Health Care General Committee

Wednesday, January 11, 2006
10:45 AM – 11:45 AM
306 HOB

COMMITTEE MEETING PACKET

Revised

Allan G. Bense
Speaker

Gayle B. Harrell
Chair

Committee Meeting Notice

HOUSE OF REPRESENTATIVES

Speaker Allan G. Bense

Health Care General Committee

Start Date and Time:	Wednesday, January 11, 2006 10:45 am
End Date and Time:	Wednesday, January 11, 2006 11:45 am
Location:	306 HOB
Duration:	1.00 hrs

Consideration of the following bill(s):

HB 371 Cancer Drug Donation Program by Harrell

Presentation of draft interim project on special needs shelters

Presentation on post hurricane power restoration for special need clients

NOTICE FINALIZED on 12/30/2005 11:02 by RANDOLPH.CHERYL

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 371 Cancer Drug Donation Program
SPONSOR(S): Harrell
TIED BILLS: **IDEN./SIM. BILLS:** SB 1310

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care General Committee		Brown-Barrios	Brown-Barrios
2) Judiciary Committee			
3) Health Care Appropriations Committee			
4) Health & Families Council			
5)			

SUMMARY ANALYSIS

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 specified by DOH by 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. Such an office, facility or pharmacy 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.

According to DOH, the bill, if enacted, will have a fiscal impact on DOH of $65,306 in FY 06/07 and $71, 079 in FY 07/08.

If enacted, the bill takes effect July 1, 2006.

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[1].

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.[2]

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.[3]

Estimates of National Expenditures for Medical Treatment for the 15 Most Common Cancers[4]

	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

[1] National Cancer Institute – Dictionary of Cancer Terms
[2] Source: Cancer Facts & Figure, American Cancer Society, 2005
[3] 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
[4] 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[5]. There are estimates that consumers leave unused approximately $1 billion worth of unused prescription drugs[6]. 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[7], Colorado[8], Nebraska[9], are among the states that have passed cancer drug donation laws and several other states are considering similar legislation.[10]

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.

[5] NCI Drug Dictionary, NIH-National Cancer Institute, 2005
[6] "Old Pills Finding New Medicine Cabinets", NY Times, May 18, 2005. This reference is to all prescription drugs not just drugs to treat cancer.
[7] Section 255.056, Wisconsin Statutes
[8] Section 25-35-101, Colorado Statute
[9] Title 181 Chapter 6, Nebraska Statute
[10] 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.[11]

[11] 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

1 A bill to be entitled
2 An act relating to the Cancer Drug Donation Program;
3 creating s. 381.94, F.S.; providing a short title;
4 creating the Cancer Drug Donation Program; providing a
5 purpose; providing definitions; providing conditions for
6 donation of cancer drugs and supplies to the program;
7 providing conditions for the acceptance of cancer drugs
8 and supplies into the program, inspection of cancer drugs
9 and supplies, and dispensation of cancer drugs and
10 supplies to eligible patients; requiring a physician's
11 office, pharmacy, hospital, hospice, or health care clinic
12 that accepts donated drugs and supplies through the
13 program to comply with certain state and federal laws;
14 authorizing a participating physician's office, pharmacy,
15 hospital, hospice, or health care clinic to charge fees
16 under certain conditions; requiring the Department of
17 Health, upon recommendation of the Board of Pharmacy, to
18 adopt certain rules; providing for the ineligibility of
19 certain persons to receive donated drugs; requiring the
20 department to establish and maintain a participant
21 registry; providing for the contents and availability of
22 the participant registry; providing immunity from civil
23 and criminal liability for donors, program participants,
24 or pharmaceutical manufacturers in certain circumstances;
25 providing an effective date.
26
27 Be It Enacted by the Legislature of the State of Florida:
28

29 Section 1. Section 381.94, Florida Statutes, is created to
30 read:
31 381.94 Cancer Drug Donation Program.--
32 (1) This act may be cited as the "Cancer Drug Donation
33 Program Act."
34 (2) There is created a Cancer Drug Donation Program within
35 the Department of Health for the purpose of authorizing and
36 facilitating the donation of cancer drugs and supplies to
37 eligible patients.
38 (3) As used in this section:
39 (a) "Cancer drug" means a prescription drug used to treat
40 cancer or its side effects or used to treat the side effects of
41 a prescription drug used to treat cancer or its side effects.
42 (b) "Department" means the Department of Health.
43 (c) "Donor" means a person, health care facility,
44 hospital, pharmacy, drug manufacturer, medical device
45 manufacturer or supplier, wholesaler of drugs or supplies, or
46 any other entity that donates cancer drugs, or supplies needed
47 to administer such drugs, in accordance with this section.
48 (d) "Eligible patient" means a person who the department
49 determines is eligible to receive cancer drugs from the program.
50 (e) "Health care facility" means a health care facility
51 licensed under chapter 395.
52 (f) "Health care clinic" means a health care clinic
53 licensed under part XIII of chapter 400.
54 (g) "Hospice" means a corporation licensed under part VI
55 of chapter 400.

