

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 1866

INTRODUCER: Senator Peaden

SUBJECT: Prescription Drug Donation Program

DATE: March 28, 2009

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Munroe	Wilson	HR	Favorable
2.			JU	
3.			HA	
4.				
5.				
6.				

I. Summary:

The bill changes the name of the “Cancer Drug Donation Program Act” to the “Prescription Drug Donation Program Act” to reflect the expansion of the program to facilitate the donation of any drug, excluding controlled substances. The bill deletes the definition for “cancer drug” and defines “prescription drug” to exclude any substance that is listed in Schedule II, III, IV, or V of s. 893.03, F.S. The definition of “participant” is expanded to include any pharmacy or dispensing practitioner that has elected to participate in the program and that accepts donated prescription drugs and supplies under the rules adopted by the Department of Health (DOH) for the program.

The bill allows any properly licensed pharmacy or dispensing practitioner to register with the DOH as a participant in the program. The bill allows the participant to accept any prescription drugs or supplies, excluding controlled substances in Schedules II-V, and allows them to dispense the donated prescription drugs or supplies to any eligible recipient, regardless of whether the eligible recipient is the participant’s patient.

This bill amends section 499.029, Florida Statutes.

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

Under s. 499.029, F.S., 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 currently participate 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.

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.), the provisions of the Cancer Drug Donation Program Act must control the operation of the program.

Controlled Substances

Chapter 893, F.S., sets forth the Florida Comprehensive Drug Abuse Prevention and Control Act. The chapter classifies controlled substances into five schedules in order to regulate the manufacture, distribution, preparation, and dispensing of the substances. Substances in Schedule I have a high potential for abuse and have no currently accepted medical use in the United States. Schedule II drugs have a high potential for abuse and a severely restricted medical use. Cocaine and morphine are examples of Schedule II drugs. Schedule III controlled substances have less potential for abuse than Schedule I or Schedule II substances and have some accepted medical use. Substances listed in Schedule III include anabolic steroids, codeine, and derivatives of barbituric acid. Schedule IV and Schedule V substances have a low potential for abuse, compared to substances in Schedules I, II, and III, and currently have accepted medical

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 28, 2009) at which the DOH maintains the registry of participant facilities in the Cancer Drug Donation Program.

uses. Substances in Schedule IV include phenobarbital, librium, and valium. Substances in Schedule V include certain stimulants and narcotic compounds.

III. Effect of Proposed Changes:

The bill changes the name of the “Cancer Drug Donation Program Act” to the “Prescription Drug Donation Program Act.” The bill expands the program to facilitate the donation of any drug, excluding controlled substances.

The bill deletes the definition for “cancer drug” and defines “prescription drug” to exclude any substance that is listed in Schedule II, III, IV, or V of s. 893.03, F.S. The definition of “participant” is expanded beyond Class II hospital pharmacies to include any pharmacy or dispensing practitioner that has elected to participate in the program and that accepts donated prescription drugs and supplies under the rules adopted by the DOH for the program.

The bill allows any properly licensed pharmacy or dispensing practitioner to register with the DOH as a participant in the program. The bill allows the participant to accept any prescription drugs or supplies, excluding controlled substances in Schedules II-V, and allows them to counsel and dispense the donated prescription drugs or supplies to any eligible recipient, regardless of whether the eligible recipient is the participant’s patient.

The bill provides an effective date of 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:

Program participants will face costs associated with storage and disposal of donated drugs. Drug disposal through a reverse distributor is estimated by the DOH at approximately 30 cents per pound. Program participants will benefit financially only through handling fees. Program drug recipients will benefit directly through reduced drug treatment costs and access to medications and supplies they may have otherwise been unable to afford to treat their disease. Program drug donators will benefit through tax write-offs for compassionate care or indigent care drugs.

C. Government Sector Impact:

The DOH reports that the bill will not have any significant fiscal impact upon the department's resources.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None. 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:

None.