SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

(This document is based only on the provisions contained in the legislation as of the latest date listed below.)

BILL: CS/SB 812

SPONSOR: Senator Lee

SUBJECT: Pharmacy Practice

DATE: April 21, 1999 REVISED: _____ _____ _____ _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Munroe	Wilson	HC	Favorable/CS
2.			FP	
3.				
4.				
5.				

I. Summary:

The bill expands the definition of the "practice of the profession of pharmacy" to include the provision of other pharmaceutical services. "Other pharmaceutical services" is defined to mean the monitoring of the patient's drug therapy and assisting the patient in the management of his or her drug therapy, and includes review of the patient's drug therapy and communication with the patient's prescribing health care provider as licensed under the medical practice act, the osteopathic practice act, the podiatric practice act, or the dental practice act, or similar law in another jurisdiction, or such provider's agent or other persons specifically authorized by the patient, regarding the drug therapy. The bill provides that a pharmacist may not alter a prescriber's directions, the diagnosis or treatment of any disease, the initiation of any drug therapy, the practice of medicine, or the practice of osteopathic medicine, unless otherwise permitted by law. The bill defines the "practice of the profession of pharmacy" to also include research.

Effective upon becoming a law, the bill revises a ground for which a pharmacist is subject to discipline, for placing in the stock of any pharmacy any part of any prescription compounded or dispensed which is returned by a patient, to exclude prescription drugs returned for reuse in a correctional facility in which unit-dose medication is dispensed to inpatients.

The bill revises the definition of "wholesale distribution" to allow governmental and nongovernmental entities to obtain drugs at government-discounted prices.

This bill amends sections 465.003 and 465.016, Florida Statutes, and s. 499.012, Florida Statutes, 1998 Supplement.

II. Present Situation:

Chapter 465, Florida Statutes, provides for the regulation of the practice of pharmacy by the Board of Pharmacy within the Department of Health. Section 465.003, F.S., provides definitions

for the practice of pharmacy. Section 465.016, F.S., provides grounds for which a pharmacist or dispensing practitioner may be subject to discipline for violating regulations governing the practice of pharmacy.

Chapter 499, Florida Statutes, provides for the regulation of drugs, cosmetics and household products by the Department of Health. Part I, ch. 499, F.S., (ss. 499.001-499.081, F.S.) sets forth the Florida Drug and Cosmetic Act, 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. The part provides uniform legislation to be administered so far as practicable in conformity with the provisions of, and regulations issued under, the Federal Food, Drug, and Cosmetic Act and the applicable portions of the Federal Trade Commission Act which prohibits the false advertising of drugs, devices, and cosmetics. Section 499.003, F.S., provides definitions for use by the department in its enforcement of the Florida Drug and Cosmetic Act.

Pt. I, ch. 499, F.S., specifies prohibited acts and requirements for the distribution of legend drugs and legend devices by pharmacies and other entities. Section 499.005(21), F.S., prohibits the wholesale distribution of any prescription drug that was purchased by a public or private hospital or other health care entity or that was donated or supplied at a reduced price to a charitable organization. Section 499.012, F.S., defines "wholesale distribution" to mean the distribution of prescription drugs to persons other than a consumer or patient and provides exceptions to the term. Section 499.014(5), F.S., authorizes the Department of Health to issue permits to restricted prescription drug distributors and to adopt rules for the distribution of prescription drugs by hospitals, health care entities, charitable organizations, or other persons not involved in wholesale distribution. The department has adopted 64F-12.023, Florida Administrative Code, to provide requirements for restricted prescription drug distributor permits. The department issues a restricted prescription drug distributor permit for a state or local government agency, or any entity eligible to purchase prescription drugs at public health services prices pursuant to the Veteran's Health Care Act (s. 602 of Pub. L. No. 102-585), to distribute its prescription drugs to a contract provider or its subcontractor for administering or dispensing to eligible patients. The department has authority to inspect all records of movement or transfer of all the prescription drugs belonging to an entity that holds a restricted prescription drug distributor permit and any discrepancies must be investigated and reported by the entity to the department.

Section 499.012, F.S., provides three classes of exceptions to the prohibitions in s. 499.005(21), F.S.: (1) certain acts conducted by an entity that holds a restricted prescription drug distributor permit in accordance with the requirements of s. 499.014, F.S.; (2) certain acts conducted in accordance with rules adopted by the Department of Health governing record keeping and handling; and (3) the dispensing of a prescription drug pursuant to a prescription, the distribution of prescription drug samples by manufacturers' representatives or distributors' representatives, or the sale, purchase, or trade of blood and blood components intended for transfusion. Under applicable federal law, the distribution of prescription drug samples or the sale, purchase, or trade of blood and blood components intended for transfusion does not constitute the wholesale distribution of prescription drugs, *21 C.F.R. 205.3(f)*.

