



## FULL ANALYSIS

### I. SUBSTANTIVE ANALYSIS

#### A. HOUSE PRINCIPLES ANALYSIS:

Provide limited government: The bill creates an additional responsibility for DOH and authorizes the development of additional rules.

Promote personal responsibility: The bill allows individuals to contribute cancer drugs on a voluntary basis.

Empower families: The bill provides opportunities for certain families with limited resources to pursue less costly cancer treatments.

#### B. EFFECT OF PROPOSED CHANGES:

##### EFFECT OF HB 371

HB 371 creates s. 381.94, F.S., to require the Department of Health (DOH) to establish and maintain a cancer drug donation program under which a person, health care facility, hospital, pharmacy, drug manufacturer, medical device manufacturer or supplier, wholesaler of drugs or supplies, or any other entity may donate cancer drugs or supplies needed to administer cancer drugs for use by an individual who meets eligibility criteria established by DOH in rule. 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 the state is ineligible to participate in the program.

Donations may be made on the premises of a physician's office, pharmacy, hospital, hospice, or health care clinic that elects or volunteers to participate in the program. An office, pharmacy, hospital, hospice, or health clinic that participates in the program may charge an individual who receives a cancer drug or supplies a nominal handling fee for receiving and dispensing the cancer drugs or supplies. Under the bill, a cancer drug or supplies needed to administer a cancer drug may be accepted and dispensed only if the drug or supplies are in their original packaging, unaltered and has an expiration date that is later than six months after the date the drug was donated. No cancer drug or supplies that are donated may be resold.

The bill requires DOH to establish and maintain a participant registry for the program. The participant registry must include the participant's name, address, and telephone number and identify whether the participant is a physician's office, pharmacy, hospital, hospice, or health care clinic. DOH must make the participant registry available to any person or entity wishing to donate cancer drugs or supplies.

Under the act, 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 program and the rules adopted by DOH 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.

In addition, a pharmaceutical manufacturer is not liable for any claim or injury arising from the transfer of any cancer drug under this section, 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.

#### BACKGROUND AND CURRENT SITUATION

Cancer is a general term for a group of diseases in which abnormal cells grow out of control. Cancer cells can invade nearby tissues and can spread through the bloodstream and lymphatic system to other parts of the body. There are several main types of cancer. Carcinoma is cancer that begins in the skin

or in tissues that line or cover internal organs. Sarcoma is cancer that begins in bone, cartilage, fat, muscle, blood vessels, or other connective or supportive tissue. Leukemia is cancer that starts in blood-forming tissue such as the bone marrow, and causes large numbers of abnormal blood cells to be produced and enter the bloodstream. Lymphoma and multiple myeloma are cancers that begin in the cells of the immune system<sup>1</sup>.

Cancer is the second leading cause of death in Florida and in the United States. In 2005, an estimated 570,000 Americans—or more than 1,500 people a day—were expected to die of cancer. Of these annual cancer deaths, 40,090 are expected in Florida. In addition, approximately 1.4 million new cases of cancer were expected to be diagnosed nationally. This figure includes an estimated 96,200 new cases that were likely to be diagnosed in Florida.<sup>2</sup>

Estimated New Cases of Cancer - 2005		
Types of Cancers	US	FL
All Cancers	1,372,910	96,200
Breast (female)	211,240	13,430
Uterine Cervix	10,370	730
Colon & Rectum	145,250	9,860
Uterine Corpus	40,880	2,520
Leukemia	34,810	2,620
Lung & Bronchus	172,570	13,130
Melanoma of the skin	59,580	4,600
Non-Hodgkin Lymphoma	56,390	3,470
Prostate	232,090	19,650
Urinary Bladder	63,210	4,890

The financial costs of cancer treatment are a burden to people diagnosed with cancer, their families, and society as a whole. Nationally, cancer treatment accounted for an estimated \$72.1 billion in 2004 in spending.<sup>3</sup>

#### Estimates of National Expenditures for Medical Treatment for the 15 Most Common Cancers<sup>4</sup>

	Percent of all new cancers (1998)	Expenditures (billions; in 2004 dollars)	Percent of all cancer treatment expenditures	Average Medicare payments* per individual in first year following diagnosis (2004 dollars)
Lung	12.7%	\$9.6	13.3%	\$24,700
Breast	15.9%	\$8.1	11.2%	\$11,000
Colorectal	10.7%	\$8.4	11.7%	\$24,200
Prostate	16.8%	\$8.0	11.1%	\$11,000
Lymphoma	4.6%	\$4.6	6.3%	\$21,500
Head/Neck	2.8%	\$3.2	4.4%	\$18,000
Bladder	4.4%	\$2.9	4.0%	\$12,300
Leukemia	2.4%	\$2.6	3.7%	\$18,000
Ovary	1.9%	\$2.2	3.1%	\$36,800
Kidney	2.6%	\$1.9	2.7%	\$25,300
Endometrial	2.9%	\$1.8	2.5%	\$16,200
Cervix	0.8%	\$1.7	2.4%	\$20,100

