STORAGE NAME: h0319.hcl
DATE: February 24, 1999

HOUSE OF REPRESENTATIVES
COMMITTEE ON
HEALTH CARE LICENSING & REGULATION
ANALYSIS

BILL #: HB 319

RELATING TO: Pharmacy Practice

SPONSOR(S): Representative Gay

COMPANION BILL(S): SB 812(s), SB 1016(c), and HB 287(c)

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

(1) HEALTH CARE LICENSING & REGULATION
(2) HEALTH CARE SERVICES
(3) INSURANCE
(4) HEALTH & HUMAN SERVICES APPROPRIATIONS
(5)

I. SUMMARY:

HB 319 makes a number of changes to ch. 465, F.S., relating to the practice of pharmacy. It amends definitions, to include a definition for “data communication device” and provides that patient records transmitted through a data communication device may not be accessed, used, or maintained by the operator or owner of such device. Also, the statutory definition of the "practice of the profession of pharmacy" is amended to include “other pharmaceutical services” which means evaluation and monitoring of a patient’s health as it relates to drug therapy and assisting in the management of such drug therapy. The revised definition expands the scope of practice of a pharmacist by authorizing a pharmacist to administer immunizations under an established protocol with a physician licensed under ch. 458 or 459, or by written agreement with a county health department. Certain conditions are established that must be met prior to a pharmacist being authorized to administer immunizations.

Correctional facilities are added to the institutional practice sites where return of unit-dose medications for reuse is permitted.

It provides that a prescription may be furnished to another person based on the written authorization of the patient. Also, the prescription may be given to treating practitioners and other pharmacists, if in the judgment of the pharmacist, such release will benefit the patient’s health, and to insurance carriers or other payors when authorized by the patient. For purposes of this section, records held in a pharmacy shall be considered held by the owner. The pharmacy owner may use such records for health care purposes and purposes reasonably related to the business and practice of pharmacy, if the records are in the aggregate and without patient ID. The bill states that this change shall not be construed to authorize or expand solicitation or marketing to the patient. It clarifies that certain abuses in release of patient records are grounds for discipline.

Section 499.012, F.S., is amended to provide for certain governmental transfers of drugs between identified entities, and a significant renumbering of the section is provided.

The bill will have minimal fiscal impact on the State, and no fiscal impact on local government and the private sector in general.

II. SUBSTANTIVE ANALYSIS:

A. PRESENT SITUATION:

Chapter 465, F.S., regulates the practice of pharmacy. The Board of Pharmacy is currently composed of nine members. Two of the members are consumer members and the remaining seven members are pharmacists.

Section 465.003, F.S., relating to definitions, does not include a definition for "data communication device".

Section 465.003(12), F.S., defines the "practice of pharmacy" as including "compounding, dispensing, and consulting concerning contents, therapeutic values, and uses of any medicinal drug and consulting concerning therapeutic values and interactions of patent or proprietary preparations, whether pursuant to prescriptions or in the absence and entirely independent of such prescriptions or orders." The phrase also includes "any other act, service, operation, or transaction incidental to, or forming a part of, any of the foregoing acts, requiring, involving, or employing the science or art of any branch of the pharmaceutical profession, study, or training, and shall expressly permit a pharmacist to transmit information from persons authorized to prescribe medicinal drugs to their patients."

While pharmacists are authorized to dispense medications and consult with patients regarding their medications, they are not authorized to evaluate and monitor the patient's health as it relates to drug therapy and assist the patient in the management of their drug therapy. A pharmacist does not have authority to diagnose and treat patients, or to alter the prescriber's directions.

Currently, the "practice of pharmacy" in Florida does not authorize pharmacists to administer immunizations under the protocol of a physician licensed under ch. 458 or 459, or by written agreement with a county health department. However, it is reported that there are 34 states which allow pharmacists to administer immunizations under various procedures, primarily pursuant to an order of a practitioner (protocol).

Present regulations allow pharmacists to order and evaluate laboratory tests in nursing homes and long term care facilities.

