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LEGISLATIVE ACTION

Senate

.

House

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Floor: WD/3R

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04/28/2009 09:21 AM

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Senator Deutch moved the following:

Senate Amendment (with title amendment)

Delete line 339

and insert:

Section 7. Section 499.029, Florida Statutes, is amended to read:

499.029 Prescription ~~Cancer~~ Drug Donation Program.—

(1) This section may be cited as the "Prescription ~~Cancer~~ Drug Donation Program Act."

(2) There is created a Prescription ~~Cancer~~ Drug Donation Program within the department for the purpose of authorizing and facilitating the donation of prescription ~~cancer~~ drugs and



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13 supplies to eligible patients.

14 (3) As used in this section, the term:

15 ~~(a) "Cancer drug" means a prescription drug that has been~~
16 ~~approved under s. 505 of the federal Food, Drug, and Cosmetic~~
17 ~~Act and is used to treat cancer or its side effects or is used~~
18 ~~to treat the side effects of a prescription drug used to treat~~
19 ~~cancer or its side effects. "Cancer drug" does not include a~~
20 ~~substance listed in Schedule II, Schedule III, Schedule IV, or~~
21 ~~Schedule V of s. 893.03.~~

22 (a) (b) "Closed drug delivery system" means a system in
23 which the actual control of the unit-dose medication package is
24 maintained by the facility rather than by the individual
25 patient.

26 (b) "Dispensing practitioner" means a practitioner
27 registered under s. 465.0276.

28 (c) "Donor" means a patient or patient representative who
29 donates prescription ~~cancer~~ drugs or supplies needed to
30 administer prescription ~~cancer~~ drugs that have been maintained
31 within a closed drug delivery system; health care facilities,
32 nursing homes, hospices, or hospitals with closed drug delivery
33 systems; or pharmacies, prescription drug manufacturers, medical
34 device manufacturers or suppliers, or wholesalers of
35 prescription drugs or supplies, in accordance with this section.
36 The term "Donor" includes a physician licensed under chapter 458
37 or chapter 459 who receives prescription ~~cancer~~ drugs or
38 supplies directly from a prescription drug manufacturer,
39 wholesale distributor, or pharmacy.

40 (d) "Eligible patient" means a person who the department
41 determines is eligible to receive prescription ~~cancer~~ drugs from



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42 the program.

43 (e) "Participant ~~facility~~" means a ~~class II hospital~~
44 pharmacy or dispensing practitioner that has elected to
45 participate in the program and that accepts donated prescription
46 ~~cancer~~ drugs and supplies under the rules adopted by the
47 department for the program.

48 (f) "Prescribing practitioner" means a physician licensed
49 under chapter 458 or chapter 459 or any other medical
50 professional with authority under state law to prescribe drugs
51 ~~cancer medication~~.

52 (g) "Prescription drug" does not include a substance listed
53 in Schedule II, Schedule III, Schedule IV, or Schedule V of s.
54 893.03.

55 (h) ~~(g)~~ "Program" means the Prescription Cancer Drug
56 Donation Program created by this section.

57 (i) ~~(h)~~ "Supplies" means any supplies used in the
58 administration of a prescription cancer drug.

59 (4) Any donor may donate prescription cancer drugs or
60 supplies to a participant ~~facility~~ that elects to participate in
61 the program and meets criteria established by the department for
62 such participation. Prescription Cancer drugs or supplies may
63 not be donated to a specific ~~cancer~~ patient, and donated
64 prescription drugs or supplies may not be resold by the
65 participant program. Prescription Cancer drugs billed to and
66 paid for by Medicaid in long-term care facilities that are
67 eligible for return to stock under federal Medicaid regulations
68 shall be credited to Medicaid and are not eligible for donation
69 under the program. A participant ~~facility~~ may provide dispensing
70 and counseling consulting services to an eligible patient



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71 ~~individuals~~ who is ~~are~~ not a patient ~~patients~~ of the participant
72 hospital.

73 (5) The prescription ~~cancer~~ drugs or supplies donated to
74 the program may be prescribed only by a prescribing practitioner
75 for use by an eligible patient and may be dispensed only by a
76 pharmacist or dispensing practitioner.

77 (6) (a) A prescription ~~cancer~~ drug may only be accepted or
78 dispensed under the program if the drug is in its original,
79 unopened, sealed container, or in a tamper-evident unit-dose
80 packaging, except that a prescription ~~cancer~~ drug packaged in
81 single-unit doses may be accepted and dispensed if the outside
82 packaging is opened but the single-unit-dose packaging is
83 unopened with tamper-resistant packaging intact.

84 (b) A prescription ~~cancer~~ drug may not be accepted or
85 dispensed under the program if the drug bears an expiration date
86 that is less than 6 months after the date the drug was donated
87 or if the drug appears to have been tampered with or mislabeled
88 as determined in paragraph (c).

89 (c) Before ~~Prior to~~ being dispensed to an eligible patient,
90 the prescription ~~cancer~~ drug or supplies donated under the
91 program shall be inspected by a pharmacist or dispensing
92 practitioner to determine that the drug and supplies do not
93 appear to have been tampered with or mislabeled.

