HOUSE AMENDMENT

Bill No. HB 331

Amendment No.

CHAMBER ACTION

Senate House

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Representative Skidmore offered the following:

Amendment (with title amendment)

Between lines 267 and 268, insert:

Section 5. 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 supplies to eligible patients.

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

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

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

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

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

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

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

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

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

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

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

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

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

(5) The prescription ~~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 or dispensing practitioner.

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

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

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

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

not required to provide reimbursement to a dispenser for donated prescription ~~cancer~~ drugs or supplies dispensed to any patient under the program.

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

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

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

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

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

(c) Necessary forms for administration of the program, including, but not limited to, forms for use by entities that

donate, accept, distribute, or dispense prescription ~~cancer~~ drugs or supplies under the program.

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

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

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

(9) A person who is eligible to receive prescription ~~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, by any other prescription drug program funded in whole or in part by the Federal Government, or by any other prescription drug program offered by a third-party insurer, unless benefits have been exhausted~~,~~ or a certain prescription ~~cancer~~ drug or supply is not covered by the prescription drug program, is ineligible to participate in the program created under this section.

(10) The department shall establish and maintain a participant ~~facility~~ registry for the program. The participant ~~facility~~ registry shall include the participant's ~~participant facility's~~ name, address, and telephone number. The department shall make the participant ~~facility~~ registry available on the department's website to any donor wishing to donate prescription ~~cancer~~ drugs or supplies to the program. The department's

website shall also contain links to prescription ~~cancer~~ drug manufacturers that offer drug assistance programs or free medication.

(11) Any donor of prescription ~~cancer~~ drugs or supplies, or any participant in the program, who exercises reasonable care in donating, accepting, distributing, or dispensing prescription ~~cancer~~ drugs or supplies under the program and the rules adopted under this section is ~~shall be~~ 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.

(12) A pharmaceutical manufacturer is not liable for any claim or injury arising from the transfer of any prescription ~~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.

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

Section 6. This act shall take effect July 1, 2009.

T I T L E A M E N D M E N T

Remove line 11 and insert:

381.981, F.S.; conforming terminology; amending s. 499.029, F.S.; renaming the Cancer Drug Donation Program as the

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Prescription Drug Donation Program; revising definitions; expanding the drugs and supplies that may be donated under the program; expanding the types of facilities and practitioners that may participate in the program; conforming provisions to changes in terminology; removing obsolete language relating to the adoption of initial rules; providing an