Section 465.016, F.S., provides various grounds for disciplinary actions against a pharmacist. One ground for disciplinary action is placing in the stock of a pharmacy any part of a prescription which is returned by a patient; however, an exception is made for a hospital, nursing home, or extended care facility in which unit-dose medication is dispensed to patients and the medication meets certain requirements.

Section 465.017, F.S., provides the authority to inspect and maintain records of a pharmacy relating to prescriptions. Such records may only be provided to the patient, his legal representative, or under certain circumstances to the patient's spouse.

A pharmacy owner is not authorized to use such records in the aggregate without patient identification data, for purposes reasonably related to the business and practice of pharmacy. Also, this section does not currently provide for records to be transmitted

through a “data communication device” or to be maintained by the operator or owner of a “data communication device.”
Chapter 499, Part I, F.S., relates to the Florida Drug and Cosmetic Act. Its purposes are to: safeguard the public health and promote the public welfare by protecting the public from injury by product use and by merchandising deceit involving drugs, devices, and cosmetics; provide uniform legislation to be administered as far as practical in conformity with the provisions of, and regulations issued under the authority of the Federal Food, Drug, and Cosmetic Act and the portion of the Federal Trade Commission Act which prohibits false advertising of drugs, devices, and cosmetics; and promote uniformity of state and federal laws, and their administration and enforcement, throughout the United States.

Section 499.012, F.S., provides for “wholesale distribution” of prescription drugs to persons other than a consumer or patient, with a number of exceptions identified. A few of the listed exceptions include the following: purchases by a hospital or other health care entity that is a member of a group purchasing organization; the sale or trade of a prescription drug by a charitable organization; the sale or trade of prescription drugs among hospitals of common ownership; the sale or trade of prescription drugs among federal, state, or local governmental health care entities that are under common control; transfers between retail pharmacies to alleviate a temporary shortage; and the purchase of a prescription drug by an emergency medical director for use by emergency medical providers acting pursuant to ch. 401, F.S.

In s. 31, ch. 98-151, Laws of Florida, changes were made to the numbering of s. 499.012, and the Department of Health was granted authority to adopt rules governing the recordkeeping, storage, and handling with respect to each of the distributions of prescription drugs specified in subparagraphs (1)(a)1., 2., 4., and 5., of this section as revised. These identified subparagraphs cover the same basic “wholesale distribution” of prescription drug exceptions identified above (prior to the 1998 changes).

The rules authorized in the 1998 change have been adopted and became effective January 26, 1999. According to the department, substantially similar authorization has been granted through rulemaking for the governmental sale or transfer of prescription drugs to any entity eligible to purchase such drugs at public health prices pursuant to s. 602 of Public Law No. 102-585 for a contract provider or its subcontractor for eligible patients under certain conditions. The rule provides for the issuance of a restricted distributor’s permit to monitor this activity. Also, the rule does not prohibit prescription drugs transferred under this authority from being billed to Medicaid.

Under the provisions of s. 20.43(6), F.S., the Secretary of the Department of Health is authorized to create ad hoc advisory committees.

B. EFFECT OF PROPOSED CHANGES:

Amends s. 465.003, F.S., relating to definitions, to include a definition for “data communication device” and to provide that patient records transmitted through a data communication device may not be accessed, used, or maintained by the operator or owner of such device.

Also, the statutory definition of the "practice of the profession of pharmacy" is amended to include “other pharmaceutical services” which means evaluation and monitoring of a patient’s health as it relates to drug therapy and assisting in the management of such drug therapy. The revised definition expands the scope of practice of a pharmacist to authorize pharmacists to administer immunizations under an established protocol with a physician licensed under ch. 458 or 459, or by written agreement with a county health department. The pharmacist must have at least $200,000 in liability insurance, complete such training as required by the board, and obtain the written approval of the pharmacy owner, if immunizations will be done while acting as an employee of the pharmacy.

Correctional facilities are added to the institutional practice sites where return of unit-dose medications for reuse is permitted.

