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****AS PASSED BY THE LEGISLATURE****
CHAPTER #: 2002-182, Laws of Florida

HOUSE OF REPRESENTATIVES
COMMITTEE ON
HEALTH REGULATION
FINAL ANALYSIS

BILL #: HB 413 **(Passed as SB 604)**

RELATING TO: Centralized Prescription Filling

SPONSOR(S): Representative Farkas

TIED BILL(S): None.

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

(1) HEALTH REGULATION YEAS 10 NAYS 0
(2) COUNCIL FOR HEALTHY COMMUNITIES YEAS 15 NAYS 0
(3)
(4)
(5)

I. SUMMARY:

THIS DOCUMENT IS NOT INTENDED TO BE USED FOR THE PURPOSE OF CONSTRUING STATUTES, OR TO BE CONSTRUED AS AFFECTING, DEFINING, LIMITING, CONTROLLING, SPECIFYING, CLARIFYING, OR MODIFYING ANY LEGISLATION OR STATUTE.

This bill defines the term “centralized prescription filling” and allows pharmacies licensed in Florida to fill a prescription for another pharmacy, at the request of that other pharmacy, without creating a transferred prescription. The intent of this bill is to allow one pharmacy to assist another in providing pharmacy services to patients.

The bill requires the pharmacies participating in centralized prescription filling to have the same owner or have a written contract with certain information included in the contract which sets forth the legal responsibilities of each pharmacy.

There is no fiscal impact to the state.

On February 19, 2002, the Council for Healthy Communities adopted one amendment which is traveling with the bill. The amendment clarifies that the filling, delivery, and return of a prescription under the central fill provision shall not be construed as a transferred prescription nor a wholesale distribution.

II. SUBSTANTIVE ANALYSIS:

A. DOES THE BILL SUPPORT THE FOLLOWING PRINCIPLES:

1.	Less Government	Yes [x]	No []	N/A []
2.	Lower Taxes	Yes []	No []	N/A [x]
3.	Individual Freedom	Yes [x]	No []	N/A []
4.	Personal Responsibility	Yes []	No []	N/A [x]
5.	Family Empowerment	Yes []	No []	N/A [x]

For any principle that received a "no" above, please explain:

B. PRESENT SITUATION:

Current Laws Regulating the Pharmacies and the Practice of Pharmacy—Chapter 465, F.S.

Current pharmacy law only authorizes pharmacies to dispense prescription drugs to the patient or an authorized agent of the patient. A pharmacy is not permitted to transfer a filled prescription to another pharmacy.

Section 465.003(6), F.S., states:

(6) "Dispense" means the transfer of possession of one or more doses of a medicinal drug by a pharmacist to the ultimate consumer or her or his agent. As an element of dispensing, the pharmacist shall, prior to the actual physical transfer, interpret and assess the prescription order for potential adverse reactions, interactions, and dosage regimen she or he deems appropriate in the exercise of her or his professional judgment, and the pharmacist shall certify that the medicinal drug called for by the prescription is ready for transfer. The pharmacist shall also provide counseling on proper drug usage, either orally or in writing, if in the exercise of her or his professional judgment counseling is necessary. The actual sales transaction and delivery of such drug shall not be considered dispensing. The administration shall not be considered dispensing.

The term "pharmacy" is defined in section 465.003(11)(a), F.S., which states:

(11)(a) "Pharmacy" includes a community pharmacy, an institutional pharmacy, a nuclear pharmacy, and a special pharmacy.

1. The term "community pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis.

2. The term "institutional pharmacy" includes every location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility, hereinafter referred to as "health care institutions," where medicinal drugs are compounded, dispensed, stored, or sold.

3. The term "nuclear pharmacy" includes every location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold. The term

"nuclear pharmacy" does not include hospitals licensed under chapter 395 or the nuclear medicine facilities of such hospitals.

4. The term "special pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold if such locations are not otherwise defined in this subsection.

Pharmacies in Florida are currently allowed to refill prescriptions which were previously filled at another pharmacy. These are referred to as transferred prescriptions and must comply with the provisions of section 465.026, F.S., which states:

465.026 Filling of certain prescriptions.--Nothing contained in this chapter shall be construed to prohibit a pharmacist licensed in this state from filling or refilling a valid prescription which is on file in a pharmacy located in this state or in another state and has been transferred from one pharmacy to another by any means, including any electronic means, under the following conditions:

(1) Prior to dispensing any transferred prescription, the dispensing pharmacist must, either verbally or by any electronic means, do all of the following:

(a) Advise the patient that the prescription on file at the other pharmacy must be canceled before it may be filled or refilled.

(b) Determine that the prescription is valid and on file at the other pharmacy and that the prescription may be filled or refilled, as requested, in accordance with the prescriber's intent expressed on the prescription.

(c) Notify the pharmacist or pharmacy where the prescription is on file that the prescription must be canceled.

