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LEGISLATIVE ACTION

Senate

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House

Senator Soto moved the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause
and insert:

Section 1. Section 381.986, Florida Statutes, is amended to
read:

381.986 Compassionate use of ~~low-THC~~ cannabis.—

(1) DEFINITIONS.—As used in this section, the term:

(a) “Applicant” means a person that has submitted an
application to the department for licensure or renewal as a
dispensing organization.



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12 (b) "Batch" means a specific quantity of cannabis product
13 that is intended to have uniform character and quality, within
14 specified limits, and is produced at the same time from one or
15 more harvests.

16 (e) "Dispensing organization" means an applicant licensed
17 organization approved by the department to cultivate, process,
18 and dispense low-THC cannabis pursuant to this section.

19 (c) ~~(b)~~ "Low-THC Cannabis" means a plant of the genus
20 Cannabis, the dried flowers of which contain 0.8 percent or less
21 of tetrahydrocannabinol and more than 10 percent of cannabidiol
22 weight for weight; the seeds thereof; the resin extracted from
23 any part of such plant; or any compound, manufacture, salt,
24 derivative, mixture, or preparation of such plant or its seeds
25 or resin that is dispensed only from a dispensing organization.

26 (d) "Cannabis product" means any product derived from
27 cannabis, including the resin extracted from any part of such
28 plant or any compound, manufacture, salt, derivative, mixture,
29 or preparation of such plant or its seeds or resin which is
30 dispensed from a dispensing organization. Cannabis products
31 include, but are not limited to, oils, tinctures, creams,
32 encapsulations, and food products. Cannabis food products may
33 not include candy or similar confectionary products that appeal
34 to children. All cannabis products must maintain concentrations,
35 weight for weight, of more than 10 percent of cannabidiol.

36 (f) "Harvest" means a specifically identified and numbered
37 quantity of cannabis cultivated using the same herbicides,
38 pesticides, and fungicides and harvested at the same time from a
39 single facility.

40 (g) "Independent testing laboratory" means a laboratory,



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41 and the managers, employees, or contractors of the laboratory,
42 which have no direct or indirect interest in a dispensing
43 organization.

44 (h)(e) "Medical use" means administration of the ordered
45 amount of ~~low-THC~~ cannabis. The term does not include:

46 1. The possession, use, or administration by smoking.

47 2. ~~The term also does not include~~ The transfer of ~~low-THC~~
48 cannabis to a person other than the qualified patient for whom
49 it was ordered or the qualified patient's legal representative
50 who is registered in the compassionate use registry on behalf of
51 the qualified patient.

52 3. The use or administration of cannabis or cannabis
53 products:

54 a. On any form of public transportation.

55 b. In any public place.

56 c. In a registered qualified patient's place of work, if
57 restricted by his or her employer.

58 d. In a correctional facility.

59 e. On the grounds of any preschool, primary school, or
60 secondary school.

61 f. On a school bus.

62 (i)(d) "Qualified patient" means a resident of this state
63 who has been added to the compassionate use registry by a
64 physician licensed under chapter 458 or chapter 459 to receive
65 ~~low-THC~~ cannabis from a dispensing organization.

66 (j)(e) "Smoking" means burning or igniting a substance and
67 inhaling the smoke. Smoking does not include the use of a
68 vaporizer.

69 (2) PHYSICIAN ORDERING.—



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70 (a) ~~Effective January 1, 2015,~~ A physician licensed under
71 chapter 458 or chapter 459 who has examined and is treating a
72 patient suffering from cancer, human immunodeficiency virus,
73 acquired immune deficiency syndrome, epilepsy, amyotrophic
74 lateral sclerosis, autism, multiple sclerosis, Crohn's disease,
75 Parkinson's disease, paraplegia, quadriplegia, or terminal
76 illness ~~a physical medical condition that chronically produces~~
77 ~~symptoms of seizures or severe and persistent muscle spasms~~ may
78 order for the patient's medical use ~~low-THC~~ cannabis to treat
79 such disease, disorder, or condition; ~~or~~ to alleviate symptoms
80 of such disease, disorder, or condition; or to alleviate
81 symptoms caused by a treatment for such disease, disorder, or
82 condition, if no other satisfactory alternative treatment
83 options exist for that patient and all of the following
84 conditions apply:

85 1. ~~(a)~~ The patient is a permanent resident of this state.

86 2. ~~(b)~~ The physician determines that the risks of ordering
87 ~~low-THC~~ cannabis are reasonable in light of the potential
88 benefit for that patient. If a patient is younger than 18 years
89 of age, a second physician must concur with this determination,
90 and such determination must be documented in the patient's
91 medical record.

92 3. ~~(c)~~ The physician registers the patient, the patient's
93 legal representative if requested by the patient, and himself or
94 herself as the orderer of ~~low-THC~~ cannabis for the named patient
95 on the compassionate use registry maintained by the department
96 and updates the registry to reflect the contents of the order.
97 If the patient is a minor, the physician must register a legal
98 representative on the compassionate use registry. The physician



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99 shall deactivate the patient's registration when treatment is
100 discontinued.

101 ~~4.(d)~~ The physician maintains a patient treatment plan that
102 includes the dose, route of administration, planned duration,
103 and monitoring of the patient's symptoms and other indicators of
104 tolerance or reaction to the ~~low-THC~~ cannabis.

105 ~~5.(e)~~ The physician submits the patient treatment plan, as
106 well as any other requested medical records, quarterly to the
107 University of Florida College of Pharmacy for research on the
108 safety and efficacy of ~~low-THC~~ cannabis on patients pursuant to
109 subsection (8).

110 ~~6.(f)~~ The physician obtains the voluntary informed consent
111 of the patient or the patient's legal guardian to treatment with
112 ~~low-THC~~ cannabis after sufficiently explaining the current state
113 of knowledge in the medical community of the effectiveness of
114 treatment of the patient's conditions or symptoms ~~condition~~ with
115 ~~low-THC~~ cannabis, the medically acceptable alternatives, and the
116 potential risks and side effects.