Pursuant to s. 499.012, F.S., the purchase or acquisition of a prescription drug by an emergency medical services medical director for use by emergency medical services providers acting within the scope of their professional practice pursuant to ch. 401, F.S., is an exception to the wholesale

distribution if conducted in accordance with the Department of Health's rules governing record keeping and handling. The department has adopted an administrative rule 64F-12.011, Florida Administrative Code, that exempts from the definition of "wholesale distribution of drugs": transfers of prescription drugs by a health care entity to an emergency transport vehicle which is under the direction of a medical director of an emergency medical services provider licensed under ch. 401, F.S., for use in the treatment of persons transported to that health care entity, to immediately restock a licensed vehicle or an emergency medical kit for prescription drugs used on that person, or to immediately restock prescription drugs on the vehicle which become unsuitable for use. Section 499.028, F.S., provides requirements for the distribution of prescription drug samples by manufacturers or distributors.

III. Effect of Proposed Changes:

The bill expands the definition of the "practice of the profession of pharmacy" to include the provision of other pharmaceutical services. "Other pharmaceutical services" is defined to mean the monitoring of the patient's drug therapy and assisting the patient in the management of his or her drug therapy, and includes review of the patient's drug therapy and communication with the patient's prescribing health care provider as licensed under the medical practice act, the osteopathic practice act, the podiatric practice act, or the dental practice act, or similar law in another jurisdiction, or such provider's agent or other persons specifically authorized by the patient, regarding the drug therapy. The bill provides that a pharmacist may not alter a prescriber's directions, the diagnosis or treatment of any disease, the initiation of any drug therapy, the practice of medicine, or the practice of osteopathic medicine, unless otherwise permitted by law. The bill defines the "practice of the profession of pharmacy" to also include research.

Effective upon becoming a law, the bill revises a ground for which a pharmacist is subject to discipline, for placing in the stock of any pharmacy any part of any prescription compounded or dispensed which is returned by a patient, to exclude prescription drugs returned for reuse in a correctional facility in which unit-dose medication is dispensed to inpatients.

The bill revises the definition of "wholesale distribution" of prescription drugs for purposes of ch. 499, F.S., the Florida Drug and Cosmetic Act, to exempt the sale, purchase, trade, or other transfer of a prescription drug from or for a federal, state, or local government agency or any entity eligible to purchase prescription drugs at public health services prices under the Veteran's Health Care Act, to a contract provider or its subcontractor for eligible patients of the entity under specified conditions. The agency or entity must obtain written authorization for the sale, purchase, trade, or other transfer of a prescription drug from the Secretary of the Department of Health. The contract provider or subcontractor must be authorized by law to administer or dispense prescription drugs. The contract provider and subcontractor must maintain separate drug inventories and maintain and provide immediate inspection of all records of transfer of all prescription drugs belonging to the entity. The contract provider must either administer or dispense the prescription drugs only to eligible patients of the agency or entity or must return the prescription drugs for or to the agency or entity. Any prescription drugs transferred by the contract provider or subcontractor may not be billed to Medicaid. All records relating to prescription drugs of a manufacturer under this exception to the definition of "wholesale distribution" must be subject to audit by the manufacturer of those drugs, without identifying

individual patient information. The entity must conduct its distribution activities in accordance with s. 499.014(5), F.S., which authorizes the Department of Health to issue permits to restricted prescription drug distributors and to adopt rules for the distribution of prescription drugs by hospitals, health care entities, charitable organizations, or other persons not involved in wholesale distribution.

The bill makes other minor and technical changes to the language in s. 499.012, F.S., providing exceptions to the definition of "wholesale distribution."

Except for section 2 of the bill, which takes effect upon the bill becoming a law, the bill will take effect July 1, 1999.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Article I, Subsections 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

A government agency or entity that purchases or transfers discounted prescription drugs under the exemption in the bill will still need to obtain a restricted prescription drug distributor permit. The department issues a restricted prescription drug distributor permit for a state or local government agency, or any entity eligible to purchase prescription drugs at public health services prices pursuant to the Veteran's Health Care Act (s. 602 of Pub. L. No. 102-585), to distribute its prescription drugs to a contract provider or its subcontractor for administering or dispensing to eligible patients. The Department of Health indicated that the biennial fee for the restricted prescription drug permit is $500 and the department estimates the issuance of 20 permits.

B. Private Sector Impact:

None.

C. Government Sector Impact:

The Department of Health will incur costs to issue the restricted prescription drug distributor permits, but has indicated that it will be absorbed with existing resources.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Amendments:

None.