

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 903 CS

Pharmacy Common Databases

SPONSOR(S): Traviesa

TIED BILLS:

IDEN./SIM. BILLS: SB 1838

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care Regulation Committee	11 Y, 0 N	Bell	Mitchell
2) Health Care Appropriations Committee	15 Y, 0 N, w/CS	Money	Massengale
3) Health & Families Council	9 Y, 0 N, w/CS	Bell	Moore
4) _____	_____	_____	_____
5) _____	_____	_____	_____

SUMMARY ANALYSIS

House Bill 903 CS changes the way Schedule II prescription drugs are processed when transferred to another pharmacy. Schedule II prescription drugs are drugs that have high potential for abuse and may lead to psychological dependence. Currently, mail-order pharmacy benefit managers (PBMs) must physically or electronically send a Schedule II prescription to their automated dispensing operation, before dispensing Schedule II prescriptions. The bill removes this regulatory step in the mail-order prescription dispensing process.

The bill creates section 456.0266, F.S., to allow the dispensing and refilling of a prescription, including Schedule II prescription drugs, that is on file in a pharmacy located anywhere in the United States. The bill proposes the following stipulations that must be met for mail-order pharmacies to transfer a prescription:

- The participating pharmacies must have the same owner and share a common database.
- The prescription information must be maintained within the common database.
- The common database must maintain a record of all persons involved, in any manner, in the dispensing or refilling of the prescription.
- All participating pharmacies must be properly licensed by their state of residence.
- The owner of the common database shall ensure that it maintains a policy and procedures manual that governs its participating pharmacies and pharmacists, which shall be made available to the board or its agent upon request.

The fiscal impact to state government cannot be determined. [See II. D. Fiscal Comments]

The effective date of the bill is July 1, 2006.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide Limited Government—The bill allows pharmacies that have the same owner and share a common database to dispense Schedule II prescription drugs without physically transferring the prescription from one location to another.

B. EFFECT OF PROPOSED CHANGES:

Present Situation

The transfer of Schedule II prescriptions is currently necessary for mail order prescription drug companies. Usually a “front-end” pharmacy processes the prescription and makes several checks before sending the prescription to the “back-end” pharmacy through a common database. The back-end pharmacy is automated and responsible for mailing out prescriptions. Currently, Schedule II prescriptions must be sent to the back-end pharmacy even if both the pharmacies share a common owner and database.

Section 465.026(7), F.S., establishes conditions under which a community pharmacy can transfer prescriptions for drugs listed in Schedule II. Under chapter 893, F.S., Schedule II drugs are defined as drugs that have a high potential for abuse, are currently accepted for medical use in treatment in the United States, and may lead to serious psychological dependence. Codeine, morphine, and methadone are all examples of Schedule II drugs.

Section 465.026(7), F.S., outlines the transfer of a prescription verbally or by electronic means to the receiving pharmacy. The transfer procedure is outlined in sections 465.026(1)-(5), and 465.026(7), F.S.

Subsections 465.026(1)-(5), F.S., require that prior to dispensing any transferred prescription a number of safety precautions are taken by the pharmacist:

- Specifying that the sending pharmacy must cancel their prescription order;
- Placing the responsibility for ensuring the accurate dispensing of the medication on the receiving pharmacy;
- Requiring the dispensing pharmacy to advise the patient that the prescription on file at the sending pharmacy must be canceled;
- Placing responsibility on the receiving pharmacist to exercise professional judgment in validating the transferred prescription;
- Providing that it is the responsibility of the pharmacy or pharmacist in the State of Florida to verify that the receiving pharmacy or pharmacist is properly licensed; and
- Providing special restrictions on the transfer of prescriptions for Schedule II controlled substances.

Effects of the Bill

House Bill 903 CS repeals the provisions in section 465.026(7), F.S., which establish conditions for a pharmacy to transfer Schedule II prescription drugs.

The bill creates section 456.0266, F.S., to allow the dispensing or refilling of a prescription, including Schedule II prescription drugs, that are on file in a pharmacy located in this state or in another state by a pharmacist located in this state or in another state, without the physical transfer of prescription (postal mail) if the following criteria 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.
- The owner of the common database shall ensure that it maintains a policy and procedures manual that governs its participating pharmacies and pharmacists, which shall be made available to the board or its agent upon request, and requires that the manual contain the following information:
 - A best practices model detailing how each pharmacy/pharmacist accessing the database will comply with federal and state laws, rules and regulations.
 - 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, and responding to information requests made by the board pursuant to section 465.1056, F.S..
 - The policy and procedure for providing adequate security to protect the confidentiality and integrity of patient information.
 - A quality assurance program.

