

1                                   A bill to be entitled  
2           An act relating to prescription drugs; creating s.  
3           499.029, F.S.; providing a short title; creating the  
4           Cancer Drug Donation Program; providing a purpose;  
5           providing definitions; providing conditions for the  
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 dispensing of cancer drugs and supplies  
10          to eligible patients; requiring a participant facility  
11          that accepts donated drugs and supplies through the  
12          program to comply with certain state and federal laws;  
13          authorizing a participant facility to charge fees under  
14          certain conditions; requiring the Department of Health,  
15          upon recommendation of the Board of Pharmacy, to adopt  
16          certain rules; providing for the ineligibility of certain  
17          persons to receive donated drugs; requiring the department  
18          to establish and maintain a participant facility registry;  
19          providing for the contents and availability of the  
20          participant facility registry; providing immunity from  
21          civil and criminal liability for donors or pharmaceutical  
22          manufacturers in certain circumstances; providing that in  
23          the event of conflict between the provisions in s.  
24          499.029, F.S., and provisions in ch. 465 or ch. 499, F.S.,  
25          the provisions in s. 499.029, F.S., shall control;  
26          providing an appropriation; amending s. 499.003, F.S.;  
27          revising the definition of the term "pedigree paper";

28 | authorizing the Department of Health to adopt rules and  
 29 | forms relating to pedigree paper requirements; amending s.  
 30 | 499.005, F.S.; revising a prohibited acts provision  
 31 | relating to pedigree papers; amending s. 499.0121, F.S.;  
 32 | requiring certain wholesale distributors taking title to a  
 33 | prescription drug to provide an invoice to the recipient  
 34 | containing certain information; requiring a recipient of a  
 35 | prescription drug to acquire from the manufacturer a  
 36 | shipping document containing specified information;  
 37 | requiring wholesale distributor to make certain  
 38 | information available to the department; providing for  
 39 | penalties; authorizing the department to adopt certain  
 40 | rules relating to the inventory and return of certain  
 41 | prescription drugs; providing an effective date.

42 |

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

44 |

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

47 | 499.029 Cancer Drug Donation Program.--

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

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

54 | (3) As used in this section:

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

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

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

67        (d) "Donor" means a patient or patient representative who  
68 donates cancer drugs or supplies needed to administer cancer  
69 drugs that have been maintained within a closed drug delivery  
70 system; health care facilities, nursing homes, hospices, or  
71 hospitals with closed drug delivery systems; or pharmacies, drug  
72 manufacturers, medical device manufacturers or suppliers, or  
73 wholesalers of drugs or supplies, in accordance with this  
74 section. "Donor" includes a physician licensed under chapter 458  
75 or chapter 459 who receives cancer drugs or supplies directly  
76 from a drug manufacturer, drug wholesaler, or pharmacy.

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

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

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

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

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

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

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

93           (l) "Pharmacist" means a person licensed under chapter  
 94 465.

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

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

99           (o) "Prescription drug" means a drug as defined in s.  
 100 465.003(8).

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

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

105           (4) Any donor may donate cancer drugs or supplies to a  
 106 participant facility that elects to participate in the program  
 107 and meets criteria established by the department for such

108 participation. Cancer drugs or supplies may not be donated to a  
109 specific cancer patient, and donated drugs or supplies may not  
110 be resold by the program. Cancer drugs billed to and paid for by  
111 Medicaid in long-term care facilities that are eligible for  
112 return to stock under federal Medicaid regulations shall be  
113 credited to Medicaid and are not eligible for donation under the  
114 program. A participant facility may provide dispensing and  
115 consulting services to individuals who are not patients of the  
116 hospital.

117 (5) The cancer drugs or supplies donated to the program  
118 may be prescribed only by a prescribing practitioner for use by  
119 an eligible patient and may be dispensed only by a pharmacist.