Provides that a prescription may be furnished to another person based on the written authorization of the patient. Also, the prescription may be given to treating practitioners and other pharmacists, if in the judgment of the pharmacist, such release will benefit the patient’s health, and to insurance carriers or other payors when authorized by the patient. For purposes of this section, records held in a pharmacy shall be considered held by the owner. The pharmacy owner may use such records for health care purposes and purposes reasonably related to the business and practice of pharmacy, if the records are in the aggregate and without patient ID. The bill states that this change shall not be construed to authorize or expand solicitation or marketing to the patient. It clarifies that certain abuses in release of patient records are grounds for discipline.

Section 499.012, F.S., is amended to provide for certain governmental transfers of drugs between identified entities, and a significant renumbering of the section is provided.

Also, the governmental sale or transfer of prescription drugs to certain entities or contract provider for eligible patients who meet certain conditions must be based on written authorization from the Secretary of the Department of Health, including a favorable recommendation of the newly-created Drug Regulation Advisory Group. The current department rule provides for the issuance of a restricted distributor’s permit to monitor this activity instead. In addition, the current rule does not prohibit prescription drugs transferred under this authority from being billed to Medicaid, which is prohibited in the bill.

The bill creates the Drug Regulation Advisory Group. It is an independent advisory group composed of 13 members appointed for 4-year terms by the Secretary, with the members representing specified industries or professions, including one consumer member and a member from the Agency for Health Care Administration. A member representing the department shall chair the meetings. The group shall meet no more than four times per year, and the members shall serve without compensation, but may be reimbursed for travel and expenses.

Technical corrections to cross references are made to a number of sections.

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?

Yes, it authorizes the “administering of immunizations by a pharmacist within the framework of an established protocol under a supervisory practitioner...or by a written agreement with a county health department.” Additional rules must be promulgated by the Boards of Medicine and Osteopathic Medicine and the Board of Pharmacy to implement the changes in the bill.

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

No. However, private organizations must fund the cost of members appointed to the newly-created advisory group. Also, it provides for certain records to be subject to audit by the manufacturer of the drugs provided.

(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?

Yes. The cost of the services provided should be covered by fees.

4. Individual Freedom:

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

N/A

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

No.

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:

Amends s.465,003, 465.016, 465.017, and 499.012, and creates s. 499.072, F.S.

E. SECTION-BY-SECTION ANALYSIS:

Section 1. Amends s. 465.003, F.S., to include a definition for “data communication device.”

Also, the statutory definition of the "practice of the profession of pharmacy" is amended to include “other pharmaceutical services” which means evaluation and monitoring of a patient’s health as it relates to drug therapy and assisting in the management of such drug therapy. The revised definition would authorize pharmacists to administer immunizations under an established protocol with a physician licensed under ch. 458 or 459, or by written agreement with a county health department. The pharmacist must have at least $200,000 in liability insurance, complete such training as required by the board, and obtain the written approval of the pharmacy owner, if immunizations will be done while acting as an employee of the pharmacy.

Section 2. Effective upon becoming law, amends s. 465.016, F.S., to add correctional facilities to the institutional practice sites where return of unit-dose medications for reuse is permitted.

Section 3. Amends s. 465.016, F.S., to prohibit use or releasing of patient records, except as authorized by this chapter or ch. 455.

Section 4. Amends s. 465.017, F.S., to provide that a prescription may be furnished to another person based on the written authorization of the patient. Also, the prescription may be given to treating practitioners and other pharmacists, if in the judgment of the pharmacist, such release will benefit the patient’s health, and to insurance carriers or other payors when authorized by the patient. For purposes of this section, records held in a pharmacy shall be considered held by the owner. The pharmacy owner may use such records for health care purposes and purposes reasonably related to the business and practice of pharmacy, if the records are in the aggregate and without patient ID. The bill states that this change shall not be construed to authorize or expand solicitation or marketing to the patient. It clarifies that certain abuses in release of patient records are grounds for discipline.

