

## HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** HB 1175 w/CS Automated Pharmacy Systems  
**SPONSOR(S):** Murman  
**TIED BILLS:** None. **IDEN./SIM. BILLS:** CS/SB 1294 (s)

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REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care	23 Y, 0 N w/CS	Mitchell	Collins
2) Appropriations			
3)			
4)			
5)			

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### SUMMARY ANALYSIS

The Committee Substitute for HB 1175 allows long-term care facilities licensed under ch. 400, F.S., and state correctional institutions operated under ch. 944, F.S., to store bulk or unit-of-use medicinal drugs and dispense the drugs using an automated pharmacy system that is operated under the supervision of a licensed pharmacist, who ensures prescriptions are valid and accurately filled. The automated pharmacy system need not be at the same location as the pharmacy.

Automated pharmacy systems perform medication counting, packaging, labeling, and electronic documentation functions. Some also dispense medications and supplies. The systems may be centralized (based in the pharmacy) or decentralized (based in long-term care facilities, nursing units, or other health facilities). By packaging medication to be given out to each patient during routine passing of medications, instead of nursing staff manually coordinating the various medications each patient needs, the systems help reduce medication errors. The time required for passing medications is also greatly reduced. The systems provide detailed tracking of medications dispensed to patients that helps improve management of patient care.

One of the barriers to pharmacy automation are state regulations, such as the definition of "dispensing," that do not allow for the use of automated technology.

The bill requires the Board of Pharmacy to adopt rules governing the use of an automated pharmacy system by January 1, 2005. The rules must specify requirements for recordkeeping, security, and labeling that permit the use of unit-dose medications. The facility or institution must maintain medication-administration records that include directions for the use of the medication and the automated pharmacy system must identify the dispensing pharmacy, the prescription number, the name of the patient, and the name of the prescribing practitioner.

The bill also prohibits an unlicensed person or entity from holding itself out or using such "drug," "pharmacy," or "apothecary," in a trade name or advertisement to imply they are licensed to practice pharmacy.

The bill permits a mail-order pharmacy to process a prescription for a controlled substance under the Drug Enforcement Administration when the pharmacies use a common database. This allows for pharmacies to fill prescriptions from a common warehouse.

The effective date of the bill is upon becoming law.

This document does not reflect the intent or official position of the bill sponsor or House of Representatives.

**STORAGE NAME:** h1175a.hc.doc  
**DATE:** March 18, 2004

## FULL ANALYSIS

### I. SUBSTANTIVE ANALYSIS

#### A. DOES THE BILL:

- |                                      |                              |                             |   |
|--------------------------------------|------------------------------|-----------------------------|---|
| 1. Reduce government?                | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |
| 2. Lower taxes?                      | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |
| 3. Expand individual freedom?        | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |
| 4. Increase personal responsibility? | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |
| 5. Empower families?                 | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |

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

#### B. EFFECT OF PROPOSED CHANGES:

The Committee Substitute for HB 1175 authorizes a Florida-licensed pharmacy to provide pharmacy services to a long-term care facility or hospice licensed under ch. 400, F.S., or a state correctional institution operated under ch. 944, F.S., through the use of an automated pharmacy system that need not be located at the same location as the licensed pharmacy.

The bill established that medicinal drugs stored in bulk or unit-of-use in an automated pharmacy system which serves a long-term care facility, hospice, or state correctional institution, are part of the inventory of the pharmacy providing the pharmacy services to that facility, and that drugs dispensed from the automated pharmacy system are considered to have been dispensed by the pharmacy.

The operation of an automated pharmacy system must be under the supervision of a Florida-licensed pharmacist although the pharmacist is not required to be at the location of the automated dispensing system. The pharmacist is required to implement policies and procedures to verify the prescriptions are valid and accurately filled.

The bill requires the Board of Pharmacy to adopt rules governing the use of an automated pharmacy system by January 1, 2005. The rules must specify requirements for recordkeeping, security, and labeling that permit the use of unit-dose medications. The facility or institution must maintain medication-administration records that include directions for the use of the medication and the automated pharmacy system must identify the dispensing pharmacy, the prescription number, the name of the patient, and the name of the prescribing practitioner.

The bill permits a mail-order pharmacy to process a prescription for a controlled substance under the Drug Enforcement Administration when the pharmacies use a common database. This allows for pharmacies to fill prescriptions from a common warehouse.

The bill prohibits an unlicensed person or entity to use the terms "drug," "pharmacy," "prescription drugs," "Rx" or "apothecary," in a trade name, sign or advertisement, to imply that the person or entity is licensed to practice pharmacy. It prohibits an unlicensed person or entity from holding itself out as licensed or registered to practice pharmacy.

