

SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

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

BILL: CS/SB 1016

SPONSOR: Health, Aging and Long-Term Care Committee and Senator Sebesta and others

SUBJECT: Pharmacy Practice

DATE: April 13, 1999 REVISED: _____

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

I. Summary:

The Committee Substitute for Senate Bill 1016 is titled the Pharmacy Patient Privacy Act of 1999. The bill expands the parties to which, and circumstances under which, a pharmacist may release a patient's prescription records without the patient's written authorization. A pharmacist is subject to discipline for the use or release of a patient's records except as authorized by the pharmacy practice act or ch. 455, F.S. The bill defines "data communication device" and provides that patient prescription records or any part thereof, if transmitted through a data communication device not under the control or ownership of a pharmacy or affiliated company or not directly between a pharmacy and a treating practitioner, may not be accessed, used, or maintained by the operator or owner of the data communication device unless specifically authorized by law. The bill provides a criminal penalty for the unauthorized use of pharmacy records when transmitted through a data communication device by any person who operates or owns a data communication device and who accesses, uses, or maintains pharmacy records in violation of the provisions of the bill. The bill authorizes the pharmacy owner to use such records internally in the aggregate without patient identification data, regardless of where such records are held, for purposes reasonably related to the business and practice of only that pharmacy.

This bill amends sections 465.003, 465.016, 465.017, 465.014, 465.015, 465.0196, 468.812, and 499.003, Florida Statutes.

This bill creates one section that has not been assigned to the Florida Statutes.

II. Present Situation:

Chapter 465, Florida Statutes, provides for the regulation of the practice of pharmacy by the Board of Pharmacy within the Department of Health. 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 representative, the patient's spouse if the patient is incapacitated, to the Department of Health, or upon the issuance of a subpoena. This section also

recognizes other exceptions for the release of records maintained in a pharmacy relating to the filling of prescriptions and the dispensing of prescription drugs in ch. 406, F.S., relating to duties and requirements for medical examiners; ch. 409, F.S., relating to the Medicaid program; ch. 455, F.S., relating the regulation of professions; ch. 499, F.S., relating to the Florida Drug and Cosmetic Act; and ch. 893, F.S., relating to controlled substances.

Section 465.003, F.S., provides definitions for the practice of pharmacy. Section 465.016, F.S., provides grounds for which a pharmacist or dispensing practitioner may be subject to discipline for violating regulations governing the practice of pharmacy. Sections 465.018 and 465.019, F.S., provide requirements for pharmacies to be permitted by the Department of Health. The Board of Pharmacy has adopted an administrative rule outlining the requirements for the transfer of records in the custody of a permitted pharmacy that is closing to another permitted pharmacy (64B16-28.202, Florida Administrative Code). The Board of Pharmacy defines “prescription files” to mean the drug dispensing records of a pharmacy which shall include all orders for drugs or medicinal supplies as defined in s. 465.003 (7), F.S., and includes dispensing records for medicinal drugs listed within s. 893.03, F.S., relating to controlled substances, issued by a duly licensed practitioner which serve to transfer possession of medicinal drugs from the pharmacy to the ultimate consumer (64B16-28.201, F.A.C.).

Part II, ch. 455, F.S., provides the general regulatory provisions for health care professions under the Department of Health. Section 455.667, F.S., provides that except upon a patient’s written authorization, and a few exceptions listed 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 455.667, F.S., expressly excludes pharmacists and pharmacies from the definition of “health care practitioner” for purposes of the section. Section 455.667, 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.

III. Effect of Proposed Changes:

The bill is titled the Pharmacy Patient Privacy Act of 1999. For purposes of the regulation of the practice of pharmacy, the bill defines “data communication device” to mean an electronic device that receives electronic information from one source and transmits or routes it to another. The bill amends s. 465.016, F.S., to subject a pharmacist to disciplinary action for the use or release of a patient’s records except as authorized by the pharmacy practice act or ch. 455, F.S.

The bill amends s. 465.017, F.S., to expand the parties to which, and circumstances under which, a pharmacist may release a patient’s prescription records without the patient’s written authorization. Under the bill, a pharmacist may release patient prescription records to health care practitioners and pharmacists consulting with or dispensing to the patient and to insurance carriers or other payors authorized by the patient to receive the records. For purposes of s. 465.017, F.S., the bill provides that the pharmacy permitholder shall be considered the custodian of records maintained in a pharmacy. The bill authorizes the pharmacy owner to use such records internally

in the aggregate without patient identification data, regardless of where such records are held, for purposes reasonably related to the business and practice of only that pharmacy.

The bill provides that patient prescription records or any part thereof, if transmitted through a data communication device not under the control or ownership of a pharmacy or affiliated company or not directly between a pharmacy and a treating practitioner, may not be accessed, used, or maintained by the operator or owner of the data communication device unless specifically authorized by law. The bill makes it a first degree misdemeanor punishable by up to 1 year in prison and a fine of not to exceed \$1,000 for the unauthorized use of pharmacy records when transmitted through a data communication device by any person who operates or owns a data communication device and who accesses, uses, or maintains pharmacy records in violation of the provisions of the bill. Legislative intent is provided that the use and sharing of patient prescription records is to improve patient care and may not be construed to authorize or expand solicitation or marketing to patients or potential patients in any manner not specifically authorized by law. The bill provides legislative intent to allow the use and sharing of such records to improve patient care, if the pharmacist acts in the best interest of his or her patient. The bill makes other minor technical changes to correct cross-references in ss. 465.014, 465.015, 465.0196, 468.812, and 499.003, F.S.

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, Section 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 Article I, Subsections 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:

Experts have raised concerns regarding recent prescription drug marketing practices and their impact on medical privacy. Several large drug store chains and thousands of independent pharmacies have been providing confidential patient information to a direct mail advertising firm that profiles and targets patients who do not refill prescriptions. The collection and sharing of patient prescription records may be intrusive to the extent many inferences may be drawn regarding the medical condition and treatment of the patient from prescription records. "The Washington Post reports that direct marketing is part of a far-reaching move by drug manufacturers and pharmacies across the country to make greater use of medical information, new technology and sophisticated marketing techniques to sell more drugs." (*American Healthline* 2/17/98) Recent articles in the *American Healthline* 3/26/98 have reported that patients who received direct mail advertising about their prescriptions filed a class-action lawsuit in federal district court against three firms, CVS Corp.(a pharmacy), Glaxo Wellcome Inc. (a pharmaceutical manufacturer) and Elensys Care Services, Inc.(a direct-mail house that conducted the mailing) alleging that the use of their names was a breach of fiduciary duty and requested that the court halt the practice. The *Wall Street Journal* reported that CVS sent to certain pharmacy customers, letters inviting them to try an antismoking patch developed by Glaxo Wellcome, Inc., if they had failed to quit smoking using other means. For the promotion, the names were provided by CVS from its prescription files and processed by Elensys. According to *American Healthline* 2/17/98, "Elensys receives prescription information on millions of individuals from 15,000 pharmacies each week, using 'some of the most sophisticated computer equipment available' to profile patients and send them 'educational materials' about drugs available for their conditions. CVS Corp. and Giant Food Inc. are two pharmacy chains in the Washington, DC, area that send information to the firm."

VIII. Amendments:

None.