117 (b) A physician who improperly orders cannabis is subject
118 to disciplinary action under the applicable practice act and
119 under s. 456.072(1)(k).

120 (3) PENALTIES.—

121 (a) A physician commits a misdemeanor of the first degree,
122 punishable as provided in s. 775.082 or s. 775.083, if the
123 physician orders ~~low-THC~~ cannabis for a patient without a
124 reasonable belief that the patient is suffering from at least
125 one of the conditions listed in subsection (2).÷

126 ~~1. Cancer or a physical medical condition that chronically~~
127 ~~produces symptoms of seizures or severe and persistent muscle~~



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128 ~~spasms that can be treated with low-THC cannabis; or~~
129 ~~2. Symptoms of cancer or a physical medical condition that~~
130 ~~chronically produces symptoms of seizures or severe and~~
131 ~~persistent muscle spasms that can be alleviated with low-THC~~
132 ~~cannabis.~~

133 (b) Any person who fraudulently represents that he or she
134 has at least one condition listed in subsection (2) ~~cancer or a~~
135 ~~physical medical condition that chronically produces symptoms of~~
136 ~~seizures or severe and persistent muscle spasms~~ to a physician
137 for the purpose of being ordered ~~low-THC~~ cannabis by such
138 physician commits a misdemeanor of the first degree, punishable
139 as provided in s. 775.082 or s. 775.083.

140 (4) PHYSICIAN EDUCATION.—

141 (a) Before ordering ~~low-THC~~ cannabis for use by a patient
142 in this state, the appropriate board shall require the ordering
143 physician licensed under chapter 458 or chapter 459 to
144 successfully complete an 8-hour course and subsequent
145 examination offered by the Florida Medical Association or the
146 Florida Osteopathic Medical Association that encompasses the
147 clinical indications for the appropriate use of ~~low-THC~~
148 cannabis, the appropriate delivery mechanisms, the
149 contraindications for such use, as well as the relevant state
150 and federal laws governing the ordering, dispensing, and
151 possessing of this substance. The first course and examination
152 shall be presented by October 1, 2014, and shall be administered
153 at least annually thereafter. Successful completion of the
154 course may be used by a physician to satisfy 8 hours of the
155 continuing medical education requirements required by his or her
156 respective board for licensure renewal. This course may be



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157 offered in a distance learning format.

158 (b) The appropriate board shall require the medical
159 director of each dispensing organization approved under
160 subsection (5) to successfully complete a 2-hour course and
161 subsequent examination offered by the Florida Medical
162 Association or the Florida Osteopathic Medical Association that
163 encompasses appropriate safety procedures and knowledge of ~~low-~~
164 ~~THC~~ cannabis.

165 (c) Successful completion of the course and examination
166 specified in paragraph (a) is required for every physician who
167 orders ~~low-THC~~ cannabis each time such physician renews his or
168 her license. In addition, successful completion of the course
169 and examination specified in paragraph (b) is required for the
170 medical director of each dispensing organization each time such
171 physician renews his or her license.

172 (d) A physician who fails to comply with this subsection
173 and who orders ~~low-THC~~ cannabis may be subject to disciplinary
174 action under the applicable practice act and under s.
175 456.072(1)(k).

176 (5) DUTIES AND POWERS OF THE DEPARTMENT. ~~By January 1,~~
177 ~~2015, The department shall:~~

178 (a) The department shall create a secure, electronic, and
179 online compassionate use registry for the registration of
180 physicians and patients as provided under this section. The
181 registry must be accessible to law enforcement agencies and to a
182 dispensing organization in order to verify patient authorization
183 for ~~low-THC~~ cannabis and record the ~~low-THC~~ cannabis dispensed.
184 The registry must prevent an active registration of a patient by
185 multiple physicians.



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186 (b)1. Beginning 7 days after the effective date of this
187 act, the department shall accept applications for licensure as a
188 dispensing organization. The department shall review each
189 application to determine whether the applicant meets the
190 criteria in subsection (6) and qualifies for licensure.

191 2. Within 10 days after receiving an application for
192 licensure, the department shall examine the application, notify
193 the applicant of any apparent errors or omissions, and request
194 any additional information the department is allowed by law to
195 require. An application for licensure must be filed with the
196 department no later than 5 p.m. on the 30th day after the
197 effective date of this act, and all applications must be
198 complete no later than 5 p.m. on the 60th day after the
199 effective date of this act.

200 3. Prior to the 75th day after the effective date of this
201 act, the department shall select by lottery two applicants who
202 meet the criteria in subsection (6) in each of the following
203 regions:

204 a. Northwest Florida, consisting of Bay, Calhoun, Escambia,
205 Franklin, Gadsden, Gulf, Holmes, Jackson, Jefferson, Leon,
206 Liberty, Madison, Santa Rosa, Okaloosa, Taylor, Wakulla, Walton,
207 and Washington Counties.

208 b. Northeast Florida, consisting of Alachua, Baker,
209 Bradford, Clay, Columbia, Dixie, Duval, Flagler, Gilchrist,
210 Hamilton, Lafayette, Levy, Marion, Nassau, Putnam, St. Johns,
211 Suwannee, and Union Counties.