The bill provides Legislative intent not to limit the current practice of pharmacy in the state.

The effective date of the bill is upon becoming law.

## CURRENT SITUATION

### **Automated Pharmacy Systems**

Automated pharmacy systems perform medication counting, packaging, labeling, and electronic documentation functions. Some systems also dispense medications and supplies. These systems may be centralized (based in the pharmacy) or decentralized (based in long-term care facilities, nursing units, or other health facilities):

- Centralized automated pharmacy systems include those that repackage medications from bulk and robotic systems that "overpackage" unit-dose medications.
- Decentralized systems store and dispense drugs and supplies in locations outside the pharmacy. These systems are electronically interfaced with a central pharmacy computer that documents and controls the drug storage and distribution process.

Decentralized systems usually feature "ATM-like" dispensing cabinets and offer secure, computer-controlled access to medications and related supplies. As soon as a pharmacy-verified order is activated, the nurse has access to the medication. Some mobile systems even move the dispensing cabinets from bed to bed and feature a terminal on the cabinet to enter and review orders.

### **Benefits to Long-Term-Care Facilities and Institutions**

Use of such machines help dramatically reduce medication errors because the machine packages the medication to be given out during the passing of medications rather than having nursing facility manually coordinate the various medications each patient needs. The time required for passing medications is greatly reduced. Automated pharmacy systems also provide a detailed tracking system of medications dispensed to patients that improves management of patient care. New medications that a patient may need or medications for new patients can be dispensed with remote pharmacy approval, rather than having to wait for the pharmacy to deliver the medications. Since controlled substances are packaged by the machine, "diversion" of these medications is also reduced.

### **Current Barriers to Implementation**

One of the major barriers to pharmacy automation continues to be the variety and unpredictability of state regulations. Many states require a new definition of "dispensing" in order to allow the use of automated technology. The Automation in Pharmacy Initiative, in cooperation with the National Association of Boards of Pharmacy, recently developed language on automation in pharmacy for inclusion in the national board's "Model State Pharmacy Act and Model Rules."

Cost is another barrier to full implementation of pharmacy automation, as are space requirements and difficulties with computer system interface. Some vendors currently offer purchase and lease options as a way of relieving the problem of cost.

### **Licensed Facilities Covered by the Bill**

#### **Long-Term Care Facilities**

"Long-term care facility" is defined for purposes of part I, of ch. 400, F.S., to mean a skilled nursing facility, nursing facility, assisted living facility, adult family-care home, board and care facility, or any other similar adult care center.

#### **Hospices**

Hospices licensed under part VI of ch. 400, F.S., provide a continuum of palliative and supportive care for the terminally ill patient and his or her family.

## **State Correctional Institutions**

“State correctional institution” is defined in ch. 944, F.S., to mean any prison, road camp, prison industry, prison forestry camp, or any prison camp or prison farm or other correctional facility, temporary or permanent, in which prisoners are housed, worked, or maintained, under the custody and jurisdiction of the Department of Corrections.

## **Florida Pilot Project and Report on Automated Medication Dispensing Machines**

In the 2000 Legislative Session, Senate Bill 1280, (ch. 2000-350, Laws of Florida) authorized a demonstration project for automated dispensing machines. The Board of Pharmacy, in cooperation with the Agency for Health Care Administration, was charged with conducting a study of the feasibility, efficiency, cost-effectiveness and safety of using automated medication dispensing machines in nursing homes.

A report summarizing the results of the study was required to be submitted by the board and the Agency for Health Care Administration to the Legislature by January 1, 2001. If the study determined that the dispensing machines would benefit residents of nursing facilities and should be allowed, then the report was required to identify any specific statutory changes necessary to allow nursing facilities to use automated medication dispensing machines.

The Department of Health reports that the Joseph L. Morse Geriatric Center volunteered to engage in the pilot project that was completed in 2003. Staff at the Department of Health indicated that the report originally due to Legislature on January 1, 2001, is currently being finalized by the Board of Pharmacy and the Agency for Health Care Administration.

## **Regulation of Pharmacies**

The Florida Board of Pharmacy regulates the practice of pharmacy in Florida under ch. 465, F.S.

### **Dispensing**

“Dispense” is defined in s. 465.003(6), F.S., 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.

As an element of dispensing, the pharmacist must:

- 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 prior to the actual physical transfer;
- Certify that the medicinal drug called for by the prescription is ready for transfer; and
- 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 of the drug must not be considered dispensing.

### **Transfer of a Prescription**

The Drug Enforcement Administration (DEA) restricts the transfer of prescriptions for Schedule II controlled drugs between pharmacies, but allows for communication or processing of such prescriptions between two pharmacies that are owned and operated by the same entity if both pharmacies share the same common database. DEA does not consider such communication of a prescription to be a transfer of the prescription. This allows for pharmacies to fill prescriptions from a common warehouse.

