

STORAGE NAME: h0287s1.hcs

DATE: March 1, 1999

**HOUSE OF REPRESENTATIVES
COMMITTEE ON
HEALTH CARE SERVICES
ANALYSIS**

BILL #: CS/HB 287

RELATING TO: Pharmacy Practice

SPONSOR(S): Committee on Health Care Services, Rep. Johnson & others

COMPANION BILL(S): HB 319, SB 812 (compare)

ORIGINATING COMMITTEE(S)/COMMITTEE(S) OF REFERENCE:

- (1) HEALTH CARE SERVICES YEAS 13 NAYS 2
 - (2) HEALTH CARE LICENSING & REGULATION
 - (3) HEALTH & HUMAN SERVICES APPROPRIATIONS
 - (4)
 - (5)
-

I. SUMMARY:

CS/HB 287 provides for the act to be cited as the "Pharmacy Patient Privacy Act of 1999." The bill defines data communication device as an electronic device that receives electronic information from one source and transmits or routes it to another, including, but not limited to, any such bridge, router, switch, or gateway.

CS/HB 287 also expands the parties to which a pharmacist may release a patient's prescription records without the written authorization of the patient to include health care practitioners and pharmacists, consulting with or dispensing to the patient, including physicians who are part of independent practice associations, physician hospital organizations, or other such organized provider groups; entities that provide compliance services; or the insurance carriers or other payors authorized by the patient to receive such records.

Additionally, the bill provides that patient prescription records 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.

Finally, CS/HB 287 makes several technical corrections to conform cross references.

This bill has no fiscal impact on the state and local government.

II. SUBSTANTIVE ANALYSIS:

A. PRESENT SITUATION:

Chapter 465, F.S., 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 only authorized to release patient prescription records to the patient, the patient's legal representative, the patient's spouse, if the patient is incapacitated, the Department of Health, or upon the issuance of a subpoena. Current law does not include provisions relating to patient prescription records transmitted through a data communication device or to records maintained by the operator or owner of a data communication device.

Today's technology has made it possible for health and medical data to be collected, analyzed, distributed, and accessed in unprecedented ways. Storage of medical records information on computers and networked databases has been proven to be extremely beneficial to health care providers, clinical researchers, insurers, and employers, but concerns have been raised that computerization of confidential computer information may threaten the privacy rights of individuals by increasing the risk of unauthorized access.

For the last several years, medical record confidentiality issues have been the subject of much legislation at both the state and federal levels. In 1998, over 300 bills referencing medical records were introduced in states throughout the country. Congress set a deadline for itself in the 1996 Health Insurance Portability and Accountability Act to pass health privacy legislation by August of 1999, in which the issue of medical records should be addressed. Legislation dealing with confidentiality of health information and patient protection has been recently introduced to Congress. If Congress fails to meet its deadline, the Secretary of Health and Human Services must issue regulations by January 2000.

In 1998, several states introduced medical records legislation relating to the protection of pharmacy prescription records. Florida, Georgia, Idaho, Maine, New Hampshire, Rhode Island, and Virginia all passed bills through at least one house that would prohibit the disclosure of prescription dispensing records. Only the New Hampshire, Georgia, and Maine bills were enacted.

Several major newspaper articles published in early 1998 sparked much concern regarding prescription drug marketing practices and their impact on medical privacy. In particular, a series of articles printed in *The Washington Post* in February 1998, brought to the public's attention that several large drug store chains and thousands of independent pharmacies were using Elensys, a database company specializing in marketing, to track patients who do not refill their prescriptions. As the manager for the pharmacies' data, Elensys would arrange for drug manufacturers to pay pharmacies for the right to send customers "educational material" which might include letters reminding the customers that they had not refilled their prescription or advertisements for new drugs produced by the manufacturing company. Many drug store chains have developed their own database operations similar to those of Elensys that allow them to target customers who have not refilled their prescriptions. (*The Washington Post*, February 15, 1998)

Proponents of these tracking methods believe that such efforts help customers to stay healthy and that the customers benefit from the reminders and information provided by the manufacturers. Proponents also maintain that no confidential information about the customer or the customer's prescription is provided to the drug manufacturer. Opponents, however, believe that these computer database marketing methods "raise concerns about patient confidentiality and blur the line between medicine and marketing." (*The Washington Post*, February 15, 1998)

