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 Regulation Committee

BILL:	SB 984
INTRODUCER:	Senator Wise
SUBJECT:	Prescription Drugs
DATE:	March 27, 2009
REVISED:	04/01/09

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Munroe	Wilson	HR	**Fav/1 amendment**
2.			CJ	
3.			JU	
4.			HA	
5.				
6.				

Please see Section VIII. for Additional Information:

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

I. Summary:

The bill creates the Drug Donation Program (program) within the Department of Health (DOH) for the purpose of authorizing and facilitating the donation of prescription drugs to the Department of Corrections (DOC). The bill specifies who may donate drugs and supplies. Donated drugs may not include controlled substances. Only a participant facility, defined as a class II hospital pharmacy that elects to participate in the program, may accept donated drugs or supplies. The bill prohibits the donation of drugs to a specific prisoner as well as resale of the donated drugs by the program. The bill requires a participant facility to provide dispensing and consulting services to the DOC.

The DOH must adopt rules to administer the bill by October 1, 2009. The rules must include, but not be limited to: eligibility criteria, including a methodology to determine priority of eligible prisoners; standards and procedures for participant facilities that accept, distribute, or dispense drugs or supplies under the program; forms for administration of the program; the maximum handling fee that may be charged by a participant facility; the categories of drugs that will be accepted for dispensing; and the maintenance and distribution of the participant registry. The DOH may exclude any drug based on its therapeutic effectiveness or high potential for abuse or diversion.

The DOH must establish and maintain a participant registry for the program. The DOH must make the participant facility registry available on its website to any donor wishing to donate drugs or supplies to the program. The bill requires the DOH to include links to manufacturers that offer drug assistance programs or free medication on the department's website.

The bill provides the DOC, any donor of drugs or supplies, or any participant in the program who exercises reasonable care in donating, accepting, distributing, or dispensing drugs or supplies under the program and its rules, immunity from civil or criminal liability and from professional disciplinary action of any kind for any injury, death, or loss to person or property relating to such activities. A pharmaceutical manufacturer is not liable for any claim or injury arising from the transfer of any drug under the bill, including liability for failure to transfer or communicate product or consumer information regarding the transferred drug, as well as the expiration date of the transferred drug.

The bill provides that if any conflict exists between the provisions in the bill and ch. 499, F.S., relating to the regulation of the wholesale distribution of drugs, or ch. 465, F.S., relating to the regulation of pharmacy, the provisions in the bill control the operation of the program.

The bill appropriates one full-time equivalent position at salary rate $42,715 and recurring funding from the Florida Drug, Device, and Cosmetic Trust Fund in the sum of $65,308 for the 2009-2010 fiscal year for the purpose of implementing the bill.

This bill creates section 499.0295, Florida Statutes, and one undesignated section of law.

II. Present Situation:

Cancer Drug Donation Program

Section 499.029, F.S., the "Cancer Drug Donation Program Act," establishes the Cancer Drug Donation Program within the DOH for the purpose of authorizing and facilitating the donation of cancer drugs and supplies to eligible patients. The section specifies the persons or entities that may donate cancer drugs and supplies, the cancer drugs that may be donated, the entities that can accept donated drugs and supplies (participant facilities), and the patients who may be eligible to receive donated drugs and supplies. Section 499.029, F.S., authorizes the DOH to adopt rules to implement the program.[1]

Participant facilities are limited to Class II hospital pharmacies that have elected to participate in the program and that accept donated cancer drugs and supplies under the rules adopted by the DOH. Three hospitals are currently participating in the program. A donation of cancer drugs or supplies may only be made to and at a participant facility. The facility may charge a handling fee sufficient to cover the cost of preparation and dispensing of donated cancer drugs or supplies. Cancer drugs or supplies donated to the program may be prescribed only by a prescribing practitioner for use by an eligible patient and may be dispensed only by a pharmacist.

