CHAPTER 2006-310

House Bill No. 371

An act relating to prescription drugs; creating s. 499.029, F.S.; providing a short title; creating the Cancer Drug Donation Program; providing a purpose; providing definitions; providing conditions for the donation of cancer drugs and supplies to the program; providing conditions for the acceptance of cancer drugs and supplies into the program, inspection of cancer drugs and supplies, and dispensing of cancer drugs and supplies to eligible patients; requiring a participant facility that accepts donated drugs and supplies through the program to comply with certain state and federal laws; authorizing a participant facility to charge fees under certain conditions; requiring the Department of Health, upon recommendation of the Board of Pharmacy, to adopt certain rules; providing for the ineligibility of certain persons to receive donated drugs; requiring the department to establish and maintain a participant facility registry; providing for the contents and availability of the participant facility registry; providing immunity from civil and criminal liability for donors or pharmaceutical manufacturers in certain circumstances; providing that in the event of conflict between the provisions in s. 499.029, F.S., and provisions in ch. 465 or ch. 499, F.S., the provisions in s. 499.029, F.S., shall control; providing an appropriation; amending s. 499.003, F.S.; revising the definition of the term "pedigree paper"; authorizing the Department of Health to adopt rules and forms relating to pedigree paper requirements; amending s. 499.005, F.S.; revising a prohibited acts provision relating to pedigree papers; amending s. 499.0121, F.S.; requiring certain wholesale distributors taking title to a prescription drug to provide an invoice to the recipient containing certain information; requiring a recipient of a prescription drug to acquire from the manufacturer a shipping document containing specified information; requiring wholesale distributor to make certain information available to the department; providing for penalties; authorizing the department to adopt certain rules relating to the inventory and return of certain prescription drugs; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 499.029, Florida Statutes, is created to read:

499.029 Cancer Drug Donation Program.—

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

(2) There is created a Cancer Drug Donation Program within the Department of Health for the purpose of authorizing and facilitating the donation of cancer drugs and supplies to eligible patients.

(3) As used in this section:

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

(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.

(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.

(c) "Department" means the Department of Health.

(d) "Donor" means a patient or patient representative who donates cancer drugs or supplies needed to administer 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, drug manufacturers, medical device manufacturers or suppliers, or wholesalers of drugs or supplies, in accordance with this section. "Donor" includes a physician licensed under chapter 458 or chapter 459 who receives cancer drugs or supplies directly from a drug manufacturer, drug wholesaler, or pharmacy.

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

(f) "Health care facility" means a health care facility licensed under chapter 395.

(g) "Health care clinic" means a health care clinic licensed under part XIII of chapter 400.

(h) "Hospice" means a corporation licensed under part VI of chapter 400.

(i) "Hospital" means a facility as defined in s. 395.002 and licensed under chapter 395.

(j) "Nursing home" means a facility licensed under part II of chapter 400.

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

(l) "Pharmacist" means a person licensed under chapter 465.

(m) "Pharmacy" means an entity licensed under chapter 465.

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

(o) "Prescription drug" means a drug as defined in s. 465.003(8).

(p) "Program" means the Cancer Drug Donation Program created by this section.

(q) "Supplies" means any supplies used in the administration of a cancer drug.

(4) Any donor may donate 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. Cancer drugs or supplies may not be donated to a specific cancer patient, and donated drugs or supplies may not be resold by the program. 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 consulting services to individuals who are not patients of the hospital.

(5) The 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.

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

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

(7)(a) A donation of cancer drugs or supplies shall be made only at a participant facility. A participant facility may decline to accept a donation. A participant facility that accepts donated 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 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 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 participant facilities that accept, store, distribute, or dispense donated 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 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 cancer drugs or supplies.

(e) Categories of 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 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 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 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 cancer drugs or supplies to the program. The department's website shall also contain links to cancer drug manufacturers that offer drug assistance programs or free medication.

(11) 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 under this section 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 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 2. There is hereby appropriated one full-time equivalent position at salary rate 42,715 and recurring funding from the Florida Drug, Device, and Cosmetic Trust Fund pursuant to s. 499.057, Florida Statutes, in the sum of $65,308 for fiscal year 2006-2007, for the purpose of implementing the Cancer Drug Donation Program under s. 499.029, Florida Statutes, as created by this act.

Section 3. Subsection (31) of section 499.003, Florida Statutes, is amended to read:

499.003 Definitions of terms used in ss. 499.001-499.081.—As used in ss. 499.001-499.081, the term:

(31) "Pedigree paper" means:

(a) A document required pursuant to s. 499.0121(6)(d) or (e); or

(b)1. Effective July 1, 2006, a document or electronic form approved by the Department of Health and containing information that records each distribution of any given legend drug, from sale by a pharmaceutical manufacturer, through acquisition and sale by any wholesaler or repackager, until final sale to a pharmacy or other person administering or dispensing the drug. The information required to be included on the form approved by the department pursuant to this subparagraph ~~a legend drug's pedigree paper~~ must at least detail the amount of the legend drug; its dosage form and strength; its lot numbers; the name and address of each owner of the legend drug and his or her signature; its shipping information, including the name and address of each person certifying delivery or receipt of the legend drug; an invoice number, a shipping document number, or another number uniquely identifying the transaction; and a certification that the recipient wholesaler has authenticated the pedigree papers. If the manufacturer or repackager has uniquely serialized the individual legend drug unit, that identifier must also be included on the form approved pursuant to this subparagraph ~~pedigree~~. It must also include the name, address, telephone number and, if available, e-mail contact information of each wholesaler involved in the chain of the legend drug's custody; or