Due to a strong outcry from customers, many of the drug store chains and pharmacies have suspended the use of the marketing firm to send material to pharmacy customers. The chains and pharmacies maintain, however, that customers benefit in receiving the kind of information and that the mailings were not "marketing programs from Elensys" but rather "education and information programs initiated and governed by the pharmacy chain." (*The Boston Globe*, February 19, 1998)

A recent survey conducted for the California Health Care Foundation by the Princeton Survey Research Associates, which surveyed 1000 Americans, showed that Americans trust doctors and hospitals with confidential medical information, but fear breach of confidentiality when information is handled and stored by private health insurance plans or others. The survey showed that a majority of Americans believe that computerization of medical records is seen as the most serious threat to medical privacy.

When asked if they would grant various groups access to personal medical records, a majority of those surveyed said they would only in cases of medical research studies conducted by the government or universities. According to the survey, Americans are least willing to allow drug companies access to their medical records for the purpose of marketing new drugs and other health care products. Seventy percent of Americans surveyed said they did not want drug companies to have access to their medical records.

B. EFFECT OF PROPOSED CHANGES:

For purposes of the regulation of the practice of pharmacy, data communication device will be defined as an electronic device that receives electronic information from one source and transmits or routes it to another, including, but not limited to, any such bridge, router, switch, or gateway. The parties to which a pharmacist may release a patient's prescription records without the written authorization of the patient will be expanded to include health care practitioners and pharmacists consulting with or dispensing to the patient, including physicians who are part of independent practice associations, physician hospital organizations, or other such organized provider groups; entities that provide compliance services; or the insurance carriers or other payors authorized by the patient to receive such records. Patient prescription records 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.

C. APPLICATION OF PRINCIPLES:

1. Less Government:

a. Does the bill create, increase or reduce, either directly or indirectly:

(1) any authority to make rules or adjudicate disputes?

No.

(2) any new responsibilities, obligations or work for other governmental or private organizations or individuals?

No.

(3) any entitlement to a government service or benefit?

No.

b. If an agency or program is eliminated or reduced:

(1) what responsibilities, costs and powers are passed on to another program, agency, level of government, or private entity?

N/A

(2) what is the cost of such responsibility at the new level/agency?

N/A

(3) how is the new agency accountable to the people governed?

N/A

2. Lower Taxes:

a. Does the bill increase anyone's taxes?

No.

b. Does the bill require or authorize an increase in any fees?

No.

c. Does the bill reduce total taxes, both rates and revenues?

No.

d. Does the bill reduce total fees, both rates and revenues?

No.

e. Does the bill authorize any fee or tax increase by any local government?

No.

3. Personal Responsibility:

a. Does the bill reduce or eliminate an entitlement to government services or subsidy?

No.

b. Do the beneficiaries of the legislation directly pay any portion of the cost of implementation and operation?

No.

4. Individual Freedom:

a. Does the bill increase the allowable options of individuals or private organizations/associations to conduct their own affairs?

No.

b. Does the bill prohibit, or create new government interference with, any presently lawful activity?

Certain drug manufacturers may be prevented from obtaining information from databases which they now use to track certain pharmacy customers.

5. Family Empowerment:

a. If the bill purports to provide services to families or children:

(1) Who evaluates the family's needs?

N/A

(2) Who makes the decisions?

N/A

(3) Are private alternatives permitted?

N/A

(4) Are families required to participate in a program?

N/A

(5) Are families penalized for not participating in a program?

N/A

b. Does the bill directly affect the legal rights and obligations between family members?

N/A

c. If the bill creates or changes a program providing services to families or children, in which of the following does the bill vest control of the program, either through direct participation or appointment authority:

(1) parents and guardians?

N/A

(2) service providers?

N/A

(3) government employees/agencies?

N/A

D. STATUTE(S) AFFECTED:

Sections 465.003, 465.016, 465.017, 465.014, 465.015, 465.0196, 468.812, and 499.003, F.S.

E. SECTION-BY-SECTION ANALYSIS:

Section 1. Provides that this act may be cited as the "Pharmacy Patient Privacy Act of 1999."