56 (h) "Hospital" means a facility as defined in s. 395.002
57 and licensed under chapter 395.
58 (i) "Participant" means a physician's office, pharmacy,
59 hospital, hospice, or health care clinic that has elected to
60 participate in the program and that accepts donated cancer drugs
61 and supplies under the rules adopted by the department for the
62 program.
63 (j) "Pharmacist" means a pharmacist licensed under chapter
64 465.
65 (k) "Pharmacy" means an entity licensed under chapter 465.
66 (l) "Physician's office" means the office of a person
67 licensed to practice medicine under chapter 458 or osteopathic
68 medicine under chapter 459.
69 (m) "Prescribing practitioner" means a physician licensed
70 under chapter 458 or any other medical professional with
71 authority under state law to prescribe cancer medication.
72 (n) "Prescription drug" means a drug as defined in s.
73 465.003(8).
74 (o) "Program" means the Cancer Drug Donation Program
75 created by this section.
76 (p) "Supplies" means any supplies used in the
77 administration of a cancer drug.
78 (4) Any person or entity may donate cancer drugs or
79 supplies to the program. Cancer drugs or supplies may be donated
80 at a physician's office, pharmacy, hospital, hospice, or health
81 care clinic that elects to participate in the program and meets
82 criteria established by the department for such participation.
83 Cancer drugs or supplies may not be donated to a specific cancer

84 patient, and donated drugs or supplies may not be resold by the
85 program.
86 (5) The cancer drug or supplies donated to the program may
87 be prescribed only by a prescribing practitioner for use by an
88 eligible patient and may be dispensed only by a pharmacist.
89 (6)(a) A cancer drug may only be accepted or dispensed
90 under the program if such drug is in its original, unopened,
91 sealed, and tamper-evident unit dose packaging, except that a
92 cancer drug packaged in single unit doses may be accepted and
93 dispensed if the outside packaging is opened but the single-
94 unit-dose packaging is unopened.
95 (b) A cancer drug may not be accepted or dispensed under
96 the program if such drug bears an expiration date that is less
97 than 6 months after the date the drug was donated or if the drug
98 is adulterated or misbranded as determined in paragraph (c).
99 (c) Prior to being dispensed to an eligible patient, the
100 cancer drug or supplies donated under the program shall be
101 inspected by a pharmacist to determine that the drug and
102 supplies are not adulterated or misbranded.
103 (d) A dispenser of donated cancer drugs or supplies may
104 not submit a claim or otherwise seek reimbursement from any
105 public or private third-party payor for donated cancer drugs or
106 supplies dispensed to any patient under the program, and a
107 public or private third-party payor is not required to provide
108 reimbursement to a dispenser for donated cancer drugs or
109 supplies dispensed to any patient under the program.
110 (7)(a) A physician's office, pharmacy, hospital, hospice,
111 or health care clinic that accepts donated cancer drugs or

112 supplies under the program shall comply with all applicable
113 provisions of state and federal law relating to the storage,
114 distribution, and dispensing of the donated cancer drugs or
115 supplies.
116 (b) A physician's office, pharmacy, hospital, hospice, or
117 health clinic that participates in the program may charge a
118 nominal handling fee for distributing or dispensing cancer drugs
119 or supplies under the program. The fee shall be established in
120 rules adopted by the department.
121 (8) The department, upon the recommendation of the Board
122 of Pharmacy, shall adopt rules to carry out the provisions of
123 this section. Initial rules under this section shall be adopted
124 no later than 90 days after the effective date of this act. The
125 rules shall include, but not be limited to:
126 (a) Eligibility criteria, including a method to determine
127 priority of eligible patients under the program.
128 (b) Standards and procedures for participants that accept,
129 store, distribute, or dispense donated cancer drugs or supplies.
130 (c) Necessary forms for administration of the program,
131 including, but not limited to, forms for use by persons or
132 entities that donate, accept, distribute, or dispense cancer
133 drugs or supplies under the program.
134 (d) The maximum handling fee that may be charged by a
135 participant that accepts and distributes or dispenses donated
136 cancer drugs or supplies.
137 (e) Categories of cancer drugs and supplies that the
138 program will accept for dispensing.
139 (f) Categories of cancer drugs and supplies that the

