

1                                   A bill to be entitled  
 2       An act relating to public health initiatives; amending s.  
 3       381.98, F.S.; establishing the Florida Public Health  
 4       Institute, Inc., and deleting provisions relating to the  
 5       Florida Public Health Foundation, Inc.; providing purposes  
 6       of the institute; providing for the institute to operate  
 7       as a not-for-profit corporation; revising composition of  
 8       the board of directors; removing obsolete language  
 9       relating to certain research; requiring annual reports to  
 10      the Legislature; amending ss. 381.855, 381.911, and  
 11      381.981, F.S.; conforming terminology; amending s.  
 12      499.029, F.S.; renaming the Cancer Drug Donation Program  
 13      as the Prescription Drug Donation Program; revising  
 14      definitions; expanding the drugs and supplies that may be  
 15      donated under the program; expanding the types of  
 16      facilities and practitioners that may participate in the  
 17      program; conforming provisions to changes in terminology;  
 18      removing obsolete language relating to the adoption of  
 19      initial rules; providing an effective date.

20  
 21 Be It Enacted by the Legislature of the State of Florida:

22  
 23           Section 1. Section 381.98, Florida Statutes, is amended to  
 24   read:  
 25           381.98 The Florida Public Health Institute ~~Foundation~~,  
 26   Inc.; establishment; purpose; mission; duties; board of  
 27   directors.--

28           (1) The Florida Public Health Institute ~~Foundation~~, Inc.,  
 29 referred to in this section as "the corporation," is established  
 30 for the purpose of advancing the knowledge and practice of  
 31 public health, including disseminating breakthrough findings in  
 32 ~~biomedical research and promoting health awareness in this state~~  
 33 ~~and providing services to the Department of Health.~~

34           ~~(2) The corporation's mission includes disseminating~~  
 35 ~~information about innovative biomedical research and clinical~~  
 36 ~~trials in this state as well as making Floridians and their~~  
 37 ~~treatment providers aware of specified diseases and conditions~~  
 38 ~~and available methods of preventing, diagnosing, treating, and~~  
 39 ~~curing those diseases and conditions.~~

40           (2)~~(3)~~ The purpose and objective of the corporation shall  
 41 be to operate exclusively for charitable, scientific, and  
 42 educational purposes; to protect and improve the health and  
 43 well-being of Florida's people and environment through  
 44 partnerships committed to program innovation, education, applied  
 45 research, and policy development; and to engage in charitable  
 46 programs dedicated to improving the health of Floridians.

47           (3)~~(4)~~ The corporation shall be established as a not-for-  
 48 profit entity qualifying under s. 501(c)(3) of the Internal  
 49 Revenue Code. The corporation may receive, hold, invest, and  
 50 administer property and any moneys acquired from private, local,  
 51 state, and federal sources, as well as technical and  
 52 professional income generated or derived from the mission-  
 53 related activities of the corporation. The corporation shall  
 54 have all of the powers conferred upon corporations organized  
 55 under chapter 617.

56        ~~(4)-(5)~~ The corporation's duties include procuring funds  
57 necessary for accomplishing the purpose and mission of the  
58 corporation. The corporation shall strive to complement,  
59 supplement, and enhance the missions of the various  
60 organizations, entities, and departments that provide public  
61 health initiatives ~~represented on its board~~ by serving as the  
62 lead corporation in the state for promoting public health  
63 awareness.

64        ~~(5)-(6)~~ The affairs of the corporation shall be managed by  
65 an executive director appointed by a board of directors.  
66 ~~consisting of:~~

67        (6) (a) The board of directors shall be elected in  
68 accordance with the bylaws of the corporation and shall include,  
69 but not be limited to, the following:

70        1.(a) The State Surgeon General or his or her designee.

