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HOUSE OF REPRESENTATIVES
COMMITTEE ON
HEALTH CARE STANDARDS & REGULATORY REFORM
BILL RESEARCH & ECONOMIC IMPACT STATEMENT

BILL #: CS/HB 1047

RELATING TO: Pharmacy

SPONSOR(S): Committee on Health Care Standards & Regulatory Reform and Representative Kelly

STATUTE(S) AFFECTED: Amends s. 465.003, 465.0125, 465.014, 465.0156, 465.016, 465.0196, 465.035, 465.186, 893.03, F.S. Reenacts ss. 316.193(5), 327.35(5), 440.102(11)(b), 458.326(3), 817.563(1), 831.31(1)(a) and (2), 856.015(1)(d), 893.02(4), 893.08(1)(b), 893.13(1)(a), (c), and (d), (2)(a), (4)(b), and (5)(b), F.S.

COMPANION BILL(S): HB 1527(c), SB 1792(s), SB 1814(c), and SB 2204(c)

ORIGINATING COMMITTEE(S)/COMMITTEE(S) OF REFERENCE:
(1) HEALTH CARE STANDARDS & REGULATORY REFORM YEAS 5 NAYS 2
(2) CRIME AND PUNISHMENT
(3) HEALTH & HUMAN SERVICES APPROPRIATIONS

I. SUMMARY:

HB 1047 amends application requirements, days allowed to report a change, and a number of other reporting changes. A pharmacy technician working under direct supervision is authorized to initiate or receive communications from a practitioner on behalf of a patient relating to prescription refills.

"Other related cognitive services" and “research” are added to the definition of the “practice of the profession of pharmacy”. Language is added to the definition which provides guidelines and limitations for the compounding of drugs by a pharmacist. This activity may not involve more than 5 percent of the total annual value of all medicinal drugs sold by the compounding pharmacy. Also, the language is clarified as to when a pharmacy is considered closed. Controlled substances may be issued pursuant to a "fax" to the extent allowed by Federal requirements.

The guidelines to the formulary committee in developing the list of approved drugs is amended to include any over-the-counter proprietary drug under Federal law that has been approved for reimbursement by the Florida Medicaid Program, any topical anti-infective, any anti-emetics, any antibiotic eye drops or ear drops, and any urinary tract anti-infective.

Section 465.0125, F.S., is amended to provide that a consultant pharmacist or a Doctor of Pharmacy is authorized to order and evaluate certain tests for persons under the care of a licensed home health agency with approval of the person’s physician (if licensed pursuant to chs. 458, 459, 461, or 466, F.S.). The maximum administrative fine is increased from $1,000 to $5,000 per count. Section 893.03(4), F.S., is amended to add “Butorphanol tartrate” to the list of drugs in schedule IV.

According to the Department of Health, the bill will have a fiscal impact on the state, and no fiscal impact on local government, or 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 seven members. Two of the members are consumer members and the remaining five members are pharmacists.

Existing law requires that within 30 days of any change of office location, corporate officer, or pharmacist, non-resident pharmacies must submit a roster of all employed pharmacists at a facility. Also required is annual disclosure of the location, names, and titles of all principal corporate officers and all pharmacists who are dispensing medicinal drugs to residents of the state. A pharmacy is considered “closed” if a pharmacist is not present and on duty at all times. However, there has been some confusion as to whether or not a pharmacy is “closed” when a pharmacist exits the pharmacy department for responding to inquiries, providing assistance, attending to personal hygiene needs, or performing other such functions for which the pharmacist is responsible.

Currently, there is a 7-member formulary committee. The formulary committee establishes a formulary of drugs and dispensing procedures used by a pharmacist when dispensing such drugs to the public. Section 465.186, F.S., provides guidelines to the committee in developing the list of approved drugs. These guidelines do not currently include any over-the-counter proprietary drug under Federal law that has been approved for reimbursement by the Florida Medicaid Program. Also, ch. 465, F.S., does not provide any specific guidelines or limitations for the compounding of drugs by a pharmacist.

There is no provision for a pharmacist practitioner licensure in the existing pharmacy law. Additionally, it does not provide for communication between a pharmacy technician and the prescribing physician. However, the board has adopted a rule that provides for a pharmacy technician to initiate communicate with a prescribing physician’s office about a refill, but the technician may not receive communication from the physician’s office approving the refill. A pharmacist may currently supervise no more than two pharmacy technicians. The statutory definition of the "practice of the profession of pharmacy" does not currently include "other related cognitive services.”

