

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.)

BILL: SB 2670

SPONSOR: Senator Campbell

SUBJECT: Pharmacy

DATE: April 10, 2003

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Munroe</u>	<u>Wilson</u>	<u>HC</u>	<u>Favorable</u>
2.	_____	_____	_____	_____
3.	_____	_____	_____	_____
4.	_____	_____	_____	_____
5.	_____	_____	_____	_____
6.	_____	_____	_____	_____

I. Summary:

The bill requires the Board of Pharmacy to adopt rules to establish practice guidelines for pharmacies to follow in disposing of records maintained in a pharmacy relating to the filling of prescriptions and the dispensing of medicinal drugs. Such rules must be consistent with the duty to preserve the confidentiality of such records in accordance with applicable state and federal law.

This bill amends s. 465.017, Florida Statutes.

II. Present Situation:

Ownership and Control of Patient Records

Subsection (4) of s. 456.057, F.S., requires health care practitioners licensed by the Department of Health who generate a medical record after making a physical or mental examination of, or administering treatment or dispensing legend drugs to, any person, upon request, to furnish, in a timely manner, to that person or that person's legal representative, without delays for legal review, a copy of all reports and records relating to that examination or treatment, including X-rays and insurance information. When a patient's psychiatric, psychological or psychotherapeutic records are requested by the patient or the patient's legal representative, the health care practitioner may provide a report in lieu of copies of the record. The furnishing of such report or copies may not be conditioned upon payment of a fee for services rendered.

Except as provided in s. 456.057, F.S., patient records may not be furnished to, and the medical condition of a patient may not be discussed with, any person other than the patient or the patient's legal representative or other health care practitioners and providers involved in the care or treatment of the patient, except upon written authorization of the patient. Such records may be

disclosed: to any person, firm or corporation that has procured or furnished such examination or treatment with the patient's consent; when compulsory physical examination is made pursuant to Rule 1.360, Florida Rules of Civil Procedure, in which case copies of the medical records shall be furnished to both the defendant and the plaintiff; in any civil or administrative action, unless otherwise prohibited by law, upon the issuance of a subpoena from a court of competent jurisdiction and proper notice to the patient or the patient's legal representative by the party seeking the records; or for statistical and scientific research, if the information is abstracted to protect the patient's identity or if written permission is received from the patient or the patient's legal representative.

Section 456.001, F.S., defines a health care practitioner as any person licensed under any of the following chapters of the Florida Statutes: ch. 457 (acupuncturists), ch. 458 (medical physicians), ch. 459 (osteopathic physicians), ch. 460 (chiropractic physicians), ch. 461 (podiatric physicians), ch. 462 (naturopaths), ch. 463 (optometrists), ch. 464 (nurses), ch. 465 (pharmacists), ch. 466 (dentists), ch. 467 (midwives), ch. 468 (audiologists, speech-language pathologists, nursing home administrators, occupational therapists, respiratory therapists, dietitians/nutritionists, athletic trainers, orthotists, pedorthists, prosthetists), ch. 478 (electrologists), ch. 480 (massage therapists), ch. 483 (clinical laboratory personnel and medical physicists), ch. 484 (opticians and hearing aid specialists), ch. 486 (physical therapists), ch. 490 (psychologists), and ch. 491 (clinical social workers, marriage and family therapists, and mental health counselors).

As used in s. 456.057, F.S., "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 to any health care practitioner's employer, if the contract or agreement between the employer and the health care practitioner designates the employer as the records owner. The following 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 regulations under which they are regulated: certified nursing assistants, *pharmacists and pharmacies*, nursing home administrators, respiratory therapists, athletic trainers, electrologists, clinical laboratory personnel, medical physicists, opticians and optical establishments, persons or entities making physical examinations for an injured person as part of personal injury protection claim, or hospitals and ambulatory surgical centers.

Licensed health care practitioners who violate the requirements of s. 456.057, F.S., are subject to discipline by the appropriate licensing authority. The Attorney General is authorized to enforce the provisions of s. 456.057, F.S., against any record owner who is not otherwise licensed in Florida, through injunctive relief and fines not to exceed \$5,000 per violation.

Chapter 465, F.S., provides for the regulation of pharmacy by the Board of Pharmacy. Section 465.017(2), F.S., specifies that except as permitted by law (specifically ch. 465, F.S., relating to pharmacy; ch. 406, F.S., relating to the Medical Examiners Act; ch. 409, F.S., relating to the Medicaid program; ch. 456, F.S., relating to the general regulatory provisions for health care professions; ch. 499, F.S., relating to drugs, devices and household products; and ch. 893, F.S., relating to controlled substances) records maintained in a pharmacy relating to the filling of

prescriptions and the dispensing of medicinal drugs may not be furnished to any person other than to the patient for whom the drugs were dispensed, or his or her legal representative, or to the Department of Health pursuant to existing law, or, in the event that the patient is incapacitated or unable to request the records, his or her spouse, except upon written authorization of such patient. Section 465.017(2), F.S., also provides that the records may be furnished in any civil or criminal proceeding upon the issuance of a subpoena from a court of competent jurisdiction and proper notice to the patient or his or her legal representative by the party seeking such records. Although there is a statutory duty for the confidentiality of such records to be preserved until their destruction, according to the Department of Health there are no guidelines in statute or rule for the disposal of these records.

Health Insurance Portability and Accountability Act of 1996

On December 20, 2000, President Clinton issued landmark rules to protect the privacy of people's medical records. The 1996 Health Insurance Portability and Accountability Act (HIPAA)¹ required the Administration to issue regulations protecting the privacy of health information. The United States Department of Health and Human Services issued Standards for Privacy of Individually Identifiable Health Information on December 28, 2000, which were originally scheduled to go into effect on February 26, 2001. The effective date for the regulations was delayed and will take effect on April 14, 2003. The regulations only apply to health plans, health care clearinghouses and certain health care providers. The regulations permit states to afford greater privacy protections to health information.² Exceptions for state law are provided for public health (authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention) and state regulatory reporting (the ability of a state to require a health plan to report, or to provide access to, information for management audits, financial audits, program monitoring and evaluation, facility licensure or certification, or individual licensure or certification.)³

III. Effect of Proposed Changes:

The bill amends s. 465.017, F.S., to require the Board of Pharmacy to adopt rules to establish practice guidelines for pharmacies to follow in disposing of records maintained in a pharmacy relating to the filling of prescriptions and the dispensing of medicinal drugs. Such rules must be consistent with the duty to preserve the confidentiality of such records in accordance with applicable state and federal law.

The bill provides an effective date of July 1, 2003.

¹ Section 262 of the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, enacted on August 21, 1996, directed the United States Department of Health and Human Services to develop standards to protect the security, including the confidentiality and integrity, of health information.

² Sections 160.201, 160.203, 160.204, and 160.205, C.F.R.

³ The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) generally preempts state health information privacy laws, unless they provide a higher level of protection than the act. (Pub. L. No.104-191, §262, 110 Stat. 1936, 2029.) However, these state privacy provisions may not be preempted if the Secretary of Health and Human Services determines that the state law has as its principal purpose the regulation of the manufacture, registration, distribution, dispensing, or other control of any controlled substances (as defined in 21 U.S.C. §802), or that is deemed a controlled substance by state law. (45 C.F.R. §160.203 (a)(2)). See also, 42 U.S.C.A. § 1320d-7.

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 Article 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 Article III, Subsection 19(f) of the Florida Constitution.

V. Economic Impact and Fiscal Note:**A. Tax/Fee Issues:**

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Amendments:

None.