

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide Limited Government / Ensure Lower Taxes – 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 ss. 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, such as:

- 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

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

HB 903 creates s. 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;
- All participating pharmacies in another state are properly registered or permitted as a nonresident or Internet pharmacy in Florida; and
- All participating pharmacists are responsible for the actual task performed in the dispensing or refilling of the prescription.

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 created in HB 903, 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 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:
Indeterminate.
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:

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 no or 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. In order to manage the increased workload, DOH would have to hire more staff.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This 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:

In order for the Department of Health (DOH) to carry out the provisions in the bill, DOH would have to repeal the conflicting regulatory rules.

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 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

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

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