed or typed so as to be capable of being understood by the pharmacist filling the prescription*. The prescription must also contain the name of the prescribing practitioner, the name and strength of the drug prescribed the quantity in both textual and numerical formats, and directions for use. The

prescription must be dated with the month written out in textual letters and signed by the prescribing practitioner on the day when issued.

Generic Drug Substitution

Florida law requires a less expensive generically equivalent drug to be substituted for a brand name drug unless the patient objects or the prescribing practitioner affirmatively prohibits the substitution by writing on the prescription that the brand name drug is medically necessary.[1] A "generically equivalent drug product" is defined to mean a drug product with the same active ingredient, finished dosage form, and strength. The generic substitution law only applies to drugs that are prescribed by brand name. If the prescription is written for a drug identified by its generic name, the pharmacist may use her or his professional judgment to select any drug product with the same active ingredients, including a brand-name drug product. The pharmacist must maintain a record of any drug substitution. Florida law governing the Medicaid program also requires generic substitution of brand-name drug products.[2]

Senate Interim Project 2006-135

Senate Interim Project Report 2006-135 describes state and federal requirements for prescriptions, which may affect the use of electronic prescribing, including generic drug substitution, specialized procedures for controlled substances, and procedures for the legibility of written prescriptions. The report outlines the procedures used by pharmacists to validate and authenticate a prescription; describes existing electronic prescribing networks and the unique measures used in such networks to ensure that the transmission of electronic prescriptions is secure; and discusses the confidentiality of pharmacy records and related patient information. The report recommends that:

- The statutes governing generic drug substitution be amended to provide a mechanism for prescribers using electronic prescribing to prevent the generic substitution of a prescribed brand name drug product when the brand name drug is deemed medically necessary;

- The law governing written prescriptions for medicinal drugs in s. 456.42, F.S., be amended to limit its application to handwritten prescriptions; and

- The provisions in ss. 456.057 and 465.017, F.S., relating to the confidentiality of patient records be amended to recognize a third party custodian of medical and pharmaceutical records and to require the custodian to be subject to the same statutory confidentiality and disclosure requirements for the records as the licensed or regulated health care practitioner who created the records.

[1] See s. 465.025, F.S.

[2] See s. 409.908(14), F.S., which requires Medicaid providers to dispense generic drugs if available at a lower cost and the Agency for Health Care Administration has not determined that the branded product is more cost-effective, unless the prescriber has requested and received approval to require the branded product. See also 42 CFR 447.331(c) relating to the Medicaid program, which provides that certain payment limitations do not apply if "a physician certifies in *his or her own handwriting* that a specific brand is medically necessary for a particular patient."

Electronic Signature Act of 1996

Florida law recognizes legal documents authorized by digital or electronic signatures. Part I, ch. 668, F.S., specifies requirements for electronic signatures. "Electronic signature" is defined to mean any letters, characters, or symbols, manifested by electronic or similar means, executed or adopted by a party with an intent to authenticate a writing. A writing is electronically signed if an electronic signature is logically associated with such writing.

III. Effect of Proposed Changes:

Section 1. Amends s. 456.057, F.S., relating to the confidentiality of and access to patient records, to define "records custodian" to mean any person or entity that: maintains documents that are authorized in subsection (2) of the section or; obtains medical records from a records owner. Subsection (2) of s. 456.057, F.S., authorizes specified persons or entities to maintain documents under the confidentiality and disclosure requirements of s. 456.057, F.S., which are required by the part or chapter under which the persons or entities are licensed or regulated.

Section 456.057, F.S., is also amended to require any health care practitioner's employer who is a records owner and any records custodian to comply with the requirements for confidentiality of and disclosure of such records or documents.

Section 2. Amends s. 465.42, F.S., relating to requirements for written prescriptions, to provide that a prescription that is electronically generated and transmitted must contain the name of the prescribing practitioner, the name and strength of the drug prescribed, the quantity of the drug prescribed in numerical format, and the direction for use of the drug. Such a prescription must be dated and signed by the prescribing practitioner only on the day issued, which signature may be in an electronic format as defined in s. 668.003(4), F.S.

Section 3. Amends s. 465.025, F.S., relating to generic drug substitution, to provide a mechanism for prescribers using electronic prescribing to prevent the generic substitution of a prescribed brand name drug product when the brand name drug is deemed medically necessary.

Section 4. Provides an effective date of July 1, 2006.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Art. VII, s. 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Art. I, s. 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Art. III, Subsection 19(f) of the Florida Constitution.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The bill may benefit health care consumers to the extent that it streamlines Florida law for electronic prescribing.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Summary of Amendments:

None.