

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

The proposed bill does not seem to implicate any of the House Principles.

B. EFFECT OF PROPOSED CHANGES:

Present Situation

Cancer Drug Donation Program

In 2006, the Legislature adopted the “Cancer Drug Donation Program Act.”¹ The Department of Health (department) maintains the program under which a donor may donate cancer drugs or supplies used to administer cancer drugs to a participant facility for dispensing to eligible recipients.

Section 499.029(8), F.S., authorizes the department to adopt rules relating to recipient eligibility criteria, standards and procedures for participant facilities, forms for administration of the program, fees charged by a participant facility, categories of cancer drugs and supplies accepted in the program, and maintenance and distribution of the participant facility registry.

Recipient Eligibility Requirements

A Florida resident who is diagnosed with cancer and has a valid prescription from their physician is eligible to receive drugs or supplies through the Cancer Drug Donation Program (program). A person is ineligible to participate in the program if he or she is eligible to receive cancer drugs or supplies through the Medicaid program, third-party insurer, or any other prescription drug program funded in whole or in part by the Federal Government, unless these benefits have been exhausted, or a certain cancer drug or supply need is not covered by the program.²

According to the department, three people have received donated cancer drugs since the program began its operation.

Donor Eligibility Requirements

Cancer drugs and supplies may be donated to a participant facility by the following individuals or entities located within Florida:³

- A patient or a patient representative, donated through a closed drug delivery system⁴ by the facility where the patient is receiving treatment;
- Health care facilities, nursing homes, hospices, or hospitals with a closed drug delivery system;
- Pharmacies, drug manufacturers, medical device manufacturers or suppliers, or wholesalers of drugs or supplies; or
- A licensed allopathic or osteopathic physician who receives cancer drugs or supplies directly from a pharmacy, drug manufacturer, or drug wholesaler.

Standards and Procedures for Participant Facilities

A Class II Institutional Pharmacy⁵ (pharmacy) that accepts, stores, and dispenses donated cancer drugs and supplies may participate in the program.⁶ Participation is voluntary. A pharmacy that elects

¹ Ch. 2006-310, Laws of Florida

² Rule 64F-12.026, F.A.C. and section 499.029(9), F.S.

³ Section 499.029(3)(d), F.S.

⁴ Section 499.029(3)(b), F.S., defines a “closed drug delivery system” as a system in which the actual control of the unit-dose medication package is maintained by the facility rather than by the individual patient.

⁵ Section 465.019(2)(b), F.S., defines “class II institutional pharmacies” as those institutional pharmacies which employ the services of a registered pharmacist who...shall provide dispensing and consulting services on the premises to patients of that institution, for use

to participate in the program must complete and submit a notice of participation form to the department. Likewise, a pharmacy may discontinue their participation in the program by completing and submitting to the department a notice of withdrawal form.

A participant pharmacy may decline to accept a donation. A cancer drug or supply may not be donated to a specific cancer patient.⁷ A dispenser of donated cancer drugs or supplies is not allowed to submit a claim or seek reimbursement for donated products dispensed under the program. However, a participant pharmacy may charge the recipient of the drug or supply a handling fee of no more than 300% of the Medicaid dispensing fee or no more than \$15, whichever is less, for each cancer drug or supply dispensed.⁸

The pharmacy must store the donated cancer drugs and supplies in a secure storage area under appropriate environmental conditions and may not be stored with non-donated inventory.⁹ All donations must be dispensed by a licensed pharmacist. Prior to being dispensed, a pharmacist must inspect the cancer drug or supplies to determine that they do not appear to be tampered with or mislabeled.¹⁰

A donation form must be signed by the donor when cancer drugs or supplies are donated to a participant pharmacy. Before a cancer drug or supply is dispensed, the recipient must sign a form and be notified both orally and in writing that the product may have been previously dispensed.¹¹ These forms include the donor or recipient's name; the recipient or dispensing pharmacy's name; the medication; medication strength, expiration date, lot number, and quantity. Each time the pharmacy destroys a donated drug or supply, the person destroying the product must complete a destruction form that includes the medication name, strength, expiration date, lot number, and quantity. The pharmacy is required to keep all donor, recipient, and destruction records on file for at least three years.¹²

According to the department, as of March 20, 2008, there are three participating pharmacies: Lee Memorial Hospital, Inc., in Ft. Myers, Halifax Medical Center in Daytona Beach, and Florida Hospital Celebration Health in Celebration. Lee Memorial Hospital has received a total of four eligible cancer drug donations as of March 18, 2008 and Halifax Medical Center has received a total of three eligible cancer drug donations as of January 17, 2008. Florida Hospital Celebration Health was approved to participate on February 20, 2008, so they do not have any data to report to date. A total of seven eligible cancer drugs have been donated to participating pharmacies statewide.¹³

Standards and Categories of Cancer Drugs and Supplies Accepted in the Program

A cancer drug is eligible for donation under this program only if the drug:¹⁴

- Is in its original, unopened, sealed container, or in a tamper-evident¹⁵ unit-dose packaging;
 - Single-unit dose drugs may be accepted if the single-unit dose packaging is unopened
- Has never been in the actual control of the patient, but rather has been maintained by a health care facility in a closed drug delivery system;
- Will not expire until at least six months after the donation is made;
- Is accompanied by a completed Cancer Drug Donation Program Donation and Destruction Record that is signed by the donor or that person's authorized representative.

on the premises of that institution.” However, section 499.029(4), F.S. states that a participant facility may provide dispensing and consulting services to individuals who are not patients of the hospital.