212 c. Central Florida, consisting of Brevard, Citrus, Hardee,
213 Hernando, Hillsborough, Indian River, Lake, Orange, Osceola,
214 Pasco, Pinellas, Polk, Seminole, St. Lucie, Sumter, and Volusia



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215 Counties.
216 d. Southwest Florida, consisting of Charlotte, Collier,
217 DeSoto, Glades, Hendry, Highlands, Lee, Manatee, Okeechobee, and
218 Sarasota Counties.
219 e. Southeast Florida, consisting of Broward, Miami-Dade,
220 Martin, Monroe, and Palm Beach Counties.
221 4. After the department has selected by lottery the 10
222 dispensing organizations pursuant to subparagraph 3., the
223 department shall select by lottery 10 more applicants who meet
224 the criteria in subsection (6) for licensure. Once licensed,
225 those applicants are authorized to operate in any region in the
226 state, but a dispensing organization may not have cultivation or
227 processing facilities outside the region in which it is
228 licensed.
229 5. The department shall license an applicant selected
230 pursuant to subparagraph 3. or subparagraph 4. unless the
231 applicant fails to pay the licensure fee within 10 days of
232 selection. If a selected applicant fails to timely pay the
233 licensure fee, the department shall select by lottery another
234 applicant from the existing pool of eligible applicants.
235 6. If the department revokes a license or denies the
236 renewal of a license pursuant to paragraph (f), the department
237 shall conduct a new lottery using the selection process outlined
238 in this paragraph. The selection process must begin 24 hours
239 after such revocation or denial.
240 7. If the department does not have a sufficient pool of
241 qualified applicants to issue 2 licenses in each region, or to
242 license 10 dispensing organizations pursuant to subparagraph 4.,
243 the department shall conduct a lottery using the process in this



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244 paragraph every 6 months until each region has 2 licensed
245 dispensing organizations and 10 additional dispensing
246 organizations are licensed, totaling 20 licensed dispensing
247 organizations in this state.

248 8. This section is exempt from s. 120.60(1) ~~Authorize the~~
249 ~~establishment of five dispensing organizations to ensure~~
250 ~~reasonable statewide accessibility and availability as necessary~~
251 ~~for patients registered in the compassionate use registry and~~
252 ~~who are ordered low-THC cannabis under this section, one in each~~
253 ~~of the following regions: northwest Florida, northeast Florida,~~
254 ~~central Florida, southeast Florida, and southwest Florida.~~

255 (c) The department shall use ~~develop~~ an application form
256 that requires the applicant to state:

257 1. Whether the application is for initial licensure or
258 renewal licensure;

259 2. The name, the physical address, the mailing address, the
260 address listed on the Department of Agriculture and Consumer
261 Services certificate required in paragraph (6)(b), and the
262 contact information for the applicant and for the nursery that
263 holds the Department of Agriculture and Consumer Services
264 certificate, if different from the applicant;

265 3. The name, address, and contact information for the
266 operating nurseryman of the organization that holds the
267 Department of Agriculture and Consumer Services certificate;

268 4. The name, address, license number, and contact
269 information for the applicant's medical director; and

270 5. All information required to be included by subsection
271 (6).

272 (d) The department shall ~~and~~ impose an initial application



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273 ~~fee of \$50,000, an initial licensure fee of \$125,000, and a~~
274 ~~biennial renewal fee of \$125,000 that is sufficient to cover the~~
275 ~~costs of administering this section. An applicant for approval~~
276 ~~as a dispensing organization must be able to demonstrate:~~

277 ~~1. The technical and technological ability to cultivate and~~
278 ~~produce low-THC cannabis. The applicant must possess a valid~~
279 ~~certificate of registration issued by the Department of~~
280 ~~Agriculture and Consumer Services pursuant to s. 581.131 that is~~
281 ~~issued for the cultivation of more than 400,000 plants, be~~
282 ~~operated by a nurseryman as defined in s. 581.011, and have been~~
283 ~~operated as a registered nursery in this state for at least 30~~
284 ~~continuous years.~~

285 ~~2. The ability to secure the premises, resources, and~~
286 ~~personnel necessary to operate as a dispensing organization.~~

287 ~~3. The ability to maintain accountability of all raw~~
288 ~~materials, finished products, and any byproducts to prevent~~
289 ~~diversion or unlawful access to or possession of these~~
290 ~~substances.~~

291 ~~4. An infrastructure reasonably located to dispense low-THC~~
292 ~~cannabis to registered patients statewide or regionally as~~
293 ~~determined by the department.~~

294 ~~5. The financial ability to maintain operations for the~~
295 ~~duration of the 2-year approval cycle, including the provision~~
296 ~~of certified financials to the department. Upon approval, the~~
297 ~~applicant must post a \$5 million performance bond.~~

298 ~~6. That all owners and managers have been fingerprinted and~~
299 ~~have successfully passed a level 2 background screening pursuant~~
300 ~~to s. 435.04.~~

301 ~~7. The employment of a medical director who is a physician~~



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302 ~~licensed under chapter 458 or chapter 459 to supervise the~~
303 ~~activities of the dispensing organization.~~

304 (e) The department shall inspect each dispensing
305 organization's properties, cultivation facilities, processing
306 facilities, and retail facilities before they begin operations
307 and at least once every 2 years thereafter. The department may
308 conduct additional announced or unannounced inspections,
309 including followup inspections, at reasonable hours in order to
310 ensure that such property and facilities maintain compliance
311 with all applicable requirements in subsections (6) and (7) and
312 to ensure that the dispensing organization has not committed any
313 other act that would endanger the health, safety, or security of
314 a qualified patient, dispensing organization staff, or the
315 community in which the dispensing organization is located.
316 Licensure under this section constitutes permission for the
317 department to enter and inspect the premises and facilities of
318 any dispensing organization. The department may inspect any
319 licensed dispensing organization, and a dispensing organization
320 must make all facility premises, equipment, documents, cannabis,
321 and cannabis products available to the department upon
322 inspection. The department may test any cannabis or cannabis
323 product in order to ensure that it is safe for human consumption
324 and that it meets the requirements in this section.

325 (f) The department may suspend or revoke a license, deny or
326 refuse to renew a license, or impose an administrative penalty
327 not to exceed \$10,000 for the following acts or omissions:

- 328 1. A violation of this section or department rule.
329 2. Failing to maintain qualifications for licensure.
330 3. Endangering the health, safety, or security of a



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331 qualified patient.

332 4. Improperly disclosing personal and confidential
333 information of the qualified patient.

334 5. Attempting to procure a license by bribery or fraudulent
335 misrepresentation.

336 6. Being convicted or found guilty of, or entering a plea
337 of nolo contendere to, regardless of adjudication, a crime in
338 any jurisdiction which directly relates to the business of a
339 dispensing organization.