2. A statement, under oath, in written or electronic form, confirming that a wholesale distributor purchases and receives the specific unit of the prescription drug directly from the manufacturer of the prescription drug and distributes the prescription drug directly, or through an intracompany transfer, to a chain pharmacy warehouse or a person authorized by law to purchase prescription drugs for the purpose of administering or dispensing the drug, as defined in s. 465.003. For purposes of this paragraph, the term "chain pharmacy warehouse" means a wholesale distributor permitted pursuant to s. 499.01 that maintains a physical location for prescription drugs

that functions solely as a central warehouse to perform intracompany transfers of such drugs to a member of its affiliated group as described in s. 499.0121(6)(h)1.

a. The information required to be included pursuant to this subparagraph must include:

(I) The following statement: "This wholesale distributor purchased the specific unit of the prescription drug directly from the manufacturer."

(II) The manufacturers' national drug code identifier and the name and address of the wholesaler and the purchaser of the prescription drug.

(III) The name of the prescription drug as it appears on the label.

(IV) The quantity, dosage form, and strength of the prescription drug.

b. The wholesale distributor must also maintain and make available to the department, upon request, the point of origin of the prescription drugs, including intracompany transfers; the date of the shipment from the manufacturer to the wholesale distributor; the lot numbers of such drugs; and the invoice numbers from the manufacturer.

The department may ~~shall~~ adopt rules and forms ~~a form~~ relating to the requirements of this subsection ~~paragraph no later than 90 days after the effective date of this act~~.

Section 4. Subsection (29) of section 499.005, Florida Statutes, is amended to read:

499.005 Prohibited acts.—It is unlawful for a person to perform or cause the performance of any of the following acts in this state:

(29) The receipt of a prescription drug pursuant to a wholesale distribution without either first receiving a pedigree paper that was attested to as accurate and complete by the wholesale distributor or complying with the provisions of s. 499.0121(6)(f)6.

Section 5. Paragraph (f) of subsection (6) of section 499.0121, Florida Statutes, is amended to read:

499.0121 Storage and handling of prescription drugs; recordkeeping.—The department shall adopt rules to implement this section as necessary to protect the public health, safety, and welfare. Such rules shall include, but not be limited to, requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.

(6) RECORDKEEPING.—The department shall adopt rules that require keeping such records of prescription drugs as are necessary for the protection of the public health.

(f)1. Effective July 1, 2006, each person who is engaged in the wholesale distribution of a prescription drug and who is not the manufacturer of that

drug must, before each wholesale distribution of such drug, provide to the person who receives the drug a pedigree paper as defined in s. 499.003(31).

2. A repackager must comply with this paragraph.

3. The pedigree paper requirements in this paragraph do not apply to compressed medical gases or veterinary legend drugs.

4. Each wholesale distributor of prescription drugs must maintain separate and distinct from other required records all statements that are required under subparagraph 1.

5. In order to verify compliance with subparagraph (d)1., each manufacturer of a prescription drug sold in this state must make available upon request distribution documentation related to its sales of prescription drugs, regardless of whether the prescription drug was sold directly by the manufacturer to a person in Florida.

6. Subparagraph 1. is satisfied when a wholesale distributor takes title to, but not possession of, a prescription drug and the prescription drug's manufacturer ships the prescription drug directly to a person authorized by law to purchase prescription drugs for the purpose of administering or dispensing the drug, as defined in s. 465.003, or a member of an affiliated group, as described in paragraph (h), with the exception of a repackager.

a. The wholesale distributor must deliver to the recipient of the prescription drug, within 14 days after the shipment notification from the manufacturer, an invoice and the following sworn statement: "This wholesale distributor purchased the specific unit of the prescription drug listed on the invoice directly from the manufacturer, and the specific unit of prescription drug was shipped by the manufacturer directly to a person authorized by law to administer or dispense the legend drug, as defined in s. 465.003, Florida Statutes, or a member of an affiliated group, as described in s. 499.0121(6)(h), Florida Statutes, with the exception of a repackager." The invoice must contain a unique cross-reference to the shipping document sent by the manufacturer to the recipient of the prescription drug.

b. The manufacturer of the prescription drug shipped directly to the recipient under this section must provide and the recipient of the prescription drug must acquire, within 14 days after receipt of the prescription drug, a shipping document from the manufacturer that contains, at a minimum:

(I) The name and address of the manufacturer, including the point of origin of the shipment, and the names and addresses of the wholesaler and the purchaser.

(II) The name of the prescription drug as it appears on the label.

(III) The quantity, dosage form, and strength of the prescription drug.

(IV) The date of the shipment from the manufacturer.

c. The wholesale distributor must also maintain and make available to the department, upon request, the lot number of such drug if not contained in the shipping document acquired by the recipient.

7. Failure of the manufacturer to provide, the recipient to acquire, or the wholesale distributor to deliver, the documentation required under subparagraph 6. shall constitute failure to acquire or deliver a pedigree paper under s. 499.0051. Forgery by the manufacturer, the recipient or the wholesale distributor of the documentation required to be acquired or delivered under subparagraph 6. shall constitute forgery of a pedigree paper under s. 499.0051.

8. The department may, by rule, specify alternatives to compliance with subparagraph 1. for a prescription drug in the inventory of a permitted prescription drug wholesaler as of June 30, 2006, and the return of a prescription drug purchased prior to July 1, 2006. The department may specify time limits for such alternatives.

Section 6. This act shall take effect July 1, 2006.

Approved by the Governor June 27, 2006.

Filed in Office Secretary of State June 27, 2006.