⁶ Rule 64F-12.026(3), F.A.C.

⁷ Section 499.029(4), F.S. and Rule 64F-12.026(3)(e)5., F.A.C.

⁸ Section 499.029(7)(b), F.S. and Rule 64F-12.026(5), F.A.C.

⁹ Rule 64F-12.026(3)(d), F.A.C.

¹⁰ Section 499.029(5)(c), F.S.

¹¹ Rule 64F-12.026(3)(e)3., F.A.C.

¹² Rule 64F-12.026(f), F.A.C.

¹³ Department of Health presentation to the House Health Quality Committee, February 19, 2008.

¹⁴ Section 499.029(6)(a)-(b), F.S.

¹⁵ Tamper evident packaging means a package that seals an individual pill in a plastic bubble typically with a foil backing.

Cancer drugs billed to and paid for by Medicaid in long-term care facilities are not eligible for donation unless they are not reimbursable by Medicaid. Controlled substances, such as morphine, oxycodone, or lorazepam, are not eligible for donation.¹⁶

Participant Facility Registry

The department is required in s. 499.029(10), F.S., to establish and maintain a participant facility registry on their website¹⁷ which includes the participant facility's name, address, and telephone number. The department's website is also required to contain links to cancer drug manufacturers that offer drug assistance programs or free medication.¹⁸

Liability

Any donor of cancer drugs or participant in the program who exercises reasonable care in participating in the program is immune from civil or criminal liability and from professional disciplinary action for any injury, death, or loss to person or property relating to the program. A pharmaceutical manufacturer is not liable for a claim or injury arising from the transfer of a cancer drug donation.¹⁹

Insurance Status of Floridians

Lack of health insurance and other barriers to health care prevent many Floridians from receiving optimal medical care. According to the 2005 national health insurance survey data, there are approximately 3.7 million Floridians (or 21% of the population) who lack health insurance.

Health Insurance Coverage of the Total Population (2005-2006)

Source of Insurance	FL Population	%	U.S. Population	%
Employer	8,407,430	47%	158,515,473	54%
Individual	927,973	5%	14,515,865	5%
Medicaid	1,809,230	10%	37,994,482	13%
Medicare	2,778,367	16%	35,049,875	12%
Other Public	276,997	2%	2,986,514	1%
Uninsured	3,722,263	21%	46,994,627	16%
Total	17,922,260	100%	296,056,836	100%

(Source: Kaiser Foundation - Florida: Health Insurance Coverage of the Total Population, states 2005-2006, U.S. 2006)

Prescription Drug Donation Programs in Other States

A total of 26 states have authorized a prescription drug repository program (see Figure 1). Of those states, seven (including Florida) limit their program to cancer drugs. The other states have authorized different variations of prescription drug repository programs. For example, the state of Ohio allows all prescription drugs, except controlled substances and drug samples, which have been kept in a closed drug delivery system to be donated to a participating pharmacy, hospital, or nonprofit clinic.²⁰ And the state of Oklahoma allows all prescription drugs, except controlled substances, which have been kept in a closed drug delivery system to be transferred from residential care homes, nursing facilities, assisted living centers, public intermediate care facilities for people with mental retardation, or pharmaceutical manufacturers to pharmacies operated by a county.²¹

¹⁶ Rule 64F-12.026(c)1., F.A.C.

¹⁷ Found at http://www.doh.state.fl.us/mqa/DDC/Cancer/info_registry.pdf (last visited March 20, 2008).

¹⁸ Found at http://www.doh.state.fl.us/mqa/DDC/Cancer/info_drugprogram.pdf (last visited March 20, 2008).

¹⁹ Section 499.029(11) and (12), F.S.