94 (d) A dispenser of donated prescription ~~cancer~~ drugs or
95 supplies may not submit a claim or otherwise seek reimbursement
96 from any public or private third-party payor for donated
97 prescription ~~cancer~~ drugs or supplies dispensed to any patient
98 under the program, and a public or private third-party payor is
99 not required to provide reimbursement to a dispenser for donated



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100 prescription cancer drugs or supplies dispensed to any patient
101 under the program.

102 (7) (a) A donation of prescription cancer drugs or supplies
103 shall be made only at a participant's participant facility. A
104 participant ~~facility~~ may decline to accept a donation. A
105 participant ~~facility~~ that accepts donated prescription cancer
106 drugs or supplies under the program shall comply with all
107 applicable provisions of state and federal law relating to the
108 storage and dispensing of the donated prescription cancer drugs
109 or supplies.

110 (b) A participant ~~facility~~ that voluntarily takes part in
111 the program may charge a handling fee sufficient to cover the
112 cost of preparation and dispensing of prescription cancer drugs
113 or supplies under the program. The fee shall be established in
114 rules adopted by the department.

115 (8) The department, upon the recommendation of the Board of
116 Pharmacy, shall adopt rules to carry out the provisions of this
117 section. ~~Initial rules under this section shall be adopted no~~
118 ~~later than 90 days after the effective date of this act.~~ The
119 rules shall include, but not be limited to:

120 (a) Eligibility criteria, including a method to determine
121 priority of eligible patients under the program.

122 (b) Standards and procedures for participants participant
123 ~~facilities~~ that accept, store, distribute, or dispense donated
124 prescription cancer drugs or supplies.

125 (c) Necessary forms for administration of the program,
126 including, but not limited to, forms for use by entities that
127 donate, accept, distribute, or dispense prescription cancer
128 drugs or supplies under the program.



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129 (d) The maximum handling fee that may be charged by a
130 participant ~~facility~~ that accepts and distributes or dispenses
131 donated prescription ~~cancer~~ drugs or supplies.

132 (e) Categories of prescription ~~cancer~~ drugs and supplies
133 that the program will accept for dispensing; however, the
134 department may exclude any drug based on its therapeutic
135 effectiveness or high potential for abuse or diversion.

136 (f) Maintenance and distribution of the participant
137 ~~facility~~ registry established in subsection (10).

138 (9) A person who is eligible to receive prescription ~~cancer~~
139 drugs or supplies under the state Medicaid program or under any
140 other prescription drug program funded in whole or in part by
141 the state, by any other prescription drug program funded in
142 whole or in part by the Federal Government, or by any other
143 prescription drug program offered by a third-party insurer,
144 unless benefits have been exhausted, or a certain prescription
145 ~~cancer~~ drug or supply is not covered by the prescription drug
146 program, is ineligible to participate in the program created
147 under this section.

148 (10) The department shall establish and maintain a
149 participant ~~facility~~ registry for the program. The participant
150 ~~facility~~ registry shall include the participant's ~~participant~~
151 ~~facility's~~ name, address, and telephone number. The department
152 shall make the participant ~~facility~~ registry available on the
153 department's website to any donor wishing to donate prescription
154 ~~cancer~~ drugs or supplies to the program. The department's
155 website shall also contain links to prescription ~~cancer~~ drug
156 manufacturers that offer drug assistance programs or free
157 medication.



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158 (11) Any donor of prescription ~~cancer~~ drugs or supplies, or
159 any participant in the program, who exercises reasonable care in
160 donating, accepting, distributing, or dispensing prescription
161 ~~cancer~~ drugs or supplies under the program and the rules adopted
162 under this section ~~is shall be~~ immune from civil or criminal
163 liability and from professional disciplinary action of any kind
164 for any injury, death, or loss to person or property relating to
165 such activities.

166 (12) A pharmaceutical manufacturer is not liable for any
167 claim or injury arising from the transfer of any prescription
168 ~~cancer~~ drug under this section, including, but not limited to,
169 liability for failure to transfer or communicate product or
170 consumer information regarding the transferred drug, as well as
171 the expiration date of the transferred drug.

172 (13) If any conflict exists between the provisions in this
173 section and the provisions in this chapter or chapter 465, the
174 provisions in this section shall control the operation of the
175 ~~Cancer Drug Donation~~ program.

176 Section 8. This act shall take effect July 1, 2009.

177
178 ===== T I T L E A M E N D M E N T =====

179 And the title is amended as follows:

180 Delete line 19

181 and insert:

182 health care clinic establishment permits; amending s.
183 499.029, F.S.; renaming the Cancer Drug Donation
184 Program as the Prescription Drug Donation Program;
185 revising definitions; expanding the drugs and supplies
186 that may be donated under the program; expanding the



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187 types of facilities and practitioners that may
188 participate in the program; conforming provisions to
189 changes in terminology; removing obsolete language
190 relating to the adoption of initial rules; providing
191 an