

**FOR CONSIDERATION By** the Committee on Regulated Industries

580-02582A-15

20157066pb

1                                   A bill to be entitled  
2       An act relating to low-THC cannabis; amending s.  
3       381.986, F.S.; defining terms; revising the illnesses  
4       and symptoms for which a physician may order a patient  
5       the medical use of low-THC cannabis in certain  
6       circumstances; providing that a physician who  
7       improperly orders low-THC cannabis is subject to  
8       specified disciplinary action; revising the duties of  
9       the Department of Health; requiring the department to  
10      create a secure, electronic, and online compassionate  
11      use registry; requiring the department to begin to  
12      accept applications for licensure as a dispensing  
13      organization according to a specified application  
14      process; requiring the department to review all  
15      applications, notify applicants of deficient  
16      applications, and request any additional information  
17      within a specified period; requiring an application  
18      for licensure to be filed and complete by specified  
19      dates; providing for a lottery for licensure as a  
20      dispensing organization in certain circumstances;  
21      authorizing the department to issue additional  
22      licenses to qualified applicants in certain  
23      circumstances; providing an exemption for the  
24      application process; requiring the department to use  
25      an application form that requires specified  
26      information from the applicant; requiring the  
27      department to impose specified application fees;  
28      requiring the department to inspect each dispensing  
29      organization's properties, cultivation facilities,

580-02582A-15

20157066pb

30 processing facilities, and retail facilities before  
31 those facilities may operate; authorizing followup  
32 inspections at reasonable hours; providing that  
33 licensure constitutes permission for the department to  
34 enter and inspect the premises and facilities of any  
35 dispensing organization; authorizing the department to  
36 inspect any licensed dispensing organization;  
37 requiring dispensing organizations to make all  
38 facility premises, equipment, documents, low-THC  
39 cannabis, and low-THC cannabis products available to  
40 the department upon inspection; authorizing the  
41 department to test low-THC cannabis or low-THC  
42 cannabis products; authorizing the department to  
43 suspend or revoke a license, deny or refuse to renew a  
44 license, or impose a maximum administrative penalty  
45 for specified acts or omissions; requiring the  
46 department to create a permitting process for vehicles  
47 used for the transportation of low-THC cannabis or  
48 low-THC cannabis products; authorizing the department  
49 to adopt rules as necessary for implementation of  
50 specified provisions and procedures, and to provide  
51 specified guidance; providing procedures and  
52 requirements for an applicant seeking licensure as a  
53 dispensing organization or the renewal of its license;  
54 requiring the dispensing organization to verify  
55 specified information of specified persons in certain  
56 circumstances; authorizing a dispensing organization  
57 to have cultivation facilities, processing facilities,  
58 and retail facilities; requiring a dispensing

580-02582A-15

20157066pb

59 organization to provide the department with specified  
60 updated information within a specified period;  
61 authorizing a dispensing organization to transport  
62 low-THC cannabis or low-THC cannabis products in  
63 vehicles in certain circumstances; requiring such  
64 vehicles to be operated by specified persons in  
65 certain circumstances; requiring a fee for a vehicle  
66 permit; requiring the signature of the designated  
67 driver with a vehicle permit application; providing  
68 for expiration of the permit in certain circumstances;  
69 requiring the department to cancel a vehicle permit  
70 upon the request of specified persons; providing that  
71 the licensee authorizes the inspection and search of  
72 his or her vehicle without a search warrant by  
73 specified persons; requiring all low-THC cannabis and  
74 low-THC cannabis products to be tested by an  
75 independent testing laboratory before the dispensing  
76 organization may dispense it; requiring the  
77 independent testing laboratory to provide the lab  
78 results to the dispensing organization for a specified  
79 determination; requiring all low-THC cannabis and low-  
80 THC cannabis products to be labeled with specified  
81 information before dispensing; requiring the  
82 University of Florida College of Pharmacy to establish  
83 and maintain a specified safety and efficacy research  
84 program; providing program requirements; requiring the  
85 department to provide information from the  
86 prescription drug monitoring program to the University  
87 of Florida as needed; requiring the Agency for Health

580-02582A-15

20157066pb

88 Care Administration to provide access to specified  
89 patient records under certain circumstances;  
90 authorizing specified individuals to manufacture,  
91 possess, sell, deliver, distribute, dispense, and  
92 lawfully dispose of reasonable quantities of low-THC  
93 cannabis; authorizing a licensed laboratory and its  
94 employees to receive and possess low-THC cannabis in  
95 certain circumstances; providing that specified rules  
96 adopted by the department are exempt from the  
97 requirement to be ratified by the Legislature;  
98 amending s. 381.987, F.S.; requiring the department to  
99 allow specified persons engaged in research to access  
100 the compassionate use registry; amending s. 893.055,  
101 F.S.; providing that persons engaged in research at  
102 the University of Florida shall have access to  
103 specified information; amending s. 893.0551, F.S.;  
104 providing a specified public records exemption for  
105 persons engaged in research at the University of  
106 Florida; providing an effective date.

107  
108 Be It Enacted by the Legislature of the State of Florida:

109  
110 Section 1. Section 381.986, Florida Statutes, is amended to  
111 read:

112 381.986 Compassionate use of low-THC cannabis.—

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

114 (a) "Applicant" means a person that has submitted an  
115 application to the department for licensure or renewal as a  
116 dispensing organization.

580-02582A-15

20157066pb

117 (b) "Batch" means a specific quantity of low-THC cannabis  
118 product that is intended to have uniform character and quality,  
119 within specified limits, and is produced at the same time from  
120 one or more harvests.