<sup>1</sup> National Cancer Institute – Dictionary of Cancer Terms

<sup>2</sup> Source: Cancer Facts & Figure, American Cancer Society, 2005

<sup>3</sup> 1963-1995: Brown ML, Lipscomb J, Snyder C. The burden of illness of cancer: economic cost and quality of life. Annual Review of Public Health 2001;22:91-113. 2004: NIH Cost of Illness Report to the U.S. Congress, 2005; National Health Care Expenditures Projections: 2003-2013

<sup>4</sup> Cancer Trend Progress Report – 2005 Update, U.S. National Institute of Health – National Cancer Institute

Pancreas	2.3%	\$1.5	2.1%	\$26,600
Melanoma	4.0%	\$1.5	2.0%	\$4,800
Esophagus	1.0%	\$0.8	1.1%	\$30,500
All Other	14.0%	\$13.4	18.5%	\$20,400

Lack of health insurance and other barriers to health care prevent many Americans from receiving optimal medical care. According to the 2003 national health survey data, there are approximately 2.9 million Floridians who lack health insurance.

### Insurance Status of Floridians

Source of Insurance	FL Population	%	US Population	%
Employer	7,956,640	48	156,270,570	54
Individual	990,350	6	13,593,990	5
Medicaid	2,007,000	12	38,352,430	13
Medicare	2,726,250	16	34,190,710	12
Uninsured	2,957,290	18	44,960,710	16
Total	16,637,520	100	287,368,410	100

(Source: Kaiser Foundation - Population Distribution by Insurance Status, state data 2002-03, U.S. 2003)

According to National Institute of Health (NIH) - Cancer Institute, there are 500 agents that are being used in the treatment of patients with cancer or cancer-related conditions<sup>5</sup>. There are estimates that consumers leave unused approximately \$1 billion worth of unused prescription drugs<sup>6</sup>. To address the issue of affordability of treatment and unused prescription medication to treat cancer, some states have established a cancer drug donation or repository program to accept unused, unopened, prescription drugs and medical supplies. Wisconsin<sup>7</sup>, Colorado<sup>8</sup>, Nebraska<sup>9</sup>, are among the states that have passed cancer drug donation laws and several other states are considering similar legislation.<sup>10</sup>

In general, the cancer donation programs that are being established in other states have similar characteristics. These characteristics include, but are not limited to:

- A mechanism to accept unused, unopened, individually packaged prescription drugs and medical supplies from individuals and health care facilities and these would be redistributed to uninsured and under-insured cancer patients.
- Preference is given to the uninsured for access to donated drugs and supplies.
- Donated drugs can be distributed only when prescribed by a doctor and dispensed by a pharmacist.
- Donated drugs and supplies must be in their original, unopened, sealed and tamper-evident packaging.
- Health facilities may charge a handling fee for dispensing donated cancer drugs but may not resell donated drugs.
- A central registry operated by a state agency to track participating facilities.

### Department of Health

The Bureau of Statewide Pharmaceutical Services is responsible for enforcing Florida's Drug and Cosmetic Act, Chapter 499, F.S. The purpose of this act is to safeguard the health of the public and protect the public from injury by product use and merchandising deceit involving drugs, devices and cosmetics, as well as false and misleading advertising. The Bureau also provides pharmaceuticals to County Health Departments annually and administers the State of Florida's pharmaceutical contracts.

<sup>5</sup> NCI Drug Dictionary, NIH-National Cancer Institute, 2005

<sup>6</sup> "Old Pills Finding New Medicine Cabinets", NY Times, May 18, 2005. This reference is to all prescription drugs not just drugs to treat cancer.

<sup>7</sup> Section 255.056, Wisconsin Statutes

<sup>8</sup> Section 25-35-101, Colorado Statute

<sup>9</sup> Title 181 Chapter 6, Nebraska Statute

<sup>10</sup> NCSL, 2005 Summary of Prescription Drug State Legislation

### Section 465.016

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 a patient; however, in a hospital, nursing home, correctional facility, or extended care facility in which dispensed unit dose medication is transferred to the facility for administration, these may be returned.

### Chapter 499

The Florida Drug and Cosmetic Act is codified in ch. 499, F.S. The Act defines “wholesale distribution” to mean distribution of prescription drugs to persons other than a consumer or patient, but does not include specified activities. Chapter 499 provides safeguards for the public health and protection from injury by product use and by merchandising deceit involving drugs, devices, and cosmetics. The chapter provides uniform legislation to be administered so far as practicable in conformity with the provisions of, and regulations issued under the authority of, the Federal Food, Drug, and Cosmetic Act and that portion of the Federal Trade Commission Act which expressly prohibits the false advertisement of drugs, devices, and cosmetics.

Section 499.014, F.S., authorizes the distribution of prescription drugs by a charitable organization under a limited permit issued by DOH.