(d) Record in writing, or by any electronic means, the prescription order, the name of the pharmacy at which the prescription was on file, the prescription number, the name of the drug and the original amount dispensed, the date of original dispensing, and the number of remaining authorized refills.

(e) Obtain the consent of the prescriber to the refilling of the prescription when the prescription, in the dispensing pharmacist's professional judgment, so requires. Any interference with the professional judgment of the dispensing pharmacist by any pharmacist or pharmacy permittee, or its agents or employees, shall be grounds for discipline.

(2) Upon receipt of a prescription transfer request, if the pharmacist is satisfied in her or his professional judgment that the request is valid, or if the request has been validated by any electronic means, the pharmacist or pharmacy must do all of the following:

(a) Transfer the information required by paragraph (1)(d) accurately and completely.

(b) Record on the prescription, or by any electronic means, the requesting pharmacy and pharmacist and the date of request.

(c) Cancel the prescription on file by electronic means or by recording the word "void" on the prescription record. No further prescription information shall be given or medication dispensed pursuant to the original prescription.

(3) If a transferred prescription is not dispensed within a reasonable time, the pharmacist shall, by any means, so notify the transferring pharmacy. Such notice shall serve to revalidate the canceled prescription. The pharmacist who has served such notice shall then cancel the prescription in the same manner as set forth in paragraph (2)(c).

(4) In the case of a prescription to be transferred from or to a pharmacy located in another state, it shall be the responsibility of the pharmacist or pharmacy located in the State of Florida to verify, whether by electronic means or otherwise, that the person or entity involved in the transfer is a licensed pharmacist or pharmacy in the other state.

(5) Electronic transfers of prescriptions are permitted regardless of whether the transferor or transferee pharmacy is open for business.

(6) The transfer of a prescription for medicinal drugs listed in Schedules III, IV, and V appearing in chapter 893 for the purpose of refill dispensing is permissible, subject to the requirements of this section and federal law. Compliance with federal law shall be deemed compliance with the requirements of this section.

Current Laws Regulating Drugs—Chapter 499, F.S.

Distribution of prescription drugs in Florida is regulated by the Department of Health, pursuant to chapter 499, F.S.

Section 499.003(11), F.S., defines "distribute or distribution" as “to sell; offer to sell; give away; transfer, whether by passage of title, physical movement, or both; deliver; or offer to deliver. The term does not mean to administer or dispense.”

Other pertinent parts of s. 499.003, F.S., are:

(16) "Immediate container" does not include package liners.

(17) "Label" means a display of written, printed, or graphic matter upon the immediate container of any drug, device, or cosmetic. A requirement made by or under authority of ss. 499.001-499.081 or rules adopted under those sections that any word, statement, or other information appear on the label is not complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any, of the retail package of such drug, device, or cosmetic or is easily legible through the outside container or wrapper.

(18) "Labeling" means all labels and other written, printed, or graphic matters:

(a) Upon a drug, device, or cosmetic, or any of its containers or wrappers; or

(b) Accompanying or related to such drug, device, or cosmetic.

(19) "Legend drug," "prescription drug," or "medicinal drug" means any drug, including, but not limited to, finished dosage forms, or active ingredients subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act or s. 465.003(8), s. 499.007(12), or s. 499.0122(1)(b) or (c).

(20) "Manufacture" means the preparation, deriving, compounding, propagation, processing, producing, or fabrication of any drug, device, or cosmetic. The term includes repackaging or

otherwise changing the container, wrapper, or labeling to further the distribution of the drug, device, or cosmetic.

(21) "Manufacturer" means a person who prepares, derives, manufactures, or produces a drug, device, or cosmetic. The term excludes pharmacies that are operating in compliance with pharmacy practice standards as defined in chapter 465 and rules adopted under that chapter.

Section 499.007, F.S., sets forth the requirements for labeling drugs, but provides that:

> A drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to prescribe such drug is exempt from the requirements of this section, except subsections (1), (8), (10), and (11) and the packaging requirements of subsections (6) and (7), if the drug bears a label that contains the name and address of the dispenser or seller, the prescription number and the date the prescription was written or filled, the name of the prescriber and the name of the patient, and the directions for use and cautionary statements. This exemption does not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail or to any drug dispensed in violation of subsection (12). The department may, by rule, exempt drugs subject to ss. 499.062-499.064 from subsection (12) if compliance with that subsection is not necessary to protect the public health, safety, and welfare.

Section 499.012(1)(a), F.S., defines “wholesale distribution" as ”the distribution of prescription drugs to persons other than a consumer or patient,” with certain exceptions. One such exemption is “the sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug for emergency medical reasons. For purposes of this sub-subparagraph, the term "emergency medical reasons" includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage.”

"Retail pharmacy" means a community pharmacy licensed under chapter 465 that purchases prescription drugs at fair market prices and provides prescription services to the public, according to s. 499.012, F.S.