[1] See Rule 64F-12.026, Florida Administrative Code. Also see the website at <www.doh.state.fl.us/mqa/DDC/Cancer/index.html> (Last visited on March 27, 2009) at which the DOH maintains the registry of participant facilities in the Cancer Drug Donation program.

A person who is eligible to receive cancer drugs or supplies under the state Medicaid program or under any other prescription drug program funded in whole or in part by Florida, the Federal government, or a third-party insurer is ineligible to participate in the program unless benefits have been exhausted or a certain cancer drug or supply is not covered. The DOH must establish and maintain a participant facility registry.

Any donor of cancer drugs or supplies, or any participant in the program, who exercises reasonable care in donating, accepting, distributing, or dispensing cancer drugs or supplies under the cancer drug donation program and the rules adopted under the Cancer Drug Donation Program Act is immune from civil or criminal liability and from professional disciplinary action of any kind for any injury, death, or loss to person or property relating to such activities. A pharmaceutical manufacturer is not liable for any claim or injury arising from the transfer of any cancer drug under this act, including, but not limited to, liability for failure to transfer or communicate product or consumer information regarding the transferred drug, as well as the expiration date of the transferred drug.

If any conflict exists between the provisions of the Cancer Drug Donation Program Act and the pharmacy practice act (ch. 465, F.S.), then the provisions of the Cancer Drug Donation Program Act must control the operation of the cancer drug donation program.

Florida Drug and Cosmetic Act

The Florida Drug and Cosmetic Act is codified at ss. 499.01–499.081, F.S., to regulate the wholesale distribution of drugs, and prohibit the use of adulterated or misbranded drugs or devices in Florida. Section 499.014, F.S., authorizes the distribution of prescription drugs by a charitable organization under a restricted prescription drug distribution permit.

Regulation of Pharmacy

Chapter 465, F.S., governs the regulation of the practice of pharmacy by the Board of Pharmacy in the DOH. Section 465.019, F.S., provides requirements for 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.

Section 465.015(2)(c), F.S., makes it unlawful for a pharmacist to sell or dispense drugs without first being furnished with a prescription. Section 465.016(1)(l), F.S., prohibits a pharmacy from placing into stock any part of any prescription compounded or dispensed which is returned by the patient. Additionally, the Board of Pharmacy has adopted an administrative rule that prohibits a pharmacist from placing into the stock of any pharmacy, any part of any prescription compounded or dispensed, which is returned by a patient, except as specified in the Board of Pharmacy rules.[2] The exception is that in a closed drug delivery system in which unit-dose medication is dispensed to in-patients, the unused unit dose of medication may be returned to the

[2] Rule 64B-16-28.118, Florida Administrative Code.

pharmacy for redispensing only if each dose is individually sealed and if each unit dose or the unit-dose system of which it is clearly a part, is labeled with the name of the drug, dosage strength, manufacturer's control number, and expiration date. A "closed drug system" means a system in which control of the unit dose medication is maintained by the facility rather than by the individual patient. A "unit-dose system" means a system in which all individually sealed unit doses are physically connected as a unit.

Under chapters 465 and 499, F.S., medications which are dispensed to a patient may not be returned to a pharmacy. This protects the public from distribution of medicine that has been stored or handled in ways that may have adulterated the medicine.

Department of Corrections Health Care Delivery System

The Office of Health Services (OHS) manages the health care delivery system of the DOC. The OHS provides comprehensive medical, dental, mental health, and pharmaceutical services, including health education, preventative care, and chronic illness clinics. The scope of health services ranges from emergency care, to inpatient hospitalization, to specialty care, as required. Health care is provided at a constitutional standard of care as mandated by the federal government. There are over 99,000 inmates in the state prison system.

The Reception and Medical Center, Lowell Pharmacy and Union Pharmacy all have Institutional Class II Pharmacy permits as well as the Community Pharmacy permit. The Marianna pharmacy in Region I only has a community permit. The other pharmacies are on site at a facility which allows the DOC to have the Institutional Class II Pharmacy permit.