340 7. Making or filing a report or record that the licensee
341 knows to be false.

342 8. Willfully failing to maintain a record required by this
343 section or rule of the department.

344 9. Willfully impeding or obstructing an employee or agent
345 of the department in the furtherance of his or her official
346 duties.

347 10. Engaging in fraud or deceit, negligence, incompetence,
348 or misconduct in the business practices of a dispensing
349 organization.

350 11. Making misleading, deceptive, or fraudulent
351 representations in or related to the business practices of a
352 dispensing organization.

353 12. Having a license or the authority to engage in any
354 regulated profession, occupation, or business that is related to
355 the business practices of a dispensing organization revoked,
356 suspended, or otherwise acted against, including the denial of
357 licensure, by the licensing authority of any jurisdiction,
358 including its agencies or subdivisions, for a violation that
359 would constitute a violation under state law. A licensing



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360 authority's acceptance of a relinquishment of licensure or a
361 stipulation, consent order, or other settlement, offered in
362 response to or in anticipation of the filing of charges against
363 the license, shall be construed as an action against the
364 license.

365 13. Violating a lawful order of the department or an agency
366 of the state, or failing to comply with a lawfully issued
367 subpoena of the department or an agency of the state.

368 (g) The department shall create a permitting process for
369 all dispensing organization vehicles used for the transportation
370 of cannabis or cannabis products.

371 (h) ~~(e)~~ The department shall monitor physician registration
372 and ordering of ~~low-THC~~ cannabis for ordering practices that
373 could facilitate unlawful diversion or misuse of ~~low-THC~~
374 cannabis and take disciplinary action as indicated.

375 (i) ~~(d)~~ The department shall adopt rules as necessary to
376 implement this section.

377 (6) DISPENSING ORGANIZATION.—

378 (a) An applicant seeking licensure as a dispensing
379 organization, or the renewal of its license, must submit an
380 application to the department. The department must review all
381 applications for completeness, including an appropriate
382 inspection of the applicant's property and facilities to verify
383 the authenticity of the information provided in, or in
384 connection with, the application. An applicant authorizes the
385 department to inspect his or her property and facilities for
386 licensure by applying under this subsection.

387 (b) In order to receive or maintain licensure as a
388 dispensing organization, an applicant must provide proof that:



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389 1. The applicant, or a separate entity that is owned solely
390 by the same persons or entities in the same ratio as the
391 applicant, possesses a valid certificate of registration issued
392 by the Department of Agriculture and Consumer Services pursuant
393 to s. 581.131 for the cultivation of more than 400,000 plants,
394 is operated by a nurseryman as defined in s. 581.011, and has
395 been operated as a registered nursery in this state for at least
396 30 continuous years.

397 2. The personnel on staff or under contract for the
398 applicant have experience cultivating and introducing multiple
399 varieties of plants in this state, including plants that are not
400 native to Florida; experience with propagating plants; and
401 experience with genetic modification or breeding of plants.

402 3. The personnel on staff or under contract for the
403 applicant include at least one person who:

404 a. Has at least 5 years' experience with United States
405 Department of Agriculture Good Agricultural Practices and Good
406 Handling Practices;

407 b. Has at least 5 years' experience with United States Food
408 and Drug Administration Good Manufacturing Practices for food
409 production;

410 c. Has a doctorate degree in organic chemistry or
411 microbiology;

412 d. Has at least 5 years' of experience with laboratory
413 procedures which includes analytical laboratory quality control
414 measures, chain of custody procedures, and analytical laboratory
415 methods;

416 e. Has experience with cannabis cultivation and processing,
417 including cannabis extraction techniques and producing cannabis



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418 products;
419 f. Has experience and qualifications in chain of custody or
420 other tracking mechanisms;
421 g. Works solely on inventory control; and
422 h. Works solely for security purposes.
423 4. The persons who have a direct or indirect interest in
424 the dispensing organization and the applicant's managers,
425 employees, and contractors who directly interact with cannabis
426 or cannabis products have been fingerprinted and have
427 successfully passed a level 2 background screening pursuant to
428 s. 435.04.
429 5. The applicant owns, or has at least a 2-year lease of,
430 all properties, facilities, and equipment necessary for the
431 cultivation and processing of cannabis. The applicant must
432 provide a detailed description of each facility and its
433 equipment, a cultivation and processing plan, and a detailed
434 floor plan. The description must include proof that:
435 a. The applicant is capable of sufficient cultivation and
436 processing to serve at least 15,000 patients with an assumed
437 daily use of 1,000 mg per patient per day of cannabis or
438 cannabis product;
439 b. The applicant has arranged for access to all utilities
440 and resources necessary to cultivate or process cannabis at each
441 listed facility; and
442 c. Each facility is secured and has theft-prevention
443 systems including an alarm system, cameras, and 24-hour security
444 personnel.
445 6. The applicant has diversion and tracking prevention
446 procedures, including:



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- 447 a. A system for tracking material through cultivation,
448 processing, and dispensing, including the use of batch and
449 harvest numbers;
- 450 b. An inventory control system for cannabis and cannabis
451 products;
- 452 c. A vehicle tracking and security system; and
453 d. A cannabis waste-disposal plan.
- 454 7. The applicant has recordkeeping policies and procedures
455 in place.
- 456 8. The applicant has a facility emergency management plan.
- 457 9. The applicant has a plan for dispensing cannabis
458 throughout the state. This plan must include planned retail
459 facilities and a delivery plan for providing cannabis and
460 cannabis products to qualified patients who cannot travel to a
461 retail facility.
- 462 10. The applicant has financial documentation, including:
- 463 a. Documentation that demonstrates the applicant's
464 financial ability to operate. If the applicant's assets, credit,
465 and projected revenues meet or exceed projected liabilities and
466 expenses and the applicant provides independent evidence that
467 the funds necessary for startup costs, working capital, and
468 contingency financing exist and are available as needed, the
469 applicant has demonstrated the financial ability to operate.
470 Financial ability to operate must be documented by:
- 471 I. The applicant's audited financial statements. If the
472 applicant is a newly formed entity and does not have a financial
473 history of business upon which audited financial statements may
474 be submitted, the applicant must provide audited financial
475 statements for the separate entity that is owned solely by the