Any patient records transmitted through a data communication device may not be accessed, used, or maintained by the operator or owner of such device.

Section 5. Technical. Amends s. 465.014, F.S., to correct references.

Section 6. Technical. Amends s. 465.015, F.S., to correct references.

Section 7. Technical. Amends s. 465.0196, F.S., to correct references.

Section 8. Technical. Amends s. 468.812, F.S., to correct references.

Section 9. Technical. Amends s. 499.003, F.S., to correct references.

Section 10. Amends s. 499.012, F.S., to provide for certain governmental transfers of drugs between identified entities, and a significant renumbering of the section is provided.

Also, the governmental sale or transfer of prescription drugs to certain entities or contract provider for eligible patients who meet certain conditions must be based on written authorization from the Secretary of the Department of Health, including a favorable recommendation of the newly-created Drug Regulation Advisory Group. The current department rule provides for the issuance of a restricted distributor's permit to monitor this activity instead. In addition, the current rule does not prohibit prescription drugs transferred under this authority from being billed to Medicaid, which is prohibited in the bill.

Section 11. Creates s. 499.072, F.S., which creates the Drug Regulation Advisory Group. It is an independent advisory group composed of 13 members appointed for 4-year terms by the Secretary, with the members representing specified industries or professions, including one consumer member and a member from the Agency for Health Care Administration. A member representing the department shall chair the meetings. The group shall meet no more than four times per year, and the members shall serve without compensation, but may be reimbursed for travel and expenses.

Section 12. Provides an effective date of July 1,1999, except as otherwise provided.

III. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT:

A. FISCAL IMPACT ON STATE AGENCIES/STATE FUNDS:

1. Non-recurring Effects:

See Fiscal Comments.

2. Recurring Effects:

See Fiscal Comments.

3. Long Run Effects Other Than Normal Growth:

None.

4. Total Revenues and Expenditures:

See Fiscal Comments.

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, other than the costs of time for members appointed to the advisory group.

2. Direct Private Sector Benefits:

   The bill provides for industry input in the department's operations through the advisory group.

   There is a potential benefit to the public due to more convenient access to immunizations.

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

   None.

D. FISCAL COMMENTS:

According to the Department of Health, the Drug Regulation Advisory Group will require staff support and will incur travel costs. Support services will be provided by existing department staff. They estimate travel costs and meals will be $3,060 per meeting. Four meetings per year will cost $12,240. These costs will be funded from the Drug, Device, and Cosmetic Act Trust Fund and will be recurring in nature.

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

A. APPLICABILITY OF THE MANDATES PROVISION:

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

B. REDUCTION OF REVENUE RAISING AUTHORITY:

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

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:

As a result of the rules adopted pursuant to the legislative changes made in 1998, the department identified a number of technical concerns about the revisions (renumbering) to s. 499.012, F.S. They recommended a renumbering of the proposed changes in the bill to alleviate their concerns. They identified several problem areas resulting from the renumbering. The language regarding specified governmental transfers is positioned in a sub-paragraph that may preclude issuance of a permit by the department for entities engaged in this activity. The permitting structure facilitates field inspection, monitoring for compliance, and allows private industry to determine whether the recipient is authorized by law to purchase or acquire prescription drugs. In addition, the proposed language provides, in sub-subparagraph (V) that records must be submitted to the agency or entity monthly. Public comment received during rule promulgation requested that this be changed to quarterly, which was included in the final rule.

Also, renumbering two other provisions creates an incongruous result. The two provisions exclude the distribution of prescription drug samples and blood products from the concept of wholesale distribution of prescription drugs.

The department recommends the adoption of an amendment that eliminates the identified problems by renumbering the section and corrects the rulemaking references.

VI. AMENDMENTS OR COMMITTEE SUBSTITUTE CHANGES:

None.

VII. SIGNATURES:

COMMITTEE ON HEALTH CARE LICENSING & REGULATION:

Prepared by:	Staff Director:
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