Currently, in order to maximize efficiencies, the DOC purchases drugs through the Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP) purchasing consortium, administered by the DOH. The MMCAP is a voluntary group purchasing organization operated by the State of Minnesota serving government-based health care facilities. The goal of MMCAP is to provide member organizations the combined purchasing power of all members to receive the best prices available for pharmaceuticals, medical supplies, and related products.

The DOC has also entered into agreements with the DOH to purchase HIV high cost drugs through a federal program called 340b pricing. The 340 Drug Pricing program limits the cost of covered outpatient drugs to certain federal grantees, federally-qualified health center look-alikes, and qualified disproportionate-share hospitals. Significant savings on pharmaceuticals can be realized for those participating in this program.

In fiscal year 2008-2009, the DOC spent approximately $70 million for drugs. HIV drugs comprise approximately $30 million of the DOC total drug cost. There are approximately 3,500 HIV inmates in the DOC's prison population.

III. Effect of Proposed Changes:

The bill creates the Drug Donation Program within the DOH for the purpose of authorizing and facilitating the donation of drugs to the DOC. The bill authorizes the donation of drugs,

excluding controlled substances, and supplies to a participant facility by any person or entity included in the definition of donor. Donor is defined to include:

- A patient or patient representative who donates drugs or supplies needed to administer drugs that have been maintained within a closed drug delivery system;
- Health care facilities, nursing homes, hospices, or hospitals that have closed drug delivery systems;
- Pharmacies, drug manufacturers, medical device manufacturers or suppliers, or wholesalers of drugs or supplies; and
- Physicians licensed under ch. 458, F.S., or ch. 459, F.S., who receive drugs directly from a drug manufacturer, wholesale distributor, or pharmacy.

A participant facility is defined as a lass II hospital pharmacy that elects to participate in the program. The participant facility must meet criteria established by the DOH for participation in the program. The bill requires a participant facility to provide dispensing and consulting services to the DOC. A closed drug delivery system means a system in which the actual control of the unit-dose medication package is maintained by the facility rather than by the individual patient.

The bill prohibits the donation of drugs to a specific prisoner as well as resale of the donated drugs by the program. Drugs billed to and paid for by Medicaid in long-term care facilities that are eligible for return to stock under federal Medicaid regulations must be credited to Medicaid and may not be donated to the program.

Donated drugs or supplies may only be prescribed by a prescribing practitioner for use by an eligible prisoner and may only be dispensed by a pharmacist. Only drugs that are in their original, unopened, sealed container or in tamper-evident unit-dose packaging will be accepted, with the exception of a drug packaged in a single-unit dose if the outside packaging is open but the single unit dose is unopened and the tamper resistant packaging is still intact. A drug that will expire within 6 months of the donation date or appears to have been tampered with or mislabeled may not be accepted by the program. The pharmacist at the participant facility must inspect the donated drug or supply to determine if it appears to be tampered with or mislabeled prior to dispensing it to an eligible prisoner. The dispenser of donated drugs or supplies is prohibited from submitting a claim or seeking reimbursement from the DOC or any public or private third-party payor for drugs and supplies dispensed to any prisoner under the program.

A donation of drugs or supplies must be made only at a participant facility which has the option to decline the donated drugs or supplies. A participant facility that accepts donations must comply with applicable state and federal laws with regard to dispensing and storage of the donated drugs or supplies. A participant facility that voluntarily takes part in the program may charge a handling fee sufficient to cover the cost of the preparation and dispensing of drugs and supplies. The handling fee must be established in rules adopted by the DOH.

Upon the recommendation of the Board of Pharmacy and the DOC, the DOH must adopt rules to administer the bill by October 1, 2009. The rules must include, but not be limited to: eligibility criteria, including a methodology to determine priority of eligible prisoners; standards and procedures for participant facilities that accept, distribute, or dispense drugs or supplies under the program; forms for administration of the program; the maximum handling fee that may be charged by a participant facility; the categories of drugs that will be accepted for dispensing; and

the maintenance and distribution of the participant registry. The DOH may exclude any drug based on its therapeutic effectiveness or high potential for abuse or diversion.