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476 same persons or entities in the same ratio as the applicant that
477 possesses the valid certificate of registration issued by the
478 Department of Agriculture and Consumer Services;

479 II. The applicant's projected financial statements,
480 including a balance sheet, an income and expense statement, and
481 a statement of cash flow for the first 2 years of operation,
482 which provides evidence that the applicant has sufficient
483 assets, credit, and projected revenues to cover liabilities and
484 expenses; and

485 III. A statement of the applicant's estimated startup costs
486 and sources of funds, including a break-even projection and
487 documentation demonstrating that the applicant has the ability
488 to fund all startup costs, working capital costs, and
489 contingency financing requirements.

490
491 All documents required under this sub-subparagraph shall be
492 prepared in accordance with generally accepted accounting
493 principles and signed by a certified public accountant. The
494 statements required by sub-sub-subparagraphs II. and III. may be
495 presented as a compilation.

496 b. A list of all subsidiaries of the applicant;

497 c. A list of all lawsuits pending and completed within the
498 past 7 years of which the applicant was a party; and

499 d. Proof of a \$1 million performance and compliance bond,
500 or other equivalent means of security deemed equivalent by the
501 department, such as an irrevocable letter of credit or a deposit
502 in a trust account or financial institution, payable to the
503 department, which must be posted once the applicant is approved
504 as a dispensing organization. The purpose of the bond is to



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505 secure payment of any administrative penalties imposed by the
506 department and any fees and costs incurred by the department
507 regarding the dispensing organization license, such as the
508 dispensing organization failing to pay 30 days after the fine or
509 costs become final. The department may make a claim against such
510 bond or security until 1 year after the dispensing
511 organization's license ceases to be valid or until 60 days after
512 any administrative or legal proceeding authorized in this
513 section involving the dispensing organization concludes,
514 including any appeal, whichever occurs later.

515 11. The employment of a medical director who is a physician
516 licensed under chapter 458 or chapter 459 to supervise the
517 activities of the dispensing organization.

518 (c) An approved dispensing organization shall maintain
519 compliance with the criteria in paragraphs (b), (d), and (e) and
520 subsection (7) demonstrated for selection and approval as a
521 dispensing organization under subsection (5) at all times.
522 Before dispensing ~~low-THC~~ cannabis or cannabis products to a
523 qualified patient or to the qualified patient's legal
524 representative, the dispensing organization shall verify the
525 identity of the qualified patient or the qualified patient's
526 legal representative by requiring the qualified patient or the
527 qualified patient's legal representative to produce a
528 government-issued identification card and shall verify that the
529 qualified patient and the qualified patient's legal
530 representative have ~~has~~ an active registration in the
531 compassionate use registry, that the order presented matches the
532 order contents as recorded in the registry, and that the order
533 has not already been filled. Upon dispensing the ~~low-THC~~



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534 cannabis, the dispensing organization shall record in the
535 registry the date, time, quantity, and form of ~~low-THC~~ cannabis
536 dispensed.

537 (d) A dispensing organization may have cultivation
538 facilities, processing facilities, and retail facilities.

539 1. All matters regarding the location of cultivation
540 facilities and processing facilities are preempted to the state.
541 Cultivation facilities and processing facilities must be closed
542 to the public, and cannabis may not be dispensed on the premises
543 of such facilities.

544 2. A municipality must determine by ordinance the criteria
545 for the number and location of, and other permitting
546 requirements for, all retail facilities located within its
547 municipal boundaries. A retail facility may be established in a
548 municipality only after such an ordinance has been created. A
549 county must determine by ordinance the criteria for the number,
550 location, and other permitting requirements for all retail
551 facilities located within the unincorporated areas of that
552 county. A retail facility may be established in the
553 unincorporated areas of a county only after such an ordinance
554 has been created. Retail facilities must have all utilities and
555 resources necessary to store and dispense cannabis and cannabis
556 products. Retail facilities must be secured and have theft-
557 prevention systems, including an alarm system, cameras, and 24-
558 hour security personnel. Retail facilities may not sell, or
559 contract for the sale of, anything other than cannabis or
560 cannabis products on the property of the retail facility. Before
561 a retail facility may dispense cannabis or a cannabis product,
562 the dispensing organization must have a computer network



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563 compliant with the federal Health Insurance Portability and
564 Accountability Act of 1996 which is able to access and upload
565 data to the compassionate use registry and which shall be used
566 by all retail facilities.

567 (e) Within 15 days after such information becoming
568 available, a dispensing organization must provide the department
569 with updated information, as applicable, including:

570 1. The location and a detailed description of any new or
571 proposed facilities.

572 2. The updated contact information, including electronic
573 and voice communication, for all dispensing organization
574 facilities.

575 3. The registration information for any vehicles used for
576 the transportation of cannabis and cannabis products, including
577 confirmation that all such vehicles have tracking and security
578 systems.

579 4. A plan for the recall of any or all cannabis or cannabis
580 products.

581 (f)1. A dispensing organization may transport cannabis or
582 cannabis products in vehicles departing from their places of
583 business only in vehicles that are owned or leased by the
584 licensee or by a person designated by the dispensing
585 organization, and for which a valid vehicle permit has been
586 issued for such vehicle by the department.

587 2. A vehicle owned or leased by the dispensing organization
588 or a person designated by the dispensing organization and
589 approved by the department must be operated by such person when
590 transporting cannabis or products from the licensee's place of
591 business.