## **Types of Pharmacies**

“Pharmacy” includes a community pharmacy, an institutional pharmacy, a nuclear pharmacy, and a special pharmacy.

- “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.
- “Institutional pharmacy” includes every location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility where medicinal drugs are compounded, dispensed, stored, or sold.
- “Nuclear pharmacy” includes every location where radioactive drugs and chemicals with the classification of medicinal drugs are compounded, dispensed, stored or sold.
- “Special pharmacy” includes every location where medicinal drugs are compounded, dispensed, stored, or sold if such locations are not otherwise defined in ch. 465, F.S.

## **Nursing Facility Pharmacies**

Nursing facilities are issued a permit under ch. 465, F.S., as “Class I institutional pharmacies.” Under s. 465.019, F.S.,

“Class I institutional pharmacies” are those institutional pharmacies in which all medicinal drugs are administered from individual prescription containers to the individual patient and in which medicinal drugs are not dispensed on the premises.

Drugs not administered to a patient within the facility, if, for example, the order is discontinued or the patient leaves the facility, must be returned to the vendor pharmacy for a credit. The pharmacist in the vendor pharmacy cannot place into the stock of the pharmacy any part of any prescription compounded or dispensed which is returned, except if the unused medication is in a unit dose or customized patient medication package individually sealed and is labeled with the name of the drug, dosage strength, manufacturer’s control number, and expiration date, if any. In the case of controlled substances Federal Law dictates the requirements.

## **State Correctional Institution Pharmacies**

State correctional institutions are issued a permit under ch. 465, F.S., as “Modified Class II institutional pharmacies.”

Modified Class II institutional pharmacies are those institutional pharmacies in short-term, primary care treatment centers that meet all the requirements for a Class II permit, except space and equipment requirements.

## **Hospice Pharmacies**

Hospices are issued a permit under ch. 465, F.S., as “Community pharmacies,” “Modified Class II institutional pharmacies,” or “Class II institutional pharmacies.”

Class II institutional pharmacies employ the services of a registered pharmacist or pharmacists who, in practicing institutional pharmacy, provide dispensing and consulting services on the premises to patients of that institution, for use on the premises of that institution.

### **C. SECTION DIRECTORY:**

**Section 1.** Amends s. 465.015, F.S., to prohibit the use of “drug,” “pharmacy,” “prescription drugs,” “Rx” or “apothecary,” in a trade name, sign or advertisement that implies pharmacy licensure and to hold oneself or organization out as so licensed.

**Section 2.** Amends s. 465.003, F.S., to provide a definition for “automated pharmacy system.”

**Section 3.** Creates s. 465.0235, F.S., to provide for the use of automated pharmacy systems by long-term care facilities, including hospices, and state correctional institutions and establish requirements.

**Section 4.** Amends s. 465.026, F.S., to permit a mail-order pharmacy to process a prescription for a controlled substance if the pharmacies use a common database.

**Section 5.** Provides an effective date of upon becoming law.

## II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

### A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

See Fiscal Comments.

### B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

### C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

According to the Department of Health, allowing the automated pharmacy systems in these facilities will reduce medication costs by eliminating waste of drugs not administered to a patient that must currently be destroyed.

### D. FISCAL COMMENTS:

The Department of Health estimates there will be an indeterminate fiscal impact from the need to inspect automated pharmacy systems that are not at the same location as an inspected pharmacy. The department predicts there may be a cost savings to the Florida Medicaid program because drugs not administered to a patient can be stored instead of destroyed.

## III. COMMENTS

### A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

**B. RULE-MAKING AUTHORITY:**

The bill provides rulemaking authority to the Board of Pharmacy.

**C. DRAFTING ISSUES OR OTHER COMMENTS:**

DOH has noted that the bill grants the authority to use automated pharmacy systems only to long-term care facilities and correctional institutions, not to all Class I and Modified Class II Institutional Pharmacies, thereby creating inequities between pharmacies holding the same permit.

**IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES**

On March 10, 2004, the Committee on Health Care adopted eight amendments and reported the bill favorably with a committee substitute. The amendments add clarifying language that the bill includes hospice facilities and requires the pharmacists to be licensed in Florida. The amendments added a provision to protect such terms as "drug," "pharmacy," from being used by unlicensed persons or entities, and prohibit unlicensed persons or entities from holding themselves out as licensed. The amendments added a provision that permits a mail-order pharmacy to process a prescription for a controlled substance under Drug Enforcement Administration when the pharmacies use a common database. This allows for pharmacies to fill prescriptions from a common warehouse.