140 program will not accept for dispensing and the reason that such
141 drugs and supplies will not be accepted.
142 (g) Maintenance and distribution of the participant
143 registry established in subsection (10).
144 (9) A person who is eligible to receive cancer drugs or
145 supplies under the state Medicaid program or under any other
146 prescription drug program funded in whole or in part by the
147 state is ineligible to participate in the program created under
148 this section.
149 (10) The department shall establish and maintain a
150 participant registry for the program. The participant registry
151 shall include the participant's name, address, and telephone
152 number and shall identify whether the participant is a
153 physician's office, pharmacy, hospital, hospice, or health care
154 clinic. The department shall make the participant registry
155 available to any person or entity wishing to donate cancer drugs
156 or supplies to the program.
157 (11) Any donor of cancer drugs or supplies, or any
158 participant in the program, who exercises reasonable care in
159 donating, accepting, distributing, or dispensing cancer drugs or
160 supplies under the program and the rules adopted under this
161 section shall be immune from civil or criminal liability and
162 from professional disciplinary action of any kind for any
163 injury, death, or loss to person or property relating to such
164 activities.
165 (12) A pharmaceutical manufacturer is not liable for any
166 claim or injury arising from the transfer of any cancer drug
167 under this section, including, but not limited to, liability for

168 failure to transfer or communicate product or consumer
169 information regarding the transferred drug, as well as the
170 expiration date of the transferred drug.
171 Section 2. This act shall take effect July 1, 2006.

Interim Project
Special Needs Shelters

Post Hurricane Power Restoration for Special Need Clients

Health Care General Committee

Wednesday, January 11, 2006
10:45 AM – 11:45 AM
306 HOB

COMMITTEE MEETING PACKET

Revised

ADDENDUM "A" (01/11/2006; 8:30 AM)

Allan G. Bense
Speaker

Gayle B. Harrell
Chair

Bill No. **HB 371**

COUNCIL/COMMITTEE ACTION

ADOPTED __ (Y/N)
ADOPTED AS AMENDED __ (Y/N)
ADOPTED W/O OBJECTION __ (Y/N)
FAILED TO ADOPT __ (Y/N)
WITHDRAWN __ (Y/N)
OTHER ____

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1 Council/Committee hearing bill: Health Care General
2 Representative(s) Harrell offered the following:
3
4 **Amendment (with title amendment)**
5 Remove everything after the enacting clause and insert:
6 Section 1. Section 381.94, Florida Statutes, is created to
7 read:
8 381.94 Cancer Drug Donation Program.--
9 (1) This act may be cited as the "Cancer Drug Donation
10 Program Act."
11 (2) There is created a Cancer Drug Donation Program within
12 the Department of Health for the purpose of authorizing and
13 facilitating the donation of cancer drugs and supplies to
14 eligible patients.
15 (3) As used in this section:
16 (a) "Cancer drug" means a prescription drug whose approved
17 application has become effective under s. 505 of the federal
18 Food, Drug and Cosmetic Act and is used to treat cancer or its
19 side effects or is used to treat the side effects of a
20 prescription drug used to treat cancer or its side effects.
21 Cancer drug pursuant to this definition shall not include a
22 substance in Schedule II, III, IV or V pursuant to s. 893.03.

23 (b) Closed drug delivery system means a system in which the
24 actual control of the unit dose medication package is maintained
25 by the facility rather than by the individual patient.
26 (c) "Department" means the Department of Health.
27 (d) "Donor" means a patient or patient representative who
28 donates cancer drugs or supplies needed to administer cancer
29 drugs that have been maintained within a closed delivery system,
30 health care facilities, nursing homes, hospices, or hospitals,
31 with closed drug delivery systems, or a pharmacy, drug
32 manufacturer, medical device manufacturer or supplier, or
33 wholesaler of drugs or supplies, in accordance with this
34 section. A donor also includes a physician licensed under
35 Chapter 458 or 459 who receives cancer drugs or supplies
36 directly from a drug manufacturer, drug wholesaler or pharmacy.
37 (e) "Eligible patient" means a person who the department
38 determines is eligible to receive cancer drugs from the program.
39 (f) "Health care facility" means a health care facility
40 licensed under chapter 395.
41 (g) "Health care clinic" means a health care clinic
42 licensed under part XIII of chapter 400.
43 (h) "Hospice" means a corporation licensed under part VI
44 of chapter 400.
45 (i) "Hospital" means a facility as defined in s. 395.002
46 and licensed under chapter 395.
47 (j) "Nursing home" means a facility licensed under part II
48 of chapter 400.
49 (k) "Participant facility " means a class II institutional
50 hospital pharmacy that has elected to participate in the program
51 and that accepts donated cancer drugs and supplies under the
52 rules adopted by the department for the program.

