STORAGE NAME: h0319s1z.hcl ****FINAL ACTION****
DATE: June 21, 1999 ****SEE FINAL ACTION STATUS SECTION****

HOUSE OF REPRESENTATIVES
COMMITTEE ON
HEALTH CARE LICENSING & REGULATION
FINAL ANALYSIS

BILL #: CS/HB 319 **(Passed as sections 118,119, and 172 of HB 2125)**

RELATING TO: Pharmacy Practice

SPONSOR(S): Committee on Health Care Licensing & Regulation and Representative Gay

COMPANION BILL(S): SB 812(I), SB 2020(c), SB 2432(c), SB 2562(c), CS/HB 287(c), and HB 1467©

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

(1) HEALTH CARE LICENSING & REGULATION YEAS 11 NAYS 0
(2) HEALTH CARE SERVICES (W/D)
(3) INSURANCE (W/D)
(4) HEALTH & HUMAN SERVICES APPROPRIATIONS (W/D)
(5) SENATE HEALTH, AGING, AND LONG-TERM CARE

I. FINAL ACTION STATUS:

CS/HB 319 passed the House on 4/19/99, and died in the Senate Committee on Health, Aging, and Long-Term Care. Its provisions passed as sections 118, 119, and 172 of HB 2125 on April 30, 1999. It was approved by the Governor on June 18, 1999, and was codified as Chapter 99-397, Laws of Florida.

II. SUMMARY:

CS/HB 319 makes a number of changes to ch. 465, F.S., relating to the practice of pharmacy. It amends the statutory definition of the "practice of the profession of pharmacy" 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.

Correctional facilities are added to the institutional practice sites where return of unit-dose medications for reuse is permitted. Increases the maximum administrative fine from $1,000 to $5,000 per offense.

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.

III. 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(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.

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.

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.

B. EFFECT OF PROPOSED CHANGES:

Amends s. 465.003, F.S., relating to definitions, to amend the statutory definition of the "practice of the profession of pharmacy" 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.

Correctional facilities are added to the institutional practice sites where return of unit-dose medications for reuse is permitted. Increases the maximum administrative fine from $1,000 to $5,000 per offense.

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, or his designee. 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.

C. APPLICATION OF PRINCIPLES:

1. <u>Less Government:</u>

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. However, 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, and 499.012, F.S.

E. SECTION-BY-SECTION ANALYSIS:

Section 118. Amends s. 465.003, F.S., to change the statutory definition of the "practice of the profession of pharmacy" 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.

Section 119. 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. Increases the administrative fine from a maximum of $1,000 to a maximum of $5,000 for each offense.

Section 172. 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 or his designee. 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 208. Provides an effective date of July 1,1999, except as otherwise provided.

IV. 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.

V. 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.

VI. COMMENTS:

None.

VII. AMENDMENTS OR COMMITTEE SUBSTITUTE CHANGES:

A strike everything amendment was adopted and the bill as amended was passed by the Committee on Health Care Licensing & Regulation on March 11, 1999, as a committee substitute. The amendment deleted the provisions related to: expanding the practice of pharmacy to include giving immunizations; communication devices; and release and ownership of a patient's prescription.

VIII. SIGNATURES:

COMMITTEE ON HEALTH CARE LICENSING & REGULATION:

Prepared by:	Staff Director:
Robert W. Coggins	Lucretia Shaw Collins

FINAL ANALYSIS PREPARED BY THE COMMITTEE ON HEALTH CARE LICENSING & REGULATION:

Prepared by:	Staff Director:
Robert W. Coggins	Lucretia Shaw Collins