The DOH must establish and maintain a participant registry for the program, which must be maintained on the DOH website. The participant facility registry must include a participant facility's name, address, and telephone number. The DOH must make the participant facility registry available on the DOH's website to any donor wishing to donate drugs or supplies to the program. The bill requires the DOH to include links to manufacturers that offer drug assistance programs or free medication on the department's website.

The bill provides the DOC, any donor of drugs or supplies, or any participant in the program who exercises reasonable care in donating, accepting, distributing, or dispensing drugs or supplies under the program and its rules immunity from civil or criminal liability and from professional disciplinary action of any kind for any injury, death, or loss to person or property relating to such activities.

A pharmaceutical manufacturer is not liable for any claim or injury arising from the transfer of any drug under the bill, including liability for failure to transfer or communicate product or consumer information regarding the transferred drug, as well as the expiration date of the transferred drug.

The bill provides that if any conflict exists between the provisions in the bill and ch. 499, F.S., relating to the regulation of the wholesale distribution of drugs, or ch. 465, F.S., relating to the regulation of pharmacy, the provisions in the bill control the operation of the program.

The bill appropriates one full-time equivalent position at salary rate $42,715 and recurring funding from the Florida Drug, Device, and Cosmetic Trust Fund in the sum of $65,308 for the 2009-2010 fiscal year for the purpose of implementing the bill.

The bill takes effect on July l, 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.

D. Other Constitutional Issues:

The bill requires the DOH to adopt rules to administer the bill by October 1, 2009. The rules must include, but not be limited to: *eligibility criteria*, including a methodology to determine priority of eligible prisoners; *standards and procedures* for participant facilities that accept, distribute, or dispense drugs or supplies under the program; forms for administration of the program; the maximum handling fee that may be charged by a participant facility; the categories of drugs that will be accepted for dispensing; and the maintenance and distribution of the participant registry.

The bill provides that if any conflict exists between the provisions in the bill and ch. 499, F.S., relating to the regulation of the wholesale distribution of drugs or ch. 465, F.S., relating to the regulation of pharmacy, the provisions in the bill control the operation of the program.

Under its rulemaking authority delegated by the Legislature, the DOH is authorized to define terms for which it is implementing duties conferred upon it. To the extent that the bill does not provide sufficient guidelines to the DOH, it raises the question of whether the bill provides adequate limitations and safeguards so that the Legislature's delegation to the DOH is not a violation of Section 3, Article II of the Florida Constitution.

Under the nondelegation doctrine, the Florida Supreme Court struck down a former section of law respecting the power of the Board of Psychological Examiners to grant certificates with the title "psychologist" and to determine the qualifications of applicants as unconstitutional in that it failed sufficiently to fix the standards to be applied and in effect delegated the application of the statute without sufficient limitations on the board's discretion.[3]

Section 3, Article II of the Florida Constitution provides that the powers of the state government shall be divided into legislative, executive, and judicial branches. No person belonging to one branch shall exercise any powers appertaining to either of the other branches unless expressly provided herein. The Florida Supreme Court recently reiterated the requirements of the nondelegation doctrine.

> [U]nder article II, section 3 of the constitution the Legislature 'may not delegate the power to enact a law or the right to exercise unrestricted discretion in applying the law.'[4] This prohibition, known as the nondelegation doctrine, requires that 'fundamental and primary policy decisions . . . be made by members of the [L]egislature who are elected to perform those tasks, and [that the] administration of legislative programs must be pursuant to some minimal standards and guidelines ascertainable by reference to the enactment establishing the program.'[5]

[3] See *Husband v. Cassel*, 130 So.2d 69 (1961).
[4] See *Bush v. Schiavo*, 885 So.2d 321 at 331 citing *Sims v. State*, 754 So.2d 657, 668 (Fla.2000).
[5] See *Bush v. Schiavo*, 885 So.2d 321 at 331 citing *Askew v. Cross Key Waterways*, 372 So.2d 913, 925 (Fla.1978).