71        2.(b) A representative of the Florida Public Health  
72 Association ~~former member of the Senate~~ appointed by the  
73 ~~President of the Senate.~~

74        3.(c) Representatives of local health departments, with at  
75 least one representative each from the southern, central, and  
76 northern geographic areas of the state ~~A former member of the~~  
77 ~~House of Representatives~~ appointed by the Speaker of the House  
78 ~~of Representatives.~~

79        4.(d) Representatives of institutions of higher learning ~~A~~  
80 ~~representative of the American Heart Association.~~

81        5.(e) Representatives of the private health care provider  
82 sector, industry or business groups, or philanthropic

83 foundations ~~A representative of the American Cancer Society,~~  
 84 ~~Florida Division, Inc.~~

85 (b) The majority of board members may not be state  
 86 employees.

87 ~~(f) A representative of the American Lung Association of~~  
 88 ~~Florida.~~

89 ~~(g) A representative of the American Diabetes Association,~~  
 90 ~~South Coastal Region.~~

91 ~~(h) A representative of the Alzheimer's Association.~~

92 ~~(i) A representative of the Epilepsy Foundation.~~

93 ~~(j) A representative of the National Parkinson Foundation.~~

94 ~~(k) A representative of the March of Dimes, Florida~~  
 95 ~~Chapter.~~

96 ~~(l) A representative of the Arthritis Foundation, Florida~~  
 97 ~~Chapter.~~

98 ~~(m) A representative of the American Liver Foundation.~~

99 ~~(n) A representative of the Florida Council for Behavioral~~  
 100 ~~Healthcare, Inc.~~

101 ~~(o) A representative of the Florida Alcohol and Drug Abuse~~  
 102 ~~Association.~~

103 ~~(p) A representative of Pharmaceutical Research and~~  
 104 ~~Manufacturers of America.~~

105 ~~(q) A representative of the Florida Public Health~~  
 106 ~~Association.~~

107 ~~(r) A representative of the Florida Association of County~~  
 108 ~~Health Officers.~~

109 ~~(s) A public health academician selected by the State~~  
 110 ~~Health Officer.~~

111 ~~(t) A representative of the Florida Academy of Family~~  
112 ~~Physicians.~~

113 ~~(u) Three consumers who have demonstrated an interest in~~  
114 ~~protecting the public health appointed by the Florida Public~~  
115 ~~Health Association.~~

116 ~~(v) A representative of the Florida Association of Health~~  
117 ~~Plans.~~

118 ~~(7) Members of the board of directors shall serve for 2-~~  
119 ~~year terms and shall serve without compensation. Each~~  
120 ~~organization represented on the board of directors shall cover~~  
121 ~~the expenses of its representative.~~

122 ~~(8) The corporation, in consultation with the Department~~  
123 ~~of Health and the Florida Center for Universal Research to~~  
124 ~~Eradicate Disease, shall facilitate communication between~~  
125 ~~biomedical researchers and health care providers each month~~  
126 ~~according to the health awareness schedule established by the~~  
127 ~~Florida Public Health Foundation, Inc., in order to ensure~~  
128 ~~ongoing dialogue between researchers, treatment providers, and~~  
129 ~~the department.~~

130 (7)~~(9)~~ The corporation and the Department of Health shall  
131 enter into partnerships with providers of continuing education  
132 for health care practitioners, including, but not limited to,  
133 hospitals and state and local medical organizations, to ensure  
134 that practitioners are aware of the most recent and complete  
135 diagnostic and treatment tools.

136 (8)~~(10)~~ The corporation may provide personnel to the  
137 Department of Health for the purpose of performing duties and  
138 responsibilities outlined in private and public grants received

139 by the Department of Health. These personnel are not state  
140 employees and are not entitled to retirement credit and other  
141 benefits provided to state employees under chapters 110 and 112.  
142 These personnel shall perform services pursuant to an agreement  
143 between the corporation and the Department of Health.

144 (9)~~(11)~~ The corporation may purchase goods, services, and  
145 property for use by the Department of Health. These purchases  
146 are not subject to the provisions of chapters 253, 255, and 287,  
147 nor to the control or direction of the Department of  
148 Environmental Protection or the Department of Management  
149 Services.

150 (10)~~(12)~~ The corporation shall provide an annual report  
151 concerning its activities ~~and finances to the Florida Center for~~  
152 ~~Universal Research to Eradicate Disease and shall provide copies~~  
153 ~~of the annual report to the Governor,~~ the President of the  
154 Senate, and the Speaker of the House of Representatives.

155 Section 2. Paragraph (a) of subsection (5) of section  
156 381.855, Florida Statutes, is amended to read:

157 381.855 Florida Center for Universal Research to Eradicate  
158 Disease.--

159 (5) There is established within the center an advisory  
160 council that shall meet at least annually.

161 (a) The council shall consist of one representative from a  
162 Florida not-for-profit institution engaged in basic and clinical  
163 biomedical research and education which receives more than \$10  
164 million in annual grant funding from the National Institutes of  
165 Health, to be appointed by the State Surgeon General from a

166 different institution each term, and one representative from and  
 167 appointed by each of the following entities:

- 168 1. Enterprise Florida, Inc.
- 169 2. BioFlorida.
- 170 3. The Biomedical Research Advisory Council.
- 171 4. The Florida Medical Foundation.
- 172 5. Pharmaceutical Research and Manufacturers of America.
- 173 6. The Florida Cancer Council.
- 174 7. The American Cancer Society, Florida Division, Inc.
- 175 8. The American Heart Association.
- 176 9. The American Lung Association of Florida.
- 177 10. The American Diabetes Association, South Coastal  
 178 Region.
- 179 11. The Alzheimer's Association.
- 180 12. The Epilepsy Foundation.
- 181 13. The National Parkinson Foundation.
- 182 14. The Florida Public Health Institute ~~Foundation~~, Inc.
- 183 15. The Florida Research Consortium.

184 Section 3. Section 381.911, Florida Statutes, is amended  
 185 to read:

186 381.911 Prostate Cancer Awareness Program.--

187 (1) To the extent that funds are specifically made  
 188 available for this purpose, the Prostate Cancer Awareness  
 189 Program is established within the Department of Health. The  
 190 purpose of this program is to implement the recommendations of  
 191 January 2000 of the Florida Prostate Cancer Task Force to  
 192 provide for statewide outreach and health education activities  
 193 to ensure that men are aware of and appropriately seek medical

194 counseling for prostate cancer as an early-detection health care  
195 measure.

196 (2) For purposes of implementing the program, the  
197 Department of Health and the Florida Public Health Institute  
198 ~~Foundation~~, Inc., may:

199 (a) Conduct activities directly or enter into a contract  
200 with a qualified nonprofit community education entity.

201 (b) Seek any available gifts, grants, or funds from the  
202 state, the Federal Government, philanthropic foundations, and  
203 industry or business groups.

204 (3) A prostate cancer advisory committee is created to  
205 advise and assist the Department of Health and the Florida  
206 Public Health Institute ~~Foundation~~, Inc., in implementing the  
207 program.

208 (a) The State Surgeon General shall appoint the advisory  
209 committee members, who shall consist of:

210 1. Three persons from prostate cancer survivor groups or  
211 cancer-related advocacy groups.

212 2. Three persons who are scientists or clinicians from  
213 public universities or research organizations.

214 3. Three persons who are engaged in the practice of a  
215 cancer-related medical specialty from health organizations  
216 committed to cancer research and control.

217 (b) Members shall serve without compensation but are  
218 entitled to reimbursement, pursuant to s. 112.061, for per diem  
219 and travel expenses incurred in the performance of their  
220 official duties.



221 (4) The program shall coordinate its efforts with those of  
 222 the Florida Public Health Institute ~~Foundation~~, Inc.

223 Section 4. Section 381.981, Florida Statutes, is amended  
 224 to read:

225 381.981 Health awareness campaigns.--

226 (1) The Florida Public Health Institute ~~Foundation~~, Inc.,  
 227 in consultation with the Department of Health, shall coordinate  
 228 monthly health awareness campaigns with national, state, and  
 229 local health care organizations and government entities  
 230 targeting a wide range of the public, including: parents;  
 231 teachers and other school employees; students in 4th through  
 232 12th grades, colleges, and universities; state agency employees;  
 233 county and local government employees; patients of county health  
 234 departments; Medicaid recipients; health care professionals and  
 235 providers; and the public in general.

236 (2) The awareness campaigns shall include the provision of  
 237 educational information about preventing, detecting, treating,  
 238 and curing the following diseases or conditions. Additional  
 239 diseases and conditions that impact the public health may be  
 240 added by the board of directors of the Florida Public Health  
 241 Institute ~~Foundation~~, Inc.; however, each of the following  
 242 diseases or conditions must be included in an awareness campaign  
 243 during at least 1 month in any 24-month period:

244 (a) Cancer, including breast, prostate, cervical, ovarian,  
 245 colorectal, and skin cancer and leukemia.

246 (b) Heart disease.

247 (c) Stroke.

- 248 (d) Lung disease, including asthma and smoking-relating  
 249 disease.
- 250 (e) Neurological disorders and disease, including  
 251 Alzheimer's disease, Parkinson's disease, and epilepsy.
- 252 (f) Gastrointestinal disease.
- 253 (g) Kidney disease.
- 254 (h) Diabetes.
- 255 (i) Liver disease.
- 256 (j) Autoimmune disorders.
- 257 (k) Birth defects and prenatal care.
- 258 (l) Obesity and malnutrition.
- 259 (m) Sexually transmissible disease.
- 260 (n) Hepatitis A, hepatitis B, and hepatitis C.
- 261 (o) Arthritis.
- 262 (p) Vaccine-preventable diseases.
- 263 (q) Infectious diseases, including HIV/AIDS.
- 264 (r) Substance abuse.
- 265 (s) Mental illness.
- 266 (t) Lupus.
- 267 (u) Osteoporosis.
- 268 (3) The health awareness campaigns shall be funded by the  
 269 Florida Public Health Institute ~~Foundation~~, Inc., and the  
 270 Department of Health to the extent that funds are available from  
 271 public and private sources.
- 272 (4) Health awareness information shall be disseminated  
 273 through all available methods, including print, audio, visual,  
 274 and electronic media.
- 275 Section 5. Section 499.029, Florida Statutes, is amended

276 to read:

277 499.029 Prescription Cancer Drug Donation Program.--

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

280 (2) There is created a Prescription Cancer Drug Donation  
281 Program within the department for the purpose of authorizing and  
282 facilitating the donation of prescription cancer drugs and  
283 supplies to eligible patients.

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

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

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

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

298 (c) "Donor" means a patient or patient representative who  
299 donates prescription cancer drugs or supplies needed to  
300 administer prescription cancer drugs that have been maintained  
301 within a closed drug delivery system; health care facilities,  
302 nursing homes, hospices, or hospitals with closed drug delivery  
303 systems; or pharmacies, prescription drug manufacturers, medical

304 device manufacturers or suppliers, or wholesalers of  
 305 prescription drugs or supplies, in accordance with this section.  
 306 The term "~~Donor~~" includes a physician licensed under chapter 458  
 307 or chapter 459 who receives prescription ~~cancer~~ drugs or  
 308 supplies directly from a prescription drug manufacturer,  
 309 wholesale distributor, or pharmacy.

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

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

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

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

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

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

329 (4) Any donor may donate prescription ~~cancer~~ drugs or  
 330 supplies to a participant ~~facility~~ that elects to participate in  
 331 the program and meets criteria established by the department for

332 such participation. Prescription ~~Cancer~~ drugs or supplies may  
333 not be donated to a specific ~~cancer~~ patient, and donated  
334 prescription drugs or supplies may not be resold by the  
335 participant ~~program~~. Prescription ~~Cancer~~ drugs billed to and  
336 paid for by Medicaid in long-term care facilities that are  
337 eligible for return to stock under federal Medicaid regulations  
338 shall be credited to Medicaid and are not eligible for donation  
339 under the program. A participant ~~facility~~ may provide dispensing  
340 and counseling ~~consulting~~ services to an eligible patient  
341 ~~individuals~~ who is ~~are~~ not a patient ~~patients~~ of the participant  
342 ~~hospital~~.

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

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

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

359 (c) Before ~~Prior to~~ being dispensed to an eligible

360 patient, the prescription ~~cancer~~ drug or supplies donated under  
 361 the program shall be inspected by a pharmacist or dispensing  
 362 practitioner to determine that the drug and supplies do not  
 363 appear to have been tampered with or mislabeled.

364 (d) A dispenser of donated prescription ~~cancer~~ drugs or  
 365 supplies may not submit a claim or otherwise seek reimbursement  
 366 from any public or private third-party payor for donated  
 367 prescription ~~cancer~~ drugs or supplies dispensed to any patient  
 368 under the program, and a public or private third-party payor is  
 369 not required to provide reimbursement to a dispenser for donated  
 370 prescription ~~cancer~~ drugs or supplies dispensed to any patient  
 371 under the program.

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

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

385 (8) The department, upon the recommendation of the Board  
 386 of Pharmacy, shall adopt rules to carry out the provisions of  
 387 this section. ~~Initial rules under this section shall be adopted~~

388 ~~no later than 90 days after the effective date of this act.~~ The  
 389 rules shall include, but not be limited to:

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

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

395 (c) Necessary forms for administration of the program,  
 396 including, but not limited to, forms for use by entities that  
 397 donate, accept, distribute, or dispense prescription ~~cancer~~  
 398 drugs or supplies under the program.

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

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

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

408 (9) A person who is eligible to receive prescription  
 409 ~~cancer~~ drugs or supplies under the state Medicaid program or  
 410 under any other prescription drug program funded in whole or in  
 411 part by the state, by any other prescription drug program funded  
 412 in whole or in part by the Federal Government, or by any other  
 413 prescription drug program offered by a third-party insurer,  
 414 unless benefits have been exhausted, or a certain prescription  
 415 ~~cancer~~ drug or supply is not covered by the prescription drug

416 program, is ineligible to participate in the program created  
417 under this section.

418 (10) The department shall establish and maintain a  
419 participant ~~facility~~ registry for the program. The participant  
420 ~~facility~~ registry shall include the participant's ~~participant~~  
421 ~~facility's~~ name, address, and telephone number. The department  
422 shall make the participant ~~facility~~ registry available on the  
423 department's website to any donor wishing to donate prescription  
424 ~~cancer~~ drugs or supplies to the program. The department's  
425 website shall also contain links to prescription ~~cancer~~ drug  
426 manufacturers that offer drug assistance programs or free  
427 medication.

428 (11) Any donor of prescription ~~cancer~~ drugs or supplies,  
429 or any participant in the program, who exercises reasonable care  
430 in donating, accepting, distributing, or dispensing prescription  
431 ~~cancer~~ drugs or supplies under the program and the rules adopted  
432 under this section is ~~shall be~~ immune from civil or criminal  
433 liability and from professional disciplinary action of any kind  
434 for any injury, death, or loss to person or property relating to  
435 such activities.

436 (12) A pharmaceutical manufacturer is not liable for any  
437 claim or injury arising from the transfer of any prescription  
438 ~~cancer~~ drug under this section, including, but not limited to,  
439 liability for failure to transfer or communicate product or  
440 consumer information regarding the transferred drug, as well as  
441 the expiration date of the transferred drug.

442 (13) If any conflict exists between the provisions in this  
443 section and the provisions in this chapter or chapter 465, the



HB 331, Engrossed 1

2009

444 | provisions in this section shall control the operation of the  
445 | ~~Cancer Drug Donation~~ program.

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

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