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592 3. A vehicle permit may be obtained by a dispensing
593 organization upon application and payment of a fee of \$5 per
594 vehicle to the department. The signature of the person
595 designated by the dispensing organization to drive the vehicle
596 must be included on the vehicle permit application. Such permit
597 remains valid and does not expire unless the licensee or any
598 person designated by the dispensing organization disposes of his
599 or her vehicle, or the licensee's license is transferred,
600 canceled, not renewed, or is revoked by the department,
601 whichever occurs first. The department shall cancel a vehicle
602 permit upon request of the licensee or owner of the vehicle.

603 4. By acceptance of a license issued under this section,
604 the licensee agrees that the licensed vehicle is, at all times
605 it is being used to transport cannabis or cannabis products,
606 subject to inspection and search without a search warrant by
607 authorized employees of the department, sheriffs, deputy
608 sheriffs, police officers, or other law enforcement officers to
609 determine that the licensee is transporting such products in
610 compliance with this section.

611 (7) TESTING AND LABELING OF CANNABIS.—

612 (a) All cannabis and cannabis products must be tested by an
613 independent testing laboratory before the dispensing
614 organization may dispense them. The independent testing
615 laboratory shall provide the dispensing organization with lab
616 results. Before dispensing, the dispensing organization must
617 determine that the lab results indicate that the cannabis or
618 cannabis product meets the definition of cannabis or cannabis
619 product, is safe for human consumption, and is free from harmful
620 contaminants.



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621 (b) All cannabis and cannabis products must be labeled
622 before dispensing. The label must include, at a minimum:

623 1. A statement that the cannabis or cannabis product meets
624 the requirements in paragraph (a);

625 2. The name of the independent testing laboratory that
626 tested the cannabis or cannabis product;

627 3. The name of the cultivation and processing facility
628 where the cannabis or cannabis product originates; and

629 4. The batch number and harvest number from which the
630 cannabis or cannabis product originates.

631 (8) SAFETY AND EFFICACY RESEARCH FOR CANNABIS.—The
632 University of Florida College of Pharmacy shall establish and
633 maintain a safety and efficacy research program for the use of
634 cannabis or cannabis products to treat qualifying conditions and
635 symptoms. The program must include a fully integrated electronic
636 information system for the broad monitoring of health outcomes
637 and safety signal detection. The electronic information system
638 must include information from the compassionate use registry;
639 provider reports, including treatment plans, adverse event
640 reports, and treatment discontinuation reports; patient reports
641 of adverse impacts; event-triggered interviews and medical chart
642 reviews performed by University of Florida clinical research
643 staff; information from external databases, including Medicaid
644 billing reports and information in the prescription drug
645 monitoring database for registered patients; and all other
646 medical reports required by the University of Florida to conduct
647 the research required by this subsection. The department must
648 provide access to information from the compassionate use
649 registry and the prescription drug monitoring database,



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650 established in s. 893.055, as needed by the University of
651 Florida to conduct research under this subsection. The Agency
652 for Health Care Administration must provide access to registered
653 patient Medicaid records, to the extent allowed under federal
654 law, as needed by the University of Florida to conduct research
655 under this subsection.

656 (9) The persons who have direct or indirect interest in the
657 dispensing organization and the dispensing organization's
658 managers, employees, and contractors who directly interact with
659 cannabis or cannabis products are prohibited from making
660 recommendations, offering prescriptions, or providing medical
661 advice to qualified patients.

662 (10) ~~(7)~~ EXCEPTIONS TO OTHER LAWS.-

663 (a) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or
664 any other ~~provision of~~ law, but subject to the requirements of
665 this section, a qualified patient and the qualified patient's
666 legal representative who is registered with the department on
667 the compassionate use registry may purchase and possess for the
668 patient's medical use up to the amount of ~~low-THC~~ cannabis
669 ordered for the patient. Nothing in this section exempts any
670 person from the prohibition against driving under the influence
671 provided in s. 316.193.

672 (b) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or
673 any other provision of law, but subject to the requirements of
674 this section, an approved dispensing organization and its
675 owners, managers, ~~and~~ employees and the owners, managers, and
676 employees of contractors who have direct contact with cannabis
677 or cannabis product may manufacture, possess, sell, deliver,
678 distribute, dispense, and lawfully dispose of reasonable



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679 quantities, as established by department rule, of ~~low-THC~~
680 cannabis. For purposes of this subsection, the terms
681 "manufacture," "possession," "deliver," "distribute," and
682 "dispense" have the same meanings as provided in s. 893.02.

683 (c) An approved dispensing organization and its owners,
684 managers, and employees are not subject to licensure or
685 regulation under chapter 465 or chapter 499 for manufacturing,
686 possessing, selling, delivering, distributing, dispensing, or
687 lawfully disposing of reasonable quantities, as established by
688 department rule, of ~~low-THC~~ cannabis.

689 (d) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or
690 any other law, but subject to the requirements of this section,
691 a licensed laboratory and its employees may receive and possess
692 cannabis for the sole purpose of testing the cannabis to ensure
693 compliance with this section.

694 (11) Rules adopted by the department under this section are
695 exempt from the requirement that they be ratified by the
696 Legislature pursuant to s. 120.541(3).

697 Section 2. Subsections (1) and (2) and paragraphs (b) and
698 (c) of subsection (3) of section 381.987, Florida Statutes, are
699 amended, and paragraph (g) is added to subsection (3) of that
700 section, to read:

701 381.987 Public records exemption for personal identifying
702 information in the compassionate use registry.-

703 (1) A patient's personal identifying information held by
704 the department in the compassionate use registry established
705 under s. 381.986, including, but not limited to, the patient's
706 name, address, telephone number, and government-issued
707 identification number, and all information pertaining to the



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708 physician's order for ~~low-THC~~ cannabis and the dispensing
709 thereof are confidential and exempt from s. 119.07(1) and s.
710 24(a), Art. I of the State Constitution.

711 (2) A physician's identifying information held by the
712 department in the compassionate use registry established under
713 s. 381.986, including, but not limited to, the physician's name,
714 address, telephone number, government-issued identification
715 number, and Drug Enforcement Administration number, and all
716 information pertaining to the physician's order for ~~low-THC~~
717 cannabis and the dispensing thereof are confidential and exempt
718 from s. 119.07(1) and s. 24(a), Art. I of the State
719 Constitution.