The Florida Supreme Court has acknowledged that "[w]here the Legislature makes the fundamental policy decision and delegates to some other body the task of implementing that policy under adequate safeguards, there is no violation of the [Delegation of Powers] doctrine."[6] "In other words, statutes granting power to the executive branch 'must clearly announce adequate standards to guide . . . in the execution of the powers delegated. The statute must so clearly define the power delegated that the [executive branch] is precluded from acting from whim, showing favoritism, or exercising unbridled discretion."[7]

In addition, the Department of Corrections has raised a concern regarding the *eligibility criteria* in the bill. Specifically, determining the *eligibility criteria* would mean that some inmates would be ineligible, which could lead to constitutional legal challenges to the eligibility requirements. A second concern would be inmates being treated with the same drug, however with some being purchased by the DOC and the rest being donated. If there was an issue with the donated drugs (tampering that went undetected or improperly read expiration dates) a legal challenge to equal protection could be raised. Litigation could result if there are constitutional challenges to equal protection regarding the eligibility requirements.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

The bill authorizes DOH to adopt handling fees for participant facilities by rules.

B. Private Sector Impact:

Drug donation program donors will benefit through tax write-offs for compassionate care or indigent care drugs.

C. Government Sector Impact:

The DOH will incur costs for developing and maintaining a database to record participants registered in the program, maintaining contact with registered participants, recruiting and registering new participants, and adopting rules. The DOH estimates that it will require one government operations consultant II and costs associated with limited travel to create and maintain the registry of program participant pharmacies, to provide technical assistance to the private sector, to develop administrative rules, and to provide ongoing program coordination. The DOH will need $66,952 in fiscal year 2009-2010 and $62,540 in fiscal year 2010-2011.

The DOH reports that there is no revenue source for the Florida Drug, Device and Cosmetic Trust Fund or any revenue source provided within the bill to fund the costs of the drug donation program created in the bill.

[6] See *Askew v. Cross Key Waterways*, 372 So.2d 913 at 921. (Fla.1978).
[7] See *Bush v. Schiavo*, 885 So.2d 321 at 331 citing *Lewis v. Bank of Pasco County*, 346 So.2d 53, 55-56 (Fla.1976).

The DOC would obtain a positive fiscal impact by not having to purchase the drugs and supplies that are donated through the program.

Participant facilities located in other state agencies would face the costs of storage and disposal. These fiscal impacts are indeterminable. The participant facilities would face costs associated with the storage and disposal of donated drugs. The DOH reports that drug disposal through a reverse distributor is estimated at about 30 cents per pound. Participant facilities would benefit through handling fees.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The DOH reports that the department will not have sufficient time to adopt rules for administering the program by the October 1, 2009, date required in the bill.

The rulemaking authority granted in the bill is confusing. The bill requires the DOH to adopt rules, but only if recommended by the Board of Pharmacy and the Department of Corrections. It may be clearer if the bill required DOH to adopt rules after consultation with the Board of Pharmacy and the DOC.

Although the bill requires donated drugs to be in "original, unopened, sealed, and tamper-evident unit dose packaging," inspection may not be sufficient to detect adulterated or counterfeit prescription drugs. The bill does not contain any provision for the accountability and responsibility of program drugs other than requirements for program participants to comply "with all applicable provisions of state and federal law relating to the storage, distribution, and dispensing of the donated drugs or supplies." The bill does not require an audit trail or the tracking of drugs. Officials at the DOH have expressed a concern that, without additional accountability, the lack of requirements on donations may contribute to drug diversion. The DOH officials have stated that they do not contemplate having any responsibility under the bill for any program oversight such as monitoring, auditing or the tracking or accounting of drugs.

VIII. Additional Information:

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

None.

B. Amendments:

Barcode 522928 by Health Regulation on April 1, 2009:
Adds osteopathic physicians to the definition of "prescribing practitioner."