### Section 893.13, F.S.

Section 893.13, F.S., provides that, except as authorized by chapter 893 (Drug Abuse Prevention and Control) and chapter 499, it is unlawful for any person to sell, manufacture, or deliver, or possess with intent to sell, manufacture, or deliver, a controlled substance.

### Florida Administrative Code

DOH has adopted rules governing the issuance of a restricted prescription drug distribution permit for charitable organizations, and for the operation of such organizations under this permit - Florida Administrative Code Rules 64F-12.015(8)(c) and 64F-12.023(1).

### U.S. Food and Drug Administration (FDA)

FDA is the federal agency responsible for ensuring that foods, drugs, biological products, and medical devices are safe and effective.

FDA regulation sec. 460.300, Return of Unused Prescription Drugs to Pharmacy Stock Compliance Policy Guide (CPG 7132.09), states that a pharmacist should not return drug products to his stock once they have been out of his possession. The FDA policy states that it could be a dangerous practice for pharmacists to accept and return to stock the unused portions of prescriptions that are returned by patrons, because he or she would no longer have any assurance of the strength, quality, purity or identity of the articles. The pharmacist or doctor dispensing a drug is legally responsible for all hazards of contamination or adulteration that may arise, should the pharmacist mix returned portions of drugs to the shelf stocks. According to FDA, investigations in the past have shown that drugs returned by patrons and subsequently resold by the pharmacist were responsible for injuries. States can allow the redistribution of unused prescription drugs for medications in pharmacies, nursing homes and long-term care facilities.

The FDA has no specific regulations regarding cancer drug donation programs and leaves the cancer donation program to the discretion of the state as long as the state enforces applicable regulations relating to prescription medication.<sup>11</sup>

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<sup>11</sup> Telephone discussion with FDA concerning HB 371, Stewart Watson, REHS LCDR, USPHS, Public Affairs Specialist Florida District - FDA

Agency for Health Care Administration

Hospitals are subject to oversight by the Agency for Health Care Administration and most are accredited by the Joint Commission for Healthcare Organizations. These entities have policies for reviewing pharmacy operations in hospitals.

C. SECTION DIRECTORY:

Section 1: Creates s. 381.94, F.S., to establish the Cancer Drug Donation Program under the Department of Health.

Section 2. Establishes an effective date for the act of July 1, 2006.

**II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT**

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None

2. Expenditures:

According to DOH, 1 FTE is needed to create and maintain the registry, to provide consultation and technical assistance, and to perform other administrative functions.

Salary and Expenses	FY 06-07	FY 07-08
	\$65,306	\$71, 079

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None

2. Expenditures:

None

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

For a pharmacy, hospital, hospice, or health care clinic that elects or volunteers to participate in the program, there will be cost associated with the processing, storage, dispensing and disposal of donated cancer drugs and supplies. This cost could be recovered fully or in part in the handling fee that is allowed by the bill for receiving and dispensing the cancer drugs or supplies.

D. FISCAL COMMENTS:

According to DOH, in order to dispense donated drugs to eligible recipients, participating hospital pharmacies will be required to obtain a Community Pharmacy Permit thus incurring an additional cost of \$255.00 for licensure.

**III. COMMENTS**

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or to take any 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 revenue.

2. Other:

None

B. RULE-MAKING AUTHORITY:

The act authorizes DOH to adopt rules to include, but not limited to:

- Eligibility criteria, including a method to determine priority of eligible patients under the program.
- Standards and procedures for participants that accept, store, distribute, or dispense donated cancer drugs or supplies.
- Necessary forms for administration of the program, including, but not limited to, forms for use by persons or entities that donate, accept, distribute, or dispense cancer drugs or supplies under the program.
- The maximum handling fee that may be charged by a participant that accepts and distributes or dispenses donated cancer drugs or supplies.
- Categories of cancer drugs and supplies that the program will accept for dispensing.
- Categories of cancer drugs and supplies that the program will not accept for dispensing and the reason that such drugs and supplies will not be accepted.
- Maintenance and distribution of the participant registry established.

C. DRAFTING ISSUES OR OTHER COMMENTS:

Although the bill prohibits 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 the state from participation in the program, the bill does not declare persons covered by a prescription drug program under Medicare Part D or other third-party insurers to be ineligible for the program.

Although the bill makes a pharmaceutical manufacturer not liable for any claim or injury arising from the transfer of any cancer drug, manufacturers of cancer supplies are not given the same immunity.

According to DOH, allowing "any person or entity" to donate drugs to the program conflicts with portions of existing state statute (Chapter 499, F.S.) and code (64B-16, F.A.C.) regarding the distribution of drugs or the re-use of dispensed drugs.

According to DOH, the bill allows dispensing to be performed only by a pharmacist. Therefore drugs donated to a physician's office, a hospice, or a health clinic setting lacking a state permitted pharmacy unless the drug(s) could not dispense to a patient. Any drugs donated would have to be transferred to a permitted pharmacy prior to dispensing.

**IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES**