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.)

BILL: CS/SB 1294

SPONSOR: Health, Aging, and Long-Term Care Committee and Senator Fasano

SUBJECT: Automated Pharmacy Systems

DATE: February 6, 2004 REVISED: _____ _____ _____ _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Munroe	Wilson	HC	Favorable/CS
2.			CJ	
3.				
4.				
5.				
6.				

I. Summary:

The bill authorizes a 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 pharmacy. Medicinal drugs stored in bulk or unit of use in an automated pharmacy system servicing a long-term care facility, hospice, or state correctional institution are part of the inventory of the pharmacy providing pharmacy services to that facility or institution, and drugs dispensed from the automated pharmacy system are considered to have been dispensed by that pharmacy. The operation of an automated pharmacy system must be under the supervision of a Florida-licensed pharmacist.

The Board of Pharmacy must 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 if the facility or institution maintains medication-administration records that include directions for the use of the medication and the automated pharmacy system identifies the dispensing pharmacy, the prescription number, the name of the patient, and the name of the prescribing practitioner.

This bill amends section 465.003, Florida Statutes.

This bill creates s. 465.0235, F.S.

II. Present Situation:

Report on Automated Medication Dispensing Machines

Section 10 of ch. 2000-350, Laws of F1orida, required the Board of Pharmacy, in cooperation with the Agency for Health Care Administration, to undertake a study of the feasibility, efficiency, cost-effectiveness, and safety of using automated medication dispensing machines in nursing facilities. The board and the Agency for Health Care Administration were authorized to establish demonstration projects in up to five nursing facilities with a Class I institutional pharmacy as part of the study. 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 developed by the Board of Pharmacy and the Agency for Health Care Administration.

Regulation of Pharmacy

Under ch. 465, F.S., the Florida Board of Pharmacy regulates the practice of pharmacy in Florida. "Dispense" is defined 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, prior to the 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, 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.

"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 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, except that nursing homes licensed under part II of chapter 400 may purchase medical oxygen for administration to residents. No medicinal drugs may be dispensed in a Class I institutional pharmacy. One exception, according to the staff of the Board of Pharmacy, is that some stock emergency drugs may be stored in an emergency box for bona fide emergency use. Drugs not administered to a patient within the facility must be returned to the vendor pharmacy for a credit, if the order for drugs is discontinued or the patient leaves the facility. The pharmacist in the vendor pharmacy may not 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 applicable.

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. 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" are those institutional pharmacies which 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. However, an institutional pharmacy located in an area or county included in an emergency order or proclamation of a state of emergency declared by the Governor may provide dispensing and consulting services to individuals who are not patients of the institution. A single dose of a medicinal drug may be obtained and administered to a patient on a valid physician's drug order under the supervision of a physician or charge nurse, consistent with good institutional practice procedures. The obtaining and administering of such single dose of a medicinal drug must be pursuant to drug-handling procedures established by a consultant pharmacist. Medicinal drugs may be dispensed in a Class II institutional pharmacy, but only in accordance with the provisions of s. 465.019, F.S.

Long-Term Care Facilities

Chapter 400, F.S., provides for the regulation of nursing homes and related health care facilities, including, long-term care facilities. Part I of ch. 400, F.S., provides requirements for the Office of State Long-Term Care Ombudsman. "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.[1]

Hospices

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

[1] See s. 400.0060, F.S.

State Correctional Institutions

Chapter 944, F.S., specifies requirements for state correctional institutions. "State correctional institution" is defined 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.

III. Effect of Proposed Changes:

Section 1. Amends s. 465.003, F.S., to define "automated pharmacy system" to mean a mechanical system that dispenses prescription drugs and maintains related transaction information.

Section 2. Creates s. 465.0235, F.S., to authorize a 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 pharmacy. Medicinal drugs stored in bulk or unit of use in an automated pharmacy system servicing a long-term care facility, hospice, or state correctional institution are part of the inventory of the pharmacy providing pharmacy services to that facility or institution, and drugs dispensed from the automated pharmacy system are considered to have been dispensed by that pharmacy. The operation of an automated pharmacy system must be under the supervision of a Florida-licensed pharmacist. To qualify as a supervisor for an automated pharmacy system, the pharmacist need not be physically present at the site of the automated pharmacy system and may supervise the system electronically.

The Board of Pharmacy must 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 if the facility or institution maintains medication-administration records that include directions for the use of the medication and the automated pharmacy system identifies the dispensing pharmacy, the prescription number, the name of the patient, and the name of the prescribing practitioner.

Section 3. Provides an effective date upon becoming a law.

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, 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 Article III, Subsection 19(f) of the Florida Constitution.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The Department of Health reports that there are high costs associated with the use of automated medication systems therefore it is difficult to estimate what potential cost savings may be realized by any facilities that utilize the automated pharmacy system as provided in the bill.

C. Government Sector Impact:

The Department of Health will incur minimal costs to administer the bill. The department reports there is no fiscal impact.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The Department of Health reports that the definition of "automated pharmacy system" is vague. There are many automated pharmacy systems. The bill does not make a distinction between single-dose or multiple dose systems. The department staff has indicated that multiple dose systems carry a greater risk for drug diversion and abuse.

The use of the term "dispense" does not conform to the use of the term in ch. 465, F.S.

The bill permits the automated dispensing system to be operating without the physical presence of the dispensing pharmacist. The Department of Health notes that the drug utilization review process customarily is performed by the dispensing pharmacist before the dispensing of any legend drug.

The bill does not specify who has the responsibility for removing the dispensed dose of medication for delivery to the long-term care facility patient or inmate if the dispensing system is located in another location. It is unclear whether the remote location of the dispensing system would allow the system to be located in another state or outside of the United States. If so, the Department of Health notes that it would create an obstacle to effective regulatory enforcement.

If a medication is dispensed and administered in error, the bill does not specify who is responsible for notifying the patient or who will be responsible for the error under an automated pharmacy system.

VIII. Amendments:

None.