C. EFFECT OF PROPOSED CHANGES:

This bill does not create a new license type, nor does it regulate an activity that is currently unregulated. Instead, it provides an alternative to wholesaling prescription drugs or transferring a patient prescription.

The bill defines the term “centralized prescription filling” as “the filling of a prescription by one pharmacy upon the request by another pharmacy to fill or refill the prescription. The term includes the performance of one pharmacy for another pharmacy of other pharmacy duties such as drug utilization review, therapeutic drug utilization review, claims adjudication, and the obtaining of refill authorizations.”

This bill authorizes Florida pharmacies to perform centralized prescription filling for another pharmacy under two situations:

(1) the pharmacies have the same owner, or
(2) the pharmacies have a written contract specifying:

   a. the services to be provided by each pharmacy;
   b. the responsibilities of each pharmacy; and

c. the manner in which each pharmacy will comply with federal and state laws, rules, and regulations.

While all Florida pharmacies are required by law to have a policy and procedure manual, this bill requires each pharmacy participating in centralized prescription filling to include specific information in the policy and procedure manual relating to centralized prescription filling. The required information includes:

- A description of how each pharmacy will comply with federal and state laws, rules, and regulations. (For example, which pharmacy will provide patient counseling.)
- The procedure for maintaining appropriate records to identify the pharmacist responsible for dispensing the prescription and counseling the patient. (This procedure will enable the Board of Pharmacy and courts to determine which pharmacist would be held responsible for errors such as misfills.)
- The procedure for tracking the prescription during each stage of the filling and dispensing process.
- The procedure for identifying on the prescription label all pharmacies involved in filling and dispensing the prescription. (The prescription bottle is often a critical piece of evidence in a medical error incident. The procedure might include using an identifying number, name, or initials to indicate which pharmacy actually filled the prescription.)
- The policy and procedure for providing adequate security to protect the confidentiality and integrity of patient information.
- The procedure to be used by the pharmacy in implementing and operating a quality assurance program designed to objectively and systematically monitor, evaluate, and improve the quality and appropriateness of patient care. (Quality assurance programs are usually designed to prevent medication errors and to reduce exposure to liability for such errors.)

The bill clarifies that the filling of a prescription by one pharmacy for another pharmacy is not to be construed as the filling of a transferred prescription.

The bill also provides rulemaking authority to the Board of Pharmacy to adopt rules necessary to implement centralized prescription filling.

D. SECTION-BY-SECTION ANALYSIS:

Section 1. Amends s. 465.003, F.S., to define the term “centralized prescription filling.”

Section 2. Creates s. 465.0265, F.S., to authorize pharmacies licensed in this state to perform centralized prescription filling; sets forth requirements for which pharmacies may participate; specifies the minimum requirements of the contracts between the pharmacies; requires a policy and procedure manual; provides statutory construction; and provides rulemaking authority.

Section 3. Provides an effective date of July 1, 2002.

III. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT:

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

See Fiscal Comments Section.

D. FISCAL COMMENTS:

The intent of this bill is to allow pharmacies to be more efficient and cost-effective. According to information provided by the Department of Health, this bill should result in reduced costs to the pharmacy.

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

A. APPLICABILITY OF THE MANDATES PROVISION:

The bill does not require a city or county to expend funds or to take any 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 state tax shared with counties or municipalities.

V. COMMENTS:

A. CONSTITUTIONAL ISSUES:

None.

B. RULE-MAKING AUTHORITY:

The Board of Pharmacy is provided authority to adopt rules necessary to implement centralized prescription filling.

C. OTHER COMMENTS:

The proponents of this bill assert that patients will benefit from this bill by having their prescriptions filled more timely. According to the Department of Health, pharmacists should have more time to counsel their patients when prescriptions are dispensed as a result of this bill.

The Florida Board of Pharmacy supports this bill.

The Agency for Health Care Administration has expressed concern relating to how this bill will affect the pharmacy audits conducted by the Medicaid program. The Legislature may wish to consider adding language which clarifies that the Medicaid laws still apply to those pharmacies which are Medicaid providers.

VI. AMENDMENTS OR COMMITTEE SUBSTITUTE CHANGES:

On February 19, 2002, the Council for Healthy Communities adopted one amendment to the original bill. The amendment clarified that the filling, delivery, and return of a prescription under the central fill provision shall not be construed as a transferred prescription nor a wholesale distribution.

VII. SIGNATURES:

COMMITTEE ON HEALTH REGULATION:

Prepared by: Staff Director:

Wendy Smith Hansen Lucretia Shaw Collins

AS REVISED BY THE COUNCIL FOR HEALTHY COMMUNITIES:

Prepared by: Council Director:
David De la Paz

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FINAL ANALYSIS PREPARED BY THE COMMITTEE ON HEALTH REGULATION:

Prepared by: Staff Director:

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