The bill allows an out-of-state pharmacist to perform all or part of the dispensing of a prescription without being licensed in Florida or being subject to regulation in Florida. Under the new provisions, there is no one pharmacist responsible for the filling of a prescription. A pharmacist is only responsible for the actual task performed (i.e., the counting of pills).

The bill requires the owner of the common database to maintain a policy and procedures manual to govern its participating pharmacies and pharmacists.

The bill also provides that no Florida licensed pharmacist is responsible for the acts and omissions of another person participating in the dispensing process, unless the pharmacist is directly supervising him or her.

The effective date of the bill is July 1, 2006.

BACKGROUND

Pharmacy Benefit Managers

Pharmacy benefit managers (PBMs) are companies under contract with managed care organizations, self-insured companies, and government programs to manage pharmacy network management, drug utilization review, outcomes management, and disease management. Medco, Caremark, and Express Scripts are three of the largest PBMs operating in the United States. The primary objective of the PBM is to save money. To this end, PBMs generally fill drug prescriptions by mail order as part of a corporate health insurance plan.

The “front-end” pharmacy of the mail order PBM operation usually receives prescriptions, performs pharmacist verification, and processes prescriptions through a drug utilization review. The “back-end” pharmacy usually communicates with the front-end pharmacy through a common database. The primary function of the back-end pharmacy is to perform automated prescription fulfillment functions.

C. SECTION DIRECTORY:

Section 1. - Amends s. 465.026, F. S., to repeal a provision that allows community pharmacies to transfer and dispense Schedule II prescriptions.

Section 2. - Creates s. 456.0266, F. S., to provide that pharmacies with a common database may dispense or refill a prescription on file without the physical transfer of a prescription.

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

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

Indeterminate.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill would allow pharmacists that enter Schedule II prescription drugs at one location to dispense the same drugs at a different location without transferring the physical prescription. The savings incurred by the company by skipping this step may be passed on to the customer.

D. FISCAL COMMENTS:

According to the Department of Health (DOH), it is difficult to estimate how many out of state pharmacies will register as an internet or nonresident pharmacy. If only a few nonresident or internet pharmacies register, there will be a minimal fiscal impact on the Department of Health (DOH).

If a large number of nonresident and internet pharmacies register with the DOH, there will be a greater fiscal impact to DOH. More registrants will result in more disciplinary actions pursued by the DOH, and there will be additional costs associated with inspecting pharmacies, and investigating and prosecuting disciplinary violations. To manage the increased workload, DOH would have to hire more staff.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

The bill does not require counties or municipalities to spend funds or take action requiring the expenditure of funds. This bill does not reduce the percentage of state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The Department of Health has the necessary rule-making authority to carry out the provisions in the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

Federal law 21 CFR 1306.11 requires that the original hard copy prescription for a Schedule II controlled substance is maintained at the dispensing pharmacy. The proposed bill seems to allow dispensing of a Substance II drug without transferring the hard copy of the prescription to the “back-end” pharmacy.

According to the federal Drug Enforcement Administration (DEA), the transfer from a “front-end” pharmacy to a “back-end” pharmacy that communicates through a common database is allowable under current regulation (federal law). The entry of prescription information into a centralized database system at one location and the ultimate dispensing of the same prescription from another location, which is owned and operated by the same company is not considered a prescription transfer by the DEA.¹

HB 903 CS and CS/SB1838 (currently in the Health and Families Council) are identical.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

On March 17, 2006 the Health Care Appropriations Committee adopted the following strike-all amendment that made the following changes:

- Specifies that the owner of the common database ensure that it maintains a policy and procedures manual that governs its participating pharmacies and pharmacists.
- Specifies that the manual be made available to the board or its agent upon request.
- Requires that the manual include the following information:
 - A best practices model detailing how each pharmacy/pharmacist accessing the database will comply with federal and state laws, rules and regulations.
 - 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, and responding to information requests made by the board pursuant to section 465.1056, F.S..
 - The policy and procedure for providing adequate security to protect the confidentiality and integrity of patient information.
 - A quality assurance program.

On April 10, 2006 the Health & Families Council adopted one amendment and reported the bill favorably. The amendment provides that no Florida licensed pharmacist is responsible for the acts and omissions of another person participating in the dispensing process, unless the pharmacist is directly supervising him or her.

The analysis is drafted to the council substitute.

¹ Letter from Drug Enforcement Administration to Merck-Medco, May 23, 2002.