Section 2. Amends s. 465.003, F.S., relating to definitions used in the regulation of the practice of pharmacy, to renumber subsections (4) through (14) as (5) through (15) and to define "data communication device" as an electronic device that receives electronic information from one

source and transmits or routes it to another, including, but not limited to, any such bridge, router, switch, or gateway.

Section 3. Amends s. 465.016, F.S., relating to disciplinary actions, to establish the use or release of a patient's record except as authorized by chapter 465 and chapter 455 as a grounds for disciplinary action.

Section 4. Amends s. 465.017, F.S., relating to authority to inspect, to expand the parties to which a pharmacy may release a patient's prescription records without the patient's written authorization to include health care practitioners and pharmacists consulting with or dispensing to the patient, including physicians who are part of independent practice associations, physician hospital organizations, or other such organized provider groups; entities that provide compliance services; or insurance carriers or other payors authorized by the patient to receive such records. For purposes of this section, records held in a pharmacy shall be considered owned by the owner of the pharmacy and the owner may use the records, without patient identification, for purposes reasonably related to the business and practice of pharmacy. Records transmitted through a data communication device not under the control or ownership of the pharmacy or affiliated company or not directly between a pharmacy and a treating practitioner may not be accessed or used by the operator or owner of the data communication device unless specifically authorized by this section. The intent of this subsection is to allow use and sharing of records to improve patient care and nothing may be construed to authorize or expand solicitation or marketing to patients or potential patients in any manner not authorized by law.

Section 5. Amends s. 465.014, F.S., relating to pharmacy technicians, to conform references to s. 465.003, F.S.

Section 6. Amends s. 465.015, F.S., relating to violations and penalties, to conform references to s. 465.003, F.S.

Section 7. Amends s. 465.0196, F.S., relating to special pharmacy permits, to conform references to s. 465.003, F.S.

Section 8. Amends s. 468.812, F.S., relating to exemptions from licensure, to conform references to s. 465.003, F.S.

Section 9. Amends s. 499.003, F.S., relating to definitions used in ss. 499.001-499.081, F.S., to conform references to s. 465.003, F.S.

Section 10. Provides an effective date of July 1, 1999.

III. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT:

A. FISCAL IMPACT ON STATE AGENCIES/STATE FUNDS:

1. Non-recurring Effects:

None.

2. Recurring Effects:

None.

3. Long Run Effects Other Than Normal Growth:

None.

4. Total Revenues and Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS AS A WHOLE:

1. Non-recurring Effects:

None.

2. Recurring Effects:

None.

3. Long Run Effects Other Than Normal Growth:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

1. Direct Private Sector Costs:

None.

2. Direct Private Sector Benefits:

None.

3. Effects on Competition, Private Enterprise and Employment Markets:

None.

D. FISCAL COMMENTS:

None.

IV. CONSEQUENCES OF ARTICLE VII, SECTION 18 OF THE FLORIDA CONSTITUTION:

A. APPLICABILITY OF THE MANDATES PROVISION:

This bill does not require counties or municipalities to spend funds or to take an action requiring the expenditure of funds.

B. REDUCTION OF REVENUE RAISING AUTHORITY:

This bill does not reduce the authority that municipalities or counties have to raise revenues.

C. REDUCTION OF STATE TAX SHARED WITH COUNTIES AND MUNICIPALITIES:

This bill does not reduce the percentage of a state tax shared with counties or municipalities.

V. COMMENTS:

None.

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VI. AMENDMENTS OR COMMITTEE SUBSTITUTE CHANGES:

On March 1, 1999, the Committee on Health care services adopted HB 287 as a Committee Substitute with the following amendments:

Amendment #1 (offered Rep. Farkas) removed the words "internally" and "only that" from language describing how a pharmacy may use patient records.

Amendment #2 (offered by Rep. Bloom) expanded the list of groups who can be furnished certain pharmacy records to include physicians who are part of independent practices associations, physician hospital organizations, or other such organized provider groups, or entities that provide compliance service.

VII. SIGNATURES:

COMMITTEE ON HEALTH CARE SERVICES:

Prepared by:

Staff Director:

Amy K. Guinan

Phil E. Williams