

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.)

Date: April 9, 1998

Revised: 04/20/98 _____

Subject: Pharmacy Practice

	<u>Analyst</u>	<u>Staff Director</u>	<u>Reference</u>	<u>Action</u>
1.	<u>Munroe</u>	<u>Wilson</u>	<u>HC</u>	<u>Fav/1 amendment</u>
2.	_____	_____	<u>BI</u>	_____
3.	_____	_____	_____	_____
4.	_____	_____	_____	_____
5.	_____	_____	_____	_____

I. Summary:

This bill revises the definition of the practice of the profession of pharmacy to add *other related cognitive services* and provides a definition for “data communication device.” The bill expands the parties to which, and the circumstances under which, a pharmacist may release patient prescription records. The bill makes other minor technical changes to statutory cross-references.

This bill substantially amends the following sections of the Florida Statutes: 465.003, 465.017, 465.014, 465.015, 465.0196, 468.812, and 499.03.

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.

Section 465.003, F.S., provides definitions for the practice of pharmacy. The definition of “practice of the profession of pharmacy” does not currently address related cognitive services. The American Heritage Dictionary defines cognition to mean the mental process or faculty by which knowledge is acquired.

Part II, chapter 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.

III. Effect of Proposed Changes:

The bill expands the definition of the “practice of the profession of pharmacy” to include the provision of other related cognitive services by pharmacists. 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 expands 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 insurance carriers or other payors authorized by the patient to receive the records and treating practitioners and other pharmacists when, in the professional judgment of the pharmacist, the release of the records protects or benefits the patient’s health, well-being, or treatment. The bill provides that patient prescription records or any part thereof, if transmitted through a data communication device and 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 other minor technical changes to statutory cross-references.

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:

Under the bill, a pharmacist may release patient prescription records to insurance carriers or other payors authorized by the patient to receive the records and treating practitioners and other pharmacists when in the **professional judgment of the pharmacist, the release of the records protects or benefits the patient's health, well-being, or treatment**. 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.

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:

#1 by Health Care:

Amends s. 465.003, F.S., to provide a definition of the term "data communication device."

Amends s. 465.016, F.S., to subject a pharmacist to disciplinary action for the use or release of a patient's records that is not authorized by the pharmacy practice act or ch. 455, F.S. Amends s. 465.017, F.S., to require pharmacy records to conform to the standard used by other health care practitioners and to authorize pharmacists to share their patient records with health care practitioners and pharmacists consulting or dispensing to the patient. 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. Amends s. 465.019, F.S., to allow an individual who is licensed to prescribe medicinal drugs in Florida to dispense up to a 24-hour supply of a medicinal drug to any patient of an emergency department of a hospital that operates a Class II institutional pharmacy, if the physician treating the patient in such hospital's emergency department determines that the medicinal drug is warranted and that community pharmacy services are not readily accessible, geographically or otherwise, to the patient. Corrects cross-references in ss. 465.014, 465.015, 465.0196, 468.812, and 499.003, F.S. Amends s. 766.101, F.S., to extend immunity from liability to the activities of a continuous quality improvement committee of a licensed pharmacy if the committee operates under the rules that have been adopted by the Board of Pharmacy. Amends s. 499.012, F.S., to revise the definition of "wholesale distributor" to allow governmental and nongovernmental entities to obtain drugs at government discounted prices when they contract with retail pharmacies and meet specified requirements. Creates s. 499.072, F.S., to establish the Drug Regulation Advisory Group, an independent advisory group to be appointed by the Secretary of the Department of Health from representatives of various organizations and to specify the terms of office, meeting frequency, travel reimbursement authorization, and purposes and duties of the advisory group.