53 (l) "Pharmacist" means a pharmacist licensed under chapter
54 465.
55 (m) "Pharmacy" means an entity licensed under chapter 465.
56 (n) "Prescribing practitioner" means a physician licensed
57 under chapter 458 or any other medical professional with
58 authority under state law to prescribe cancer medication.
59 (o) "Prescription drug" means a drug as defined in s.
60 465.003(8).
61 (p) "Program" means the Cancer Drug Donation Program
62 created by this section.
63 (q) "Supplies" means any supplies used in the
64 administration of a cancer drug.
65 (4) Any donor may donate cancer drugs or supplies to a
66 participant facility that elects to participate in the program
67 and meets criteria established by the department for such
68 participation. Cancer drugs or supplies may not be donated to a
69 specific cancer patient, and donated drugs or supplies may not
70 be resold by the program. A participant facility may provide
71 dispensing and consulting services to individuals who are not
72 patients of the hospital.
73 (5) The cancer drug or supplies donated to the program may
74 be prescribed only by a prescribing practitioner for use by an
75 eligible patient and may be dispensed only by a pharmacist.
76 (6)(a) A cancer drug may only be accepted or dispensed
77 under the program if such drug is in its original, unopened,
78 sealed container, or in a tamper-evident unit dose packaging,
79 except that a cancer drug packaged in single unit doses may be
80 accepted and dispensed if the outside packaging is opened but
81 the single-unit-dose packaging if unopened with tamper-resistant
82 packaging intact.

83 (b) A cancer drug may not be accepted or dispensed under
84 the program if such drug bears an expiration date that is less
85 than 6 months after the date the drug was donated or if the drug
86 is appears to have been tampered with or mislabeled as
87 determined in paragraph (c).
88 (c) Prior to being dispensed to an eligible patient, the
89 cancer drug or supplies donated under the program shall be
90 inspected by a pharmacist to determine that the drug and
91 supplies do not appear to have been tampered with or mislabeled.
92 (d) A dispenser of donated cancer drugs or supplies may
93 not submit a claim or otherwise seek reimbursement from any
94 public or private third-party payor for donated cancer drugs or
95 supplies dispensed to any patient under the program, and a
96 public or private third-party payor is not required to provide
97 reimbursement to a dispenser for donated cancer drugs or
98 supplies dispensed to any patient under the program.
99 (7)(a) A donation of cancer drugs shall be made only at a
100 participant facility. A participant facility may decline to
101 accept a donation. A participant facility that accepts donated
102 cancer drugs or supplies under the program shall comply with all
103 applicable provisions of state and federal law relating to the
104 storage and dispensing of the donated cancer drugs or supplies.
105 (b) A participant facility that voluntarily takes part in
106 the program may charge a handling fee sufficient to cover the
107 cost of preparation and dispensing of cancer drugs or supplies
108 under the program. The fee shall be established in rules adopted
109 by the department.
110 (8) The department, upon the recommendation of the Board
111 of Pharmacy, shall adopt rules to carry out the provisions of
112 this section. Initial rules under this section shall be adopted

113 no later than 90 days after the effective date of this act. The
114 rules shall include, but not be limited to:
115 (a) Eligibility criteria, including a method to determine
116 priority of eligible patients under the program.
117 (b) Standards and procedures for participant facilities
118 that accept, store, distribute, or dispense donated cancer drugs
119 or supplies.
120 (c) Necessary forms for administration of the program,
121 including, but not limited to, forms for use by entities that
122 donate, accept, distribute, or dispense cancer drugs or supplies
123 under the program.
124 (d) The maximum handling fee that may be charged by a
125 participant facility that accepts and distributes or dispenses
126 donated cancer drugs or supplies.
127 (e) Categories of cancer drugs and supplies that the
128 program will accept for dispensing, however, the department may
129 exclude any drug based on its therapeutic effectiveness or high
130 potential for abuse or diversion.
131 (f) Maintenance and distribution of the participant
132 facility registry established in subsection (10).
133 (9) A person who is eligible to receive cancer drugs or
134 supplies under the state Medicaid program or under any other
135 prescription drug program funded in whole or in part by the
136 state, or by any other prescription drug program funded in whole
137 or in part by the federal government, or by any other
138 prescription drug program offered by a third-party insurer,
139 unless benefits have been exhausted, or a certain cancer drug or
140 cancer supply is not covered by the prescription drug program,
141 or is ineligible to participate in the program created under
142 this section.