Consultant pharmacists may order and evaluate laboratory or clinical testing for persons under the care of a nursing home when authorized by the medical director. However, in order to qualify for such authority, the consultant pharmacist must have completed such additional training as required by the board.

Section 465.022, F.S., authorizing the board to adopt rules does not currently authorize rules related to the “functions of a pharmacist in a community pharmacy, or minimum staffing levels of pharmacists based upon anticipated workload”.

Section 465.035, F.S., provides that a pharmacist may not dispense controlled substances based upon reception of a “fax” of the original prescription. Other medicinal drugs may be dispensed under certain conditions. Section 893.03, F.S., lists the various Schedules (I through V) of drugs controlled by 21 C.F.R. Every several years, it must be updated to conform to the Federal requirements. The maximum administrative fine that may be imposed by the board is $1,000 per count.

B. EFFECT OF PROPOSED CHANGES:

The bill amends application requirements, days allowed to report a change, and periodic reporting for non-resident pharmacies to parallel the requirements for in-state community pharmacies. It requires designation of a "prescription department manager" and deletes the requirement for reporting of staff pharmacists and staff pharmacist changes.

"Other related cognitive services" and “research” are added to the definition of the “practice of the profession of pharmacy”. Also, the language is clarified as to when a pharmacy is considered closed.

Controlled substances may be issued pursuant to a "fax" to the extent allowed by Federal requirements. Also, language is added to the definition “practice of pharmacy” which provides guidelines and limitations for the compounding of drugs by a pharmacist. This activity may not involve more than 5 percent of the total annual value of all medicinal drugs sold by the compounding pharmacy.

Section 465.186, F.S., which provides guidelines to the formulary committee in developing the list of approved drugs is amended to include any over-the-counter proprietary drug under Federal law that has been approved for reimbursement by the Florida Medicaid Program, any topical anti-infectives, any anti-emetics, any antibiotic eye drops or ear drops, and any urinary tract anti-infectives.

A pharmacy technician working under direct supervision is authorized to initiate or receive communications from a practitioner on behalf of a patient relating to prescription refills.

Section 465.0125, F.S., is amended to provide that a consultant pharmacist or a Doctor of Pharmacy is authorized to order and evaluate certain tests for persons under the care of a licensed home health agency when authorized by the person’s physician (if licensed pursuant to chs. 458, 459, 461, or 466, F.S.). To qualify for this added authority, an additional 3 hours of continuing education relating to laboratory and clinical testing is required.

The maximum administrative fine is increased from $1,000 to $5,000 per count.

Section 893.03(4), F.S., is amended to add “Butorphanol tartrate” to the list of drugs in schedule IV. For the purposes of incorporating the amendment to s. 893.03, F.S., a number of sections and subsections are reenacted.

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?

Yes. It authorizes the Board of Pharmacy to adopt rules related to a consultant pharmacist or a Doctor of Pharmacy being authorized to order and evaluate certain tests for persons under the care of a licensed home health agency in certain instances.

(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?

None.

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

Not Applicable.

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

Not Applicable.

2. <u>Lower Taxes:</u>

a. Does the bill increase anyone's taxes?

No.

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

No. But the bill increases the maximum administrative fine from $1,000 to $5,000 per count.

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. Fees are charged to cover any expanded services provided.

4. Individual Freedom:

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

      Not Applicable.

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

      No. However, it could be inferred that granting the Board of Pharmacy the authority to determine the number of pharmacists a pharmacy must employ based on workload would be new governmental interference.

5. Family Empowerment:

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

      (1) Who evaluates the family's needs?

      Not Applicable.

      (2) Who makes the decisions?

      Not Applicable.

      (3) Are private alternatives permitted?

      Not Applicable.

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

      Not Applicable.

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

Not Applicable.

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

No.

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?

Not Applicable.

(2) service providers?

Not Applicable.

(3) government employees/agencies?

Not Applicable.

D. SECTION-BY-SECTION ANALYSIS:

Section 1. Amends s. 465.003, F.S., relating to definitions to include"other related cognitive services" and “research” in the definition of the “practice of the profession of pharmacy”. Also, language is added to the definition which provides guidelines and limitations for the compounding of drugs by a pharmacist. This activity may not involve more than 5 percent of the total annual value of all medicinal drugs sold by the compounding pharmacy. In addition, the language is clarified as to when a pharmacy is considered closed.

