

SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

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

Prepared By: Health Care Committee

BILL: CS/SB 1838

INTRODUCER: Health Care Committee and Senator Haridopolos

SUBJECT: Pharmacy Common Databases

DATE: March 16, 2006

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Munroe	Wilson	HE	Fav/CS
2.	_____	_____	_____	_____
3.	_____	_____	_____	_____
4.	_____	_____	_____	_____
5.	_____	_____	_____	_____
6.	_____	_____	_____	_____

I. Summary:

The bill repeals subsection 465.026(7), F.S., which authorizes a Florida-licensed pharmacy that only receives and transfers prescriptions for dispensing by another pharmacy to *transfer* a Schedule II controlled substance prescription. The subsection also authorizes the pharmacy receiving the prescription to ship, mail, or deliver into Florida, in any manner, the dispensed Schedule II medicinal drug under specified conditions.

In lieu of the provisions of subsection 465.026(7), F.S., the bill creates a new section of statute that authorizes the dispensing or refilling of a prescription on file in a pharmacy located in Florida or in another state by a pharmacist licensed in Florida or another state *without requiring* the *transfer* of the prescription if all of the following conditions are met: the participating pharmacies have the *same owner and share a common database*; the prescription information is *maintained within the common database*; the common database *maintains a record of all persons involved in the dispensing or refilling of the prescription*; all participating *pharmacies are properly licensed by their state of residence*; and the owner of a common database *maintains a policy and procedures manual* with specified elements that governs participating pharmacies and pharmacists.

This bill amends section 465.026, Florida Statutes.

This bill creates section 465.0266, Florida Statutes.

II. Present Situation:

Regulation of Pharmacy

Chapter 465, F.S., governs the practice of pharmacy. The chapter provides definitions for purposes of the regulation of pharmacy. Section 465.003, F.S., defines “dispense” to mean 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.¹ As part of dispensing, the pharmacist must, before 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 must certify that the medicinal drug called for by the prescription is ready for transfer. The pharmacist must also provide counseling on proper drug usage, if in her or his professional judgment counseling is necessary. The actual sales transaction and delivery of such drug is not to be considered dispensing. The administration of the drug is not to be considered dispensing.

The “practice of the profession of pharmacy” is defined in s. 465.003(13), F.S., to include compounding, dispensing, and consulting concerning contents, therapeutic values, and uses of any medicinal drug; 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; and 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 ch. 458, F.S., relating to medicine; ch. 459, F.S., relating to osteopathic medicine; ch. 461, F.S., relating to podiatric medicine; ch. 466, F.S., relating to dentistry; or similar statutory provision in another jurisdiction, or such provider’s agent or such other persons as specifically authorized by the patient, regarding the drug therapy. Subsection 465.003(13), F.S., may not be interpreted to permit an alteration of 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 “practice of the profession of pharmacy” in s. 465.003(13), F.S., also includes any other act, service, operation, research, 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 does not expressly permit a pharmacist to transmit information from persons authorized to prescribe medicinal drugs to their patients.

Section 465.026, F.S., provides that nothing in ch. 465, F.S., shall prohibit a Florida-licensed pharmacist from filling or refilling a valid prescription which is on file in a pharmacy located in Florida or in another state and that has been transferred from one pharmacy to another by any means, if before dispensing the transferred prescription, the dispensing pharmacist, either verbally or by any electronic means, does all of the following:

¹ See also Rule 64B16-27.400(3), Florida Administrative Code, which specifies that only a Florida-licensed pharmacist may make the final check of the completed prescription thereby assuming the complete responsibility for its preparation and accuracy.

- Advises the patient that the prescription on file at the other pharmacy must be cancelled before it may be filled or refilled;
- Determines 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 in the prescription;
- Notifies the pharmacy or pharmacist where the prescription is on file that the prescription must be canceled;
- Records in writing, or by any electronic means, the prescription order, the name of the pharmacy at which the prescription is 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; and
- Obtains the consent of the prescriber to the refilling of the prescription when the prescription, in the dispensing pharmacist's professional judgment, requires so.²

Upon receipt of a prescription transfer request, the pharmacist must take specified actions outlined in s. 465.026(2), F.S., which include accurately and completely transferring specified information, recording the requesting pharmacy and pharmacist and the date of the request on the prescription, and canceling the prescription on file by electronic means or by recording the word "void" on the prescription record. If a transferred prescription is not dispensed within a reasonable time, the pharmacist must notify the transferring pharmacy. This notice will revalidate the cancelled prescription and the pharmacist who provided the notice must then cancel the transferred prescription. The transfer of a prescription for medicinal drugs listed in Schedules III, IV, and V appearing in ch. 893, F.S., for the purpose of refill dispensing is permitted, subject to the requirements of s. 465.026, F.S., and federal law. Compliance with federal law is deemed compliance with s. 465.026, F.S.³

Subsection 465.026(7), F.S., provides that a community pharmacy licensed under ch. 465, F.S., which only receives and transfers prescriptions for dispensing by another pharmacy may transfer a prescription for a medicinal drug listed in Schedule II under ch. 893, F.S. The pharmacy receiving the prescription may ship, mail, or deliver into Florida, in any manner, the dispensed Schedule II medicinal drug under the following conditions:

- The pharmacy receiving and dispensing the transferred prescription maintains at all times a valid, unexpired license, permit, or registration to operate the pharmacy in compliance with the laws of the state in which the pharmacy is located and from which the medicinal drugs are dispensed;
- The community pharmacy and the receiving pharmacy are owned and operated by the same person and share a centralized database; and
- The community pharmacy assures its compliance with the federal laws and subsections 465.026(1)-(5), F.S.

² See s. 465.026(1), F.S.