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

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

132 (c) Prior to being dispensed to an eligible patient, the  
133 cancer drug or supplies donated under the program shall be

134 inspected by a pharmacist to determine that the drug and  
135 supplies do not appear to have been tampered with or mislabeled.

136 (d) A dispenser of donated cancer drugs or supplies may  
137 not submit a claim or otherwise seek reimbursement from any  
138 public or private third-party payor for donated cancer drugs or  
139 supplies dispensed to any patient under the program, and a  
140 public or private third-party payor is not required to provide  
141 reimbursement to a dispenser for donated cancer drugs or  
142 supplies dispensed to any patient under the program.

143 (7) (a) A donation of cancer drugs or supplies shall be  
144 made only at a participant facility. A participant facility may  
145 decline to accept a donation. A participant facility that  
146 accepts donated cancer drugs or supplies under the program shall  
147 comply with all applicable provisions of state and federal law  
148 relating to the storage and dispensing of the donated cancer  
149 drugs or supplies.

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

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

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

162        (b) Standards and procedures for participant facilities  
163 that accept, store, distribute, or dispense donated cancer drugs  
164 or supplies.

165        (c) Necessary forms for administration of the program,  
166 including, but not limited to, forms for use by entities that  
167 donate, accept, distribute, or dispense cancer drugs or supplies  
168 under the program.

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

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

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

178        (9) A person who is eligible to receive cancer drugs or  
179 supplies under the state Medicaid program or under any other  
180 prescription drug program funded in whole or in part by the  
181 state, by any other prescription drug program funded in whole or  
182 in part by the Federal Government, or by any other prescription  
183 drug program offered by a third-party insurer, unless benefits  
184 have been exhausted, or a certain cancer drug or supply is not  
185 covered by the prescription drug program, is ineligible to  
186 participate in the program created under this section.

187        (10) The department shall establish and maintain a  
188 participant facility registry for the program. The participant  
189 facility registry shall include the participant facility's name,  
190 address, and telephone number. The department shall make the  
191 participant facility registry available on the department's  
192 website to any donor wishing to donate cancer drugs or supplies  
193 to the program. The department's website shall also contain  
194 links to cancer drug manufacturers that offer drug assistance  
195 programs or free medication.

196        (11) Any donor of cancer drugs or supplies, or any  
197 participant in the program, who exercises reasonable care in  
198 donating, accepting, distributing, or dispensing cancer drugs or  
199 supplies under the program and the rules adopted under this  
200 section shall be immune from civil or criminal liability and  
201 from professional disciplinary action of any kind for any  
202 injury, death, or loss to person or property relating to such  
203 activities.

204        (12) A pharmaceutical manufacturer is not liable for any  
205 claim or injury arising from the transfer of any cancer drug  
206 under this section, including, but not limited to, liability for  
207 failure to transfer or communicate product or consumer  
208 information regarding the transferred drug, as well as the  
209 expiration date of the transferred drug.

210        (13) If any conflict exists between the provisions in this  
211 section and the provisions in this chapter or chapter 465, the  
212 provisions in this section shall control the operation of the  
213 Cancer Drug Donation Program.



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

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

223           499.003 Definitions of terms used in ss. 499.001-  
 224 499.081.--As used in ss. 499.001-499.081, the term:

225           (31) "Pedigree paper" means:

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

228           (b)1. Effective July 1, 2006, a document or electronic  
 229 form approved by the Department of Health and containing  
 230 information that records each distribution of any given legend  
 231 drug, from sale by a pharmaceutical manufacturer, through  
 232 acquisition and sale by any wholesaler or repackager, until  
 233 final sale to a pharmacy or other person administering or  
 234 dispensing the drug. The information required to be included on  
 235 the form approved by the department pursuant to this  
 236 subparagraph ~~a legend drug's pedigree paper~~ must at least detail  
 237 the amount of the legend drug; its dosage form and strength; its  
 238 lot numbers; the name and address of each owner of the legend  
 239 drug and his or her signature; its shipping information,  
 240 including the name and address of each person certifying