720 (3) The department shall allow access to the registry,
721 including access to confidential and exempt information, to:

722 (b) A dispensing organization approved by the department
723 pursuant to s. 381.986 which is attempting to verify the
724 authenticity of a physician's order for ~~low-THC~~ cannabis,
725 including whether the order had been previously filled and
726 whether the order was written for the person attempting to have
727 it filled.

728 (c) A physician who has written an order for ~~low-THC~~
729 cannabis for the purpose of monitoring the patient's use of such
730 cannabis or for the purpose of determining, before issuing an
731 order for ~~low-THC~~ cannabis, whether another physician has
732 ordered the patient's use of ~~low-THC~~ cannabis. The physician may
733 access the confidential and exempt information only for the
734 patient for whom he or she has ordered or is determining whether
735 to order the use of ~~low-THC~~ cannabis pursuant to s. 381.986.

736 (g) Persons engaged in research at the University of



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737 Florida pursuant to s. 381.986(8).

738 Section 3. Section 385.211, Florida Statutes, is amended to
739 read:

740 385.211 Refractory and intractable epilepsy treatment and
741 research at recognized medical centers.—

742 (1) As used in this section, the term "~~low-THC~~ cannabis"
743 means "~~low-THC~~ cannabis" as defined in s. 381.986 that is
744 dispensed only from a dispensing organization as defined in s.
745 381.986.

746 (2) Notwithstanding chapter 893, medical centers recognized
747 pursuant to s. 381.925 may conduct research on cannabidiol and
748 ~~low-THC~~ cannabis. This research may include, but is not limited
749 to, the agricultural development, production, clinical research,
750 and use of liquid medical derivatives of cannabidiol and ~~low-THC~~
751 cannabis for the treatment for refractory or intractable
752 epilepsy. The authority for recognized medical centers to
753 conduct this research is derived from 21 C.F.R. parts 312 and
754 316. Current state or privately obtained research funds may be
755 used to support the activities described in this section.

756 Section 4. Subsection (3) of section 893.02, Florida
757 Statutes, is amended to read:

758 893.02 Definitions.—The following words and phrases as used
759 in this chapter shall have the following meanings, unless the
760 context otherwise requires:

761 (3) "Cannabis" means all parts of any plant of the genus
762 *Cannabis*, whether growing or not; the seeds thereof; the resin
763 extracted from any part of the plant; and every compound,
764 manufacture, salt, derivative, mixture, or preparation of the
765 plant or its seeds or resin. ~~The term does not include "low-THC~~



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766 ~~cannabis," as defined in s. 381.986, if manufactured, possessed,~~
767 ~~sold, purchased, delivered, distributed, or dispensed, in~~
768 ~~conformance with s. 381.986.~~

769 Section 5. Paragraph (b) of subsection (7) of section
770 893.055, Florida Statutes, is amended to read:

771 893.055 Prescription drug monitoring program.—

772 (7)

773 (b) A pharmacy, prescriber, or dispenser shall have access
774 to information in the prescription drug monitoring program's
775 database which relates to a patient of that pharmacy,
776 prescriber, or dispenser in a manner established by the
777 department as needed for the purpose of reviewing the patient's
778 controlled substance prescription history. Persons engaged in
779 research at the University of Florida pursuant to s. 381.986(8)
780 shall have access to information in the prescription drug
781 monitoring program's database which relates to qualified
782 patients as defined in s. 381.986(1) for the purpose of
783 conducting such research. Other access to the program's database
784 shall be limited to the program's manager and to the designated
785 program and support staff, who may act only at the direction of
786 the program manager or, in the absence of the program manager,
787 as authorized. Access by the program manager or such designated
788 staff is for prescription drug program management only or for
789 management of the program's database and its system in support
790 of the requirements of this section and in furtherance of the
791 prescription drug monitoring program. Confidential and exempt
792 information in the database shall be released only as provided
793 in paragraph (c) and s. 893.0551. The program manager,
794 designated program and support staff who act at the direction of



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795 or in the absence of the program manager, and any individual who
796 has similar access regarding the management of the database from
797 the prescription drug monitoring program shall submit
798 fingerprints to the department for background screening. The
799 department shall follow the procedure established by the
800 Department of Law Enforcement to request a statewide criminal
801 history record check and to request that the Department of Law
802 Enforcement forward the fingerprints to the Federal Bureau of
803 Investigation for a national criminal history record check.

804 Section 6. Paragraph (h) is added to subsection (3) of
805 section 893.0551, Florida Statutes, to read:

806 893.0551 Public records exemption for the prescription drug
807 monitoring program.—

808 (3) The department shall disclose such confidential and
809 exempt information to the following persons or entities upon
810 request and after using a verification process to ensure the
811 legitimacy of the request as provided in s. 893.055:

812 (h) Persons engaged in research at the University of
813 Florida pursuant to s. 381.986(8).

814 Section 7. Section 1004.441, Florida Statutes, is amended
815 to read:

816 1004.441 Refractory and intractable epilepsy treatment and
817 research.—

818 (1) As used in this section, the term "~~low-THC~~ cannabis"
819 means "~~low-THC~~ cannabis" as defined in s. 381.986 that is
820 dispensed only from a dispensing organization as defined in s.
821 381.986.

822 (2) Notwithstanding chapter 893, state universities with
823 both medical and agricultural research programs, including those



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824 that have satellite campuses or research agreements with other
825 similar institutions, may conduct research on cannabidiol and
826 ~~low-THC~~ cannabis. This research may include, but is not limited
827 to, the agricultural development, production, clinical research,
828 and use of liquid medical derivatives of cannabidiol and ~~low-THC~~
829 cannabis for the treatment for refractory or intractable
830 epilepsy. The authority for state universities to conduct this
831 research is derived from 21 C.F.R. parts 312 and 316. Current
832 state or privately obtained research funds may be used to
833 support the activities authorized by this section.

