The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Health and Human Services Appropriations Committee

BILL:	CS/CS/SB 1868
INTRODUCER:	Health and Human Services Appropriations Committee, Health Regulation Committee and Senator Peaden
SUBJECT:	Prescribed Drugs
DATE:	April 15, 2009 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Munroe	Wilson	HR	**Fav/CS**
2.	Peters	Peters	HA	**Fav/CS**
3.				
4.				
5.				
6.				

Please see Section VIII. for Additional Information:

A. COMMITTEE SUBSTITUTE.....	X	Statement of Substantial Changes
B. AMENDMENTS.....		Technical amendments were recommended
		Amendments were recommended
		Significant amendments were recommended

I. Summary:

The bill revises the definition of "institutional formulary system" to allow dispensing by a practicing pharmacist *for* a nursing home Class I, or *in* a Class II, institutional pharmacy. The bill authorizes adoption of an institutional formulary that identifies drugs that may be dispensed by a practicing pharmacist *for* a nursing home Class I, or *in* a Class II, institutional pharmacy. The bill provides additional requirements for policies and procedures for an institutional formulary system in a nursing home Class I institutional pharmacy. The bill revises the definition of "standard reference compendium" as used in the law relating to coverage for use of drugs in the treatment of cancer. The bill revises the requirements for written prescriptions of medicinal drugs, including those for controlled substances.

There is no fiscal impact related to this bill.

This bill amends section 465.003, 465.019, 627.4239, 456.42, and 893.04, Florida Statutes.

II. Present Situation:

Practice of Pharmacy

Chapter 465, F.S., provides for the regulation of the practice of the profession of pharmacy. The chapter defines "institutional formulary system" to mean a method whereby the medical staff evaluates, appraises, and selects those medicinal drugs or proprietary preparations which in the medical staff's clinical judgment are most useful in patient care, and which are available for dispensing by a practicing pharmacist in a Class II institutional pharmacy.[1]

"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 ch. 400, F.S., may purchase medical oxygen for administration to residents.[2] No medicinal drugs may be dispensed in a Class I institutional pharmacy.[3]

"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.[4] 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.[5] However, 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.[6] The obtaining and administering of such single dose of a medicinal drug must be pursuant to drug-handling procedures established by a consultant pharmacist.[7] Medicinal drugs may be dispensed in a Class II institutional pharmacy, but only in accordance with the provisions of this section.

In a Class II institutional pharmacy, an institutional formulary system may be adopted with approval of the medical staff for the purpose of identifying those medicinal drugs and proprietary preparations that may be dispensed by the pharmacists employed in such institution.[8] A facility with a Class II institutional pharmacy permit which is operating under the formulary system must establish policies and procedures for the development of the system in accordance with the joint standards of the American Hospital Association and American Society of Hospital Pharmacists for the utilization of a hospital formulary system, which formulary must be approved by the medical staff.[9]

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[1] See section 465.003(7), F.S.
[2] See section 465.019(2)(a), F.S.
[3] *Id.*
[4] See s. 465.019(2)(b), F.S.
[5] *Id.*
[6] *Id.*
[7] *Id.*
[8] See s. 465.019(6), F.S.
[9] *Id.*

Formulary System

Pharmacy and therapeutics committees evaluate medications and develop and implement strategies to manage medication use though a formulary system. "A formulary system is the ongoing process through which a health care organization establishes policies regarding the use of drugs, therapies, and drug-related products and identifies those that are most medically appropriate and cost-effective to best serve the health interests of a given patient population."[10] The concept of therapeutic interchange has aroused much controversy and debate. [11] The practice of therapeutic interchange occurs when pharmacists collaborate with physicians and other health care professionals to develop policies and implement programs that improve drug use to provide the best possible patient care at the most affordable cost. Therapeutic interchange is appropriate in institutional settings that have a functioning formulary system and a pharmacy and therapeutics committee. Critics of therapeutic interchange argue that therapeutic exchange should not be a blanket policy to allow pharmacists to choose an alternative agent from an entire class or category of drugs. Therapeutic interchange programs that use a formulary system have been used successfully in the hospital setting for many years. An inpatient institutional setting where care is rendered in a highly controlled setting where patients are constantly being monitored is very different from an outpatient care situation.[12]