143 (10) The department shall establish and maintain a
144 participant facility registry for the program. The participant
145 facility registry shall include the participant facility's name,
146 address, and telephone number. The department shall make the
147 participant facility registry available on the department's
148 website to any participant facility wishing to donate cancer
149 drugs or supplies to the program. The department's web site
150 shall also contain links to cancer drug manufacturers that offer
151 drug assistance program or offer free medication.
152 (11) Any donor of cancer drugs or supplies, or any
153 participant facility in the program, who exercises reasonable
154 care in donating, accepting, distributing, or dispensing cancer
155 drugs or supplies under the program and the rules adopted under
156 this section shall be immune from civil or criminal liability
157 and from professional disciplinary action of any kind for any
158 injury, death, or loss to person or property relating to such
159 activities.
160 (12) A pharmaceutical or cancer supply manufacturer is not
161 liable for any claim or injury arising from the donation and use
162 of any cancer drug under this section, including, but not
163 limited to, liability for failure to transfer or communicate
164 product or consumer information regarding the donated drug or
165 supply, as well as the expiration date of the donated drug or
166 supply.
167 (13) If any conflict exists between the provisions
168 contained in s.381.94 and provisions in Chapter 465 or 499, the
169 provisions contained in s. 381.94 shall control as to the
170 operation of the Cancer Drug Donation Program.
171 Section 2. This act shall take effect July 1, 2006.
172
173

174 ========== T I T L E A M E N D M E N T ==========
175 Remove the entire title and insert:
176 A bill to be entitled
177 An act relating to the Cancer Drug Donation Program;
178 creating s. 381.94, F.S.; providing a short title;
179 creating the Cancer Drug Donation Program; providing a
180 purpose; providing definitions; providing conditions for
181 donation of cancer drugs and supplies to the program;
182 providing conditions for the acceptance of cancer drugs
183 and supplies into the program, inspection of cancer drugs
184 and supplies, and dispensation of cancer drugs and
185 supplies to eligible patients; requiring a participant
186 facility that accepts donated drugs and supplies through
187 the program to comply with certain state and federal laws;
188 authorizing a participating participant facility to charge
189 fees under certain conditions; requiring the Department of
190 Health, upon recommendation of the Board of Pharmacy, to
191 adopt certain rules; providing for the ineligibility of
192 certain persons to receive donated drugs; requiring the
193 department to establish and maintain a participant
194 facility registry; providing for the contents and
195 availability of the participant facility registry;
196 providing immunity from civil and criminal liability for
197 donors, pharmaceutical manufacturers, or cancer supply
198 manufacture in certain circumstances; providing that in
199 the event of conflict between the provisions in s.381.94
200 and provisions in Chapter 465 or 499, the provisions in s.
201 381.94 control; providing an effective date.

THE FLORIDA HOUSE OF REPRESENTATIVES

Interim Project Report

November 2005

Health Care General Committee

(Document Currently Under Review)

REVIEW OF FLORIDA'S SPECIAL NEEDS SHELTERS

SUMMARY

The function of special needs shelters in Florida is to provide safe refuge to individuals who because of a health or medical condition require the supervision of a health care professional during a disaster. The Department of Health is the primary agency under the Emergency Support Function-8 operations to maintain and staff special needs shelters. The intent of special needs shelters is to provide, to the extent practicable under emergency conditions, an environment in which the current level of a special needs individual's health can be sustained.

Special needs individuals are registered with their county and as such are eligible for special needs shelter housing and care during a disaster. The level of care that is provided in a special needs shelter generally goes beyond the basic first aid level of care that is available in the general population shelters. Moreover, certain services are available to special needs individuals that may not be available in general shelters.

The focus of this interim project is to provide members with a basic understanding of:

- Special needs shelter operations;
- The special needs registration process;
- An assessment as to whether special needs individuals are being served.

This report describes:

- The institutional environment of special needs shelters and how this fits into the larger picture of disaster response;
- The statutory basis for special needs shelters—the individuals they are supposed to serve, the services they are meant to provide, who is to oversee these shelters.
- Florida's unique environmental basis for emergency and disaster planning;
- The various agencies involved in emergency management and the roles each agency is designated to play.