834 Section 8. This act shall take effect upon becoming a law.

835

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

837 And the title is amended as follows:

838 Delete everything before the enacting clause
839 and insert:

840

A bill to be entitled

841

An act relating to cannabis; amending s. 381.986,

842

F.S.; defining terms; revising the illnesses and

843

symptoms for which a physician may order a patient the

844

medical use of cannabis in certain circumstances;

845

providing that a physician who improperly orders

846

cannabis is subject to specified disciplinary action;

847

revising the duties of the Department of Health;

848

requiring the department to create a secure,

849

electronic, and online compassionate use registry;

850

requiring the department to begin to accept

851

applications for licensure as a dispensing

852

organization according to a specified application



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853 process; requiring the department to review all
854 applications, notify applicants of deficient
855 applications, and request any additional information
856 within a specified period; requiring an application
857 for licensure to be filed and complete by specified
858 dates; requiring the department to select two
859 applicants in specified regions for licensure as a
860 dispensing organization; requiring the department to
861 issue 10 additional licenses to qualified applicants
862 by lottery; authorizing applicants to operate in any
863 region of the state; prohibiting a dispensing
864 organization from having cultivation or processing
865 facilities outside the region in which it is licensed;
866 requiring the department to select by lottery another
867 applicant in certain circumstances; requiring the
868 department to conduct a new lottery after the
869 revocation or the denial of renewal of a license;
870 requiring the department to conduct a lottery at
871 specified intervals if there are available dispensing
872 organization licenses; providing an exemption for the
873 application process; requiring the department to use
874 an application form that requires specified
875 information from the applicant; requiring the
876 department to impose specified application fees;
877 requiring the department to inspect each dispensing
878 organization's properties, cultivation facilities,
879 processing facilities, and retail facilities before
880 those facilities may operate; authorizing followup
881 inspections at reasonable hours; providing that



882 licensure constitutes permission for the department to
883 enter and inspect the premises and facilities of any
884 dispensing organization; authorizing the department to
885 inspect any licensed dispensing organization;
886 requiring dispensing organizations to make all
887 facility premises, equipment, documents, cannabis, and
888 cannabis products available to the department upon
889 inspection; authorizing the department to test
890 cannabis or cannabis products; authorizing the
891 department to suspend or revoke a license, deny or
892 refuse to renew a license, or impose a maximum
893 administrative penalty for specified acts or
894 omissions; requiring the department to create a
895 permitting process for vehicles used for the
896 transportation of cannabis or cannabis products;
897 authorizing the department to adopt rules as necessary
898 for implementation of specified provisions and
899 procedures, and to provide specified guidance;
900 providing procedures and requirements for an applicant
901 seeking licensure as a dispensing organization or the
902 renewal of its license; requiring the dispensing
903 organization to verify specified information of
904 specified persons in certain circumstances;
905 authorizing a dispensing organization to have
906 cultivation facilities, processing facilities, and
907 retail facilities; authorizing a retail facility to be
908 established in a municipality only after such an
909 ordinance has been created; authorizing a retail
910 facility to be established in the unincorporated areas



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911 of a county only after such an ordinance has been
912 created; requiring retail facilities to have all
913 utilities and resources necessary to store and
914 dispense cannabis and cannabis products; requiring
915 retail facilities to be secured with specified theft-
916 prevention systems; requiring a dispensing
917 organization to provide the department with specified
918 updated information within a specified period;
919 authorizing a dispensing organization to transport
920 cannabis or cannabis products in vehicles in certain
921 circumstances; requiring such vehicles to be operated
922 by specified persons in certain circumstances;
923 requiring a fee for a vehicle permit; requiring the
924 signature of the designated driver with a vehicle
925 permit application; providing for expiration of the
926 permit in certain circumstances; requiring the
927 department to cancel a vehicle permit upon the request
928 of specified persons; providing that the licensee
929 authorizes the inspection and search of his or her
930 vehicle without a search warrant by specified persons;
931 requiring all cannabis and cannabis products to be
932 tested by an independent testing laboratory before the
933 dispensing organization may dispense it; requiring the
934 independent testing laboratory to provide the lab
935 results to the dispensing organization for a specified
936 determination; requiring all cannabis and cannabis
937 products to be labeled with specified information
938 before dispensing; requiring the University of Florida
939 College of Pharmacy to establish and maintain a



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940 specified safety and efficacy research program;
941 providing program requirements; requiring the
942 department to provide information from the
943 prescription drug monitoring program to the University
944 of Florida as needed; requiring the Agency for Health
945 Care Administration to provide access to specified
946 patient records under certain circumstances;
947 prohibiting persons who have direct or indirect
948 interest in a dispensing organization and the
949 dispensing organization's managers, employees, and
950 contractors who directly interact with cannabis and
951 cannabis products from making recommendations,
952 offering prescriptions, or providing medical advice to
953 qualified patients; providing that the act does not
954 provide an exception to the prohibition against
955 driving under the influence; authorizing specified
956 individuals to manufacture, possess, sell, deliver,
957 distribute, dispense, and lawfully dispose of
958 reasonable quantities of cannabis; authorizing a
959 licensed laboratory and its employees to receive and
960 possess cannabis in certain circumstances; providing
961 that specified rules adopted by the department are
962 exempt from the requirement to be ratified by the
963 Legislature; amending s. 381.987, F.S.; conforming
964 provisions to changes made by the act; requiring the
965 department to allow specified persons engaged in
966 research to access the compassionate use registry;
967 amending ss. 385.221 and 893.02, F.S.; conforming
968 provisions to changes made by the act; amending s.



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969 893.055, F.S.; providing that persons engaged in
970 research at the University of Florida shall have
971 access to specified information; amending s. 893.0551,
972 F.S.; providing a specified public records exemption
973 for persons engaged in research at the University of
974 Florida; amending s. 1004.441, F.S.; conforming
975 provisions to changes made by the act; providing an
976 effective date.