²⁰ Rule 4729-35-02 and Rule 4729-35-04, Ohio Administrative Code

²¹ Section 59-367.3, Oklahoma Statute

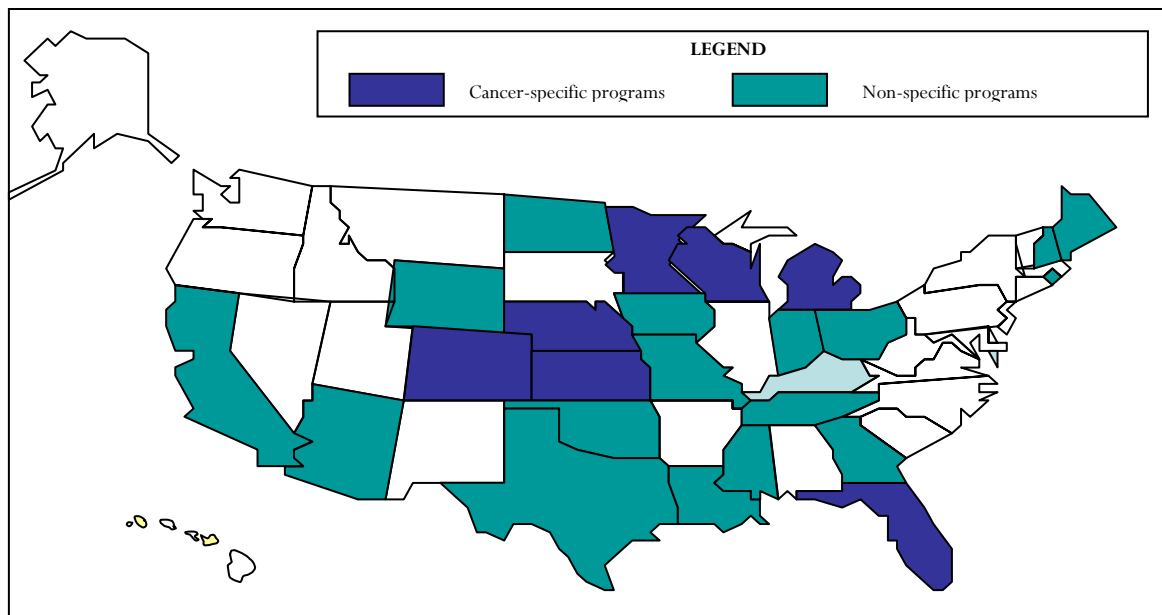


Figure 1²²

Effect of Proposed Changes

The proposed bill amends the existing Cancer Drug Donation Program within the department by:

- Expanding the types of drugs that may be donated, from cancer drugs and supplies to all non-schedule prescription drugs and supplies.
- Expanding the facilities that participate in the program, from a class II hospital pharmacy to any pharmacy or dispensing practitioner.

The proposed bill deletes the definition of “department”, as this term is defined for all of part I of chapter 499 in s. 499.003, F.S.

The proposed bill deletes the definition of “health care clinic”, as this term is not substantively used in the statute creating the Cancer Drug Donation Program.

C. SECTION DIRECTORY:

Section 1: Amends s. 499.029, relating to the Prescription Drug Donation Program.

Section 2: Provides an effective date of July 1, 2008.

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:

²² Department of Health presentation to the House Health Quality Committee, February 19, 2008.

1. Revenues:

None

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Pharmacies that participate will incur costs associated with processing, storage, dispensing, and disposal of the donated drugs and supplies. This cost could be recovered fully or in part by the handling fee authorized in the bill. However, if the donation program is not covered under an insurance program or coverage is exhausted a patient would incur the cost of the handling fee. Program participants may directly benefit through any reduced drug treatment costs and access to medications/supplies that they may not otherwise be able to afford.

D. FISCAL COMMENTS:

In 2006 the department was appropriated 1 full-time equivalent position, salary rate 42,715, and \$65,308 from the Drug, Device, and Cosmetic Trust Fund to create and maintain the registry, to provide consultation and technical assistance, and to perform other administrative functions. Because of the extended scope of the bill, additional staff may be needed to support the program depending upon the rate of participation. However, there is very limited participation in the current program. As of January 2008, there were only two participating facilities and they have processed a total of seven donations.

In addition, the Medicaid program may realize a higher incidence of medications being credited back to the program because of the expansion.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or take 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 appears to provide adequate rulemaking authority for the department.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The Department of Health suggested the following amendments:

- The term "dispensing practitioner" is not otherwise defined in chapter 499, part I, F.S.

Remove line 32 and insert:

(b) "Dispensing Practitioner" means a practitioner authorized by law to prescribe drugs, and may dispense such drugs to his or her patients in the regular course of his or her practice as provided in s. 465.0276.

(c) "Donor" means a patient or patient representative

- A pharmacist or dispensing practitioner provide dispensing and “counseling” services. As written, the proposed bill provides that the participant may provide dispensing and counseling services to an individual who is not a patient of the participant. This amendment is offered to clarify that the individual must be an “eligible recipient” under this program.

Remove lines 85 - 86 and insert:

participant ~~facility~~ may provide dispensing and counseling ~~consulting~~ services to an eligible recipient individuals who is are not a patient

D. STATEMENT OF THE SPONSOR

None.

IV. AMENDMENTS/COUNCIL SUBSTITUTE CHANGES