American Society of Health System Pharmacists

In 1942, hospital pharmacists established the American Society of Hospital Pharmacists. In 1995, the Society changed its name to the American Society of Health-System Pharmacists.[13] The mission of the American Society of Health-System Pharmacists is to advance and support the professional practice of pharmacists in hospitals and health systems and serve as their collective voice on issues related to medication use and public health.

Coverage for Use of Drugs in Treatment of Cancer

For purposes of the required insurance coverage of approved cancer drugs, s. 627.4239, F.S., defines "standard reference compendium" to mean: the United States Pharmacopeia Drug Information; the American Medical Association Drug Evaluations; or the American Hospital Formulary Service Drug Information.

The Social Security Act Section 1861(t)(2)(B)(ii)(I) recognizes the following compendia: the American Medical Association Drug Evaluations (AMA-DE), the United States Pharmacopoeia-Drug Information (USP-DI) or its successor publication, and the American Hospital Formulary

[10] See Linda S. Tyler, et al. "ASHP Guidelines on the Pharmacy and Therapeutics Committee and the Formulary System," Am J Health –Syst Pharm Vol 65, July 1, 2008. See also, "Principles of a Sound Drug Formulary System in Hawkins, B, ed. Best Practices for Hospital and Health-system Pharmacy: Positions and Guidance Documents of ASHP. Bethesda, MD: American Society of Health-System Pharmacists; 2006:110-3.

[11] "Therapeutic Interchange, Guidelines (ACCP)," American College of Clinical Pharmacy, Pharmacotherapy, Vol. 13, No. 3 1993. See also ACCP Position Statement "Guidelines for Therapeutic Interchange—2004" American College of Clinical Pharmacy, Pharmacotherapy 2005;25(11):1666-1680.

[12] Id.

[13] See "The Early Years of ASHP: A History Compiled by Jamilla-ann Bethune, William A. Zellmer, and Waneta Sage-Gagne, 2002. Found at: < http://www.ashp.org/s_ashp/docs/files/AboutASHP_EarlyYears.pdf > (Last visited on April 7, 2009).

Service-Drug Information (AFHS-DI) as authoritative sources for use in the determination of a "medically–accepted indication" of drugs and biologicals used off-label in an anticancer chemotherapeutic regimen.[14] Changes have occurred in the pharmaceutical reference industry so that fewer statutorily named compendia are available for reference, the AMA-DE and the USP-DI are no longer published. Thomson Micromedex has designated Drug Points as the successor to the USP-DI. The Centers for Medicare and Medicaid Services has established, by rule, a process to recognize and or delete existing compendia.

III. Effect of Proposed Changes:

The bill redefines "institutional formulary" to allow dispensing by a practicing pharmacist *for* a nursing home Class I, or *in* a Class II, institutional pharmacy. The bill authorizes the adoption of an institutional formulary that identifies drugs that may be dispensed by a practicing pharmacist *for* a Class I, or *in* a Class II, institutional pharmacy. The institutional formulary may only be adopted with the approval of the medical staff.

A Class I or Class II institutional pharmacy which is operating under the formulary system must establish policies and procedures for the development of the system, in accordance with the joint standards of the American Hospital Association and American Society of Hospital Pharmacists. The bill provides requirements for policies and procedures for an institutional formulary system in a nursing home Class I institutional pharmacy. The policies and procedures for an institutional formulary system in a nursing home Class I institutional pharmacy must:

- Be approved by the medical staff;
- Openly provide detailed methods and criteria for the selection and objective evaluation of all available pharmaceuticals;
- Include policies for the development, maintenance, approval, dissemination, and notification to prescribers of the drug formulary and for continuous and comprehensive review of formulary drugs;
- Provide for regular monitoring of compliance with the policies and procedures and of clinical outcomes in circumstances in which a substitution of drugs has occurred;
- Provide a mechanism to inform the prescriber before any substitution of drugs by using a method of communication designated by the prescriber on the prescription for such purpose, require the method of communication to be noted in the patient's chart, and require the prescriber to provide annual written prior approval for the substitution of drugs on the institutional formulary to be allowed for the prescriber's patients;
- Establish a process that allows any individual prescriber to opt out of the formulary system entirely;
- Establish a process that allows any individual prescriber to opt out of the formulary system with respect to a particular patient;
- Provide a mechanism to ensure that patients or guardians are informed of any change of an existing prescription to a formulary substitute;
- Include policies stating that practitioners are not penalized for prescribing nonformulary drug products that are medically necessary; and

[14] See "Compendia 1861(t)(2) Anti-cancer" on the website for the Centers for Medicare & Medicaid Services at: <http://www.cms.hhs.gov/CoverageGenInfo/02_compendia.asp> (Last visited on April 7, 2009).

- Be consistent with applicable state and federal laws and with rules of the Department of Health and the Board of Pharmacy.

The bill amends s. 627.4239, F.S., relating to coverage for use of drugs in the treatment of cancer, to update the definition of "standard reference compendium" to mean an authoritative compendium identified by the Secretary of the United States Department of Health and Human Services and recognized by the federal Centers for Medicare and Medicaid Services.

The bill amends s. 456.42, F.S., relating to written prescriptions for medicinal drugs, to require that a written prescription for a controlled substance have the quantity of the drug prescribed in both textual and numerical formats and be dated with the abbreviated month written on the face of the prescription. Requirements for written prescriptions for medicinal drugs are modified to delete a requirement that the quantity of the drug prescribed be in both textual and numerical formats and be dated with the abbreviated month written out in textual letters. Additionally, the bill authorizes the pharmacist to dispense a controlled substance and require a photographic identification without documenting certain information and authorizes the pharmacist to dispense a controlled substance without verification of the quantity or date written on the prescription if the pharmacy previously dispensed another prescription for the person to whom the prescription was written.

The effective date of the bill is July 1, 2009.

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, Section 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 Article I, Section 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. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

On lines 51-52, the bill refers to the American Society of Hospital Pharmacists. The Society has changed its name to the American Society of Health-System Pharmacists.

VII. Related Issues:

None.

VIII. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health and Human Services Appropriations Committee on April 15, 2009:

- Requires the prescriber to provide annual written prior approval for the substitution of drugs in the institutional formulary to be allowed for the prescriber's patients.
- Modifies requirements for written prescriptions for medicinal drugs to delete a requirement that the quantity of the drug prescribed be in both textual and numerical formats and be dated with the abbreviated month written out in textual letters.
- Requires that a written prescription for a controlled substance have the quantity of the drug prescribed and be dated with the month written on the face of the prescription.
- Authorizes a pharmacist to dispense a controlled substance and require valid photographic identification without documenting certain information.
- Authorizes a pharmacist to dispense a controlled substance without verification of certain information by the prescriber under certain circumstances.

CS by Health Regulation on April 7, 2009:

- Revises the definition of "institutional formulary system" to allow dispensing by a practicing pharmacist *for* a nursing home Class I, or *in* a Class II, institutional pharmacy rather than *in* a Class I or Class II institutional pharmacy.
- Authorizes adoption of an institutional formulary that identifies drugs that may be dispensed by a practicing pharmacist *for* a nursing home Class I or *in* a Class II institutional pharmacy rather than a practicing pharmacist employed in such institution.
- Provides additional requirements for policies and procedures for an institutional formulary system in a nursing home Class I institutional pharmacy.
- Revises the definition of "standard reference compendium" as used in the law relating to coverage for use of drugs in the treatment of cancer.

B. Amendments:

None.