241 delivery or receipt of the legend drug; an invoice number, a  
242 shipping document number, or another number uniquely identifying  
243 the transaction; and a certification that the recipient  
244 wholesaler has authenticated the pedigree papers. If the  
245 manufacturer or repackager has uniquely serialized the  
246 individual legend drug unit, that identifier must also be  
247 included on the form approved pursuant to this subparagraph  
248 pedigree. It must also include the name, address, telephone  
249 number and, if available, e-mail contact information of each  
250 wholesaler involved in the chain of the legend drug's custody;  
251 or

252 2. A statement, under oath, in written or electronic  
253 form, confirming that a wholesale distributor purchases and  
254 receives the specific unit of the prescription drug directly  
255 from the manufacturer of the prescription drug and distributes  
256 the prescription drug directly, or through an intracompany  
257 transfer, to a chain pharmacy warehouse or a person authorized  
258 by law to purchase prescription drugs for the purpose of  
259 administering or dispensing the drug, as defined in s. 465.003.  
260 For purposes of this paragraph, the term "chain pharmacy  
261 warehouse" means a wholesale distributor permitted pursuant to  
262 s. 499.01 that maintains a physical location for prescription  
263 drugs that functions solely as a central warehouse to perform  
264 intracompany transfers of such drugs to a member of its  
265 affiliated group as described in s. 499.0121(6)(h)1.

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

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

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

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

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

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

284  
 285        The department may ~~shall~~ adopt rules and forms ~~a form~~ relating  
 286 to the requirements of this subsection ~~paragraph~~ ~~no later than~~  
 287 ~~90 days after the effective date of this act.~~

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

290        499.005 Prohibited acts.--It is unlawful for a person to  
 291 perform or cause the performance of any of the following acts in  
 292 this state:

293        (29) The receipt of a prescription drug pursuant to a  
 294 wholesale distribution without either first receiving a pedigree

295 | paper that was attested to as accurate and complete by the  
 296 | wholesale distributor or complying with the provisions of s.  
 297 | 499.0121(6)(f)6.

298 | Section 5. Paragraph (f) of subsection (6) of section  
 299 | 499.0121, Florida Statutes, is amended to read:

300 | 499.0121 Storage and handling of prescription drugs;  
 301 | recordkeeping.--The department shall adopt rules to implement  
 302 | this section as necessary to protect the public health, safety,  
 303 | and welfare. Such rules shall include, but not be limited to,  
 304 | requirements for the storage and handling of prescription drugs  
 305 | and for the establishment and maintenance of prescription drug  
 306 | distribution records.

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

310 | (f)1. Effective July 1, 2006, each person who is engaged  
 311 | in the wholesale distribution of a prescription drug and who is  
 312 | not the manufacturer of that drug must, before each wholesale  
 313 | distribution of such drug, provide to the person who receives  
 314 | the drug a pedigree paper as defined in s. 499.003(31).

315 | 2. A repackager must comply with this paragraph.

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

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

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

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

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

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

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

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

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

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

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

366        7. Failure of the manufacturer to provide, the recipient  
367 to acquire, or the wholesale distributor to deliver, the  
368 documentation required under subparagraph 6. shall constitute  
369 failure to acquire or deliver a pedigree paper under s.  
370 499.0051. Forgery by the manufacturer, the recipient or the  
371 wholesale distributor of the documentation required to be  
372 acquired or delivered under subparagraph 6. shall constitute  
373 forgery of a pedigree paper under s. 499.0051.

374        8. The department may, by rule, specify alternatives to  
375 compliance with subparagraph 1. for a prescription drug in the

HB 371, Engrossed 2

2006

376 | inventory of a permitted prescription drug wholesaler as of June  
377 | 30, 2006, and the return of a prescription drug purchased prior  
378 | to July 1, 2006. The department may specify time limits for such  
379 | alternatives.

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