³ See s. 465.026(2), F.S.

Controlled Substances

Controlled substances are drugs that have a high potential for abuse. Prescribers must be authorized by the United States Drug Enforcement Agency (DEA) to prescribe controlled substances. Controlled substances are classified in Schedules I through V. Substances in Schedule I have a high potential for abuse and have no currently accepted medical use in the United States. Schedule II drugs have a high potential for abuse and have a severely restricted medical use. Schedule III controlled substances have less potential for abuse than Schedule I or Schedule II substances and have some accepted medical use. Schedule IV and Schedule V substances have a low potential for abuse, compared to substances in Schedules I, II, and III, and currently have accepted medical use.

Applicable federal regulations may preempt state law requirements for prescriptions for controlled substances. Federal law does not currently permit the electronic transmission of prescriptions for controlled substances. The DEA is currently researching the issue of whether to permit electronic transmission of prescriptions for controlled substances. Current federal regulations require prescriptions for controlled substances to be either written and manually signed by the practitioners, or for Schedules III – V prescriptions, they may be orally transmitted to the pharmacy and the pharmacy must then reduce the oral prescription to writing.⁴ A prescription for a Schedule II controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy via facsimile equipment if *the original written*, signed prescription is presented to the pharmacist for review before the actual dispensing of the controlled substance, with specified exceptions.⁵ Faxing may be used to facilitate the dispensing of a Schedule II prescription, but only if the pharmacy receives the original written, signed prescription before dispensing the drug to the patient.⁶

Merck-Medco, a pharmacy benefits manager, recently sought clarification from the DEA on whether its pharmacies that receive and process prescriptions for Schedule II drugs that are communicated through a common database with other pharmacies to perform prescription filling functions, including the dispensing of the same prescription, were in compliance with federal regulation. Officials at DEA determined that Merck-Medco's process is not considered a prescription transfer by the DEA.⁷

III. Effect of Proposed Changes:

Section 1. Amends s. 465.026, F.S., to delete subsection (7), which provides procedures for a community pharmacy licensed under ch. 465, F.S., which *only receives and transfers* prescriptions for dispensing by another pharmacy *to transfer* a prescription for a medicinal drug listed in Schedule II under ch. 893, F.S. Under this subsection, the pharmacy receiving the prescription may ship, mail, or deliver into Florida, in any manner, the dispensed Schedule II medicinal drug under the following conditions:

⁴ See 21 CFR 1306.05, 21 CFR 1306.11, and 21 CFR 1306.21.

⁵ See 21 CFR 1306.11(a).

⁶ Id.

⁷ See May 23, 2002, Letter from DEA officials sent to officials at Merck-Medco.

- The pharmacy receiving and dispensing the transferred prescription maintains at all times a valid, unexpired license, permit, or registration to operate the pharmacy in compliance with the laws of the state in which the pharmacy is located and from which the medicinal drugs are dispensed;
- The community pharmacy and the receiving pharmacy are owned and operated by the same person and share a centralized database; and
- The community pharmacy assures its compliance with the federal laws and subsections 465.026(1)-(5), F.S.

Section 2. Creates s. 465.0266, F.S., to provide that the dispensing or refilling of a prescription on file in a pharmacy located in Florida or in another state by a pharmacist licensed in Florida or another state shall not require the *transfer* of the prescription if all of the following conditions are met:

- The participating pharmacies have the same owner and share a common database;
- The prescription information is maintained within the common database;
- The common database maintains a record of all persons involved, in any manner, in the dispensing or refilling of the prescription;
- All participating pharmacies are properly licensed by their state of residence; and
- The owner of the common database maintains a policy and procedures manual with specified elements that governs participating pharmacies and pharmacists.

The manual must include: a best-practices model detailing how each pharmacy and pharmacist accessing the common database will comply with applicable law and rules; the procedure for maintaining appropriate records for regulatory oversight for tracking the prescription during each stage of the filling and dispensing process, identifying the pharmacists involved in filling and dispensing the prescription and counseling the patient, and responding to requests for information made by the Florida Board of Pharmacy; the policy and procedures to provide adequate security to protect the confidentiality and integrity of patient information; and a quality assurance program to improve the quality and appropriateness of patient care through the use of the common database.

Section 3. Provides an effective date of July 1, 2006.

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 Art. II, s. 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 Art. I, s. 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 Art. III, Subsection 19(f) of the Florida Constitution.

V. Economic Impact and Fiscal Note:**A. Tax/Fee Issues:**

None.

B. Private Sector Impact:

The bill would authorize pharmacies that have the same owner and share a common database to accept a prescription for Schedule II drugs in Florida or another state without a physical transfer of the original “hard copy” prescription to dispense the drugs from another pharmacy or multiple pharmacies when specified conditions in the bill are met. Pharmacies that do so may save the costs associated with physical transfer of the prescription.

C. Government Sector Impact:

The Department of Health has indicated that the bill may increase the number of nonresident pharmacy registrations and internet pharmacy permits in Florida. The department notes that it cannot determine the number of pharmacies that will participate in dispensing and filling functions under a common owner of a database. Therefore, the fiscal impact of the bill on the department’s regulatory enforcement of Florida pharmacy law is indeterminate.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The Department of Health has indicated the bill conflicts with the definition of “dispensing” under Florida pharmacy law which requires one pharmacist to take full responsibility for accurate filling of a prescription and to perform all the tasks necessary for the correct filling of the prescription. Under the bill it is unclear whether the dispensing pharmacist will be responsible for all the tasks that are defined within the practice of the profession of pharmacy that are necessary to dispense the prescription filled by pharmacies under the owner of a common database.

VIII. Summary of Amendments:

None.

This Senate staff analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.