Section 2. Amends s. 465.0125, F.S., to provide that a consultant pharmacist or a Doctor of Pharmacy is authorized to order and evaluate certain tests for persons under the care of a licensed home health agency with approval of the person’s physician (if licensed pursuant to chs. 458, 459, 461, or 466, F.S.). To qualify for this added authority, an additional 3 hours of continuing education relating to laboratory and clinical testing is required. The board is authorize to adopt rules covering the requirements for this section.

Section 3. Amends s. 465.014, F.S., relating to pharmacy technicians to authorize a pharmacy technician working under direct supervision to initiate or receive communications from a practitioner on behalf of a patient relating to prescription refills.

Section 4. Amends s. 465.0156, F.S., relating to registration of nonresident pharmacies to amend application requirements, days allowed to report a change, and periodic

reporting for non-resident pharmacies to parallel the requirements for in-state community pharmacies. It requires designation of a "prescription department manager" and deletes the requirement for reporting of staff pharmacists and staff pharmacist changes.

Section 5. Amends s. 465.016, F.S., relating to discipline by increasing the maximum administrative fines from $1,000 to $5,000 per count.

Section 6. Amends s. 465.0196, F.S., relating to pharmacy permits to correct a cross-reference.

Section 7. Amends s. 465.035, F.S., relating to dispensing of drugs pursuant to a “fax” to authorize that controlled substances may be issued pursuant to a "fax" to the extent allowed by Federal requirements.

Section 8. Amends s. 465.186, F.S., relating to the approved formulary to include any over-the-counter proprietary drug under Federal law that has been approved for reimbursement by the Florida Medicaid Program, any topical anti-infective, any anti-emetics, any antibiotic eye drops or ear drops, and any urinary tract anti-infective.

Section 9. Amends s. 893.03 relating to drug schedules to add “Butorphanol tartrate” to the list of drugs in schedule IV.

Section 10. For the purposes of incorporating the amendment to s. 893.03, F.S., the following sections are reenacted: 316.193, 327.35, 440.102, 458.326, 817.563, 831.31, 856.015, 893.02, 893.08, and 893.13, F.S.

Section 11. Provides an effective date of July 1, 1997.

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:

Indeterminate. However, the increase in administrative fines from $1,000 to $5,000 per count may increase the penalties charged to those pharmacists or pharmacies that violate the law.

2. Direct Private Sector Benefits:

Indeterminate.

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

None.

D. FISCAL COMMENTS:

The Department of Health does not reflect any additional personnel costs to the department from the provisions of the bill. However, they do reflect increased administrative fines of $90,000 for fiscal 1997-98.

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 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:

The Board of Pharmacy opposes authorizing a pharmacy technician to initiate or receive communications with a practitioner or their agent regarding refill authorization requests. Also, the Bureau of Pharmacy Services, Department of Health, raises a legal question that changing the definition of "practice of pharmacy" to allow pharmacists to sell compounded drugs to practitioners for "office use" conflicts with both Federal and state laws on manufacturing and wholesaling of drugs. Further, the risks associated with this practice outweigh the benefits to Florida citizens.

VI. AMENDMENTS OR COMMITTEE SUBSTITUTE CHANGES:

There were seven amendments adopted and the bill was made a committee substitute. The amendments were as follows:

1) The term "administration" was deleted from the proposal to include it in the definition of the "practice of pharmacy".

2) The term "research" was added to the definition of the "practice of pharmacy".

3) The proposal to establish a pharmacist practitioner license was deleted from the bill.

4) It clarifies that a consultant pharmacist can order certain tests when authorized by the patient's physician (licensed under chs. 458, 459, 461, or 466 , F.S.).

5) It deleted the term "and related information" from the information a pharmacy technician may discuss with a physician about prescription refills.

6) It deleted from the bill the proposal to grant the Board of Pharmacy authority to adopt workload standards for pharmacies.

7) It deleted the drug "Carisoprodol" from the list of schedule IV drugs.

VII. SIGNATURES:

COMMITTEE ON HEALTH CARE STANDARDS & REGULATORY REFORM:
Prepared by: Legislative Research Director:

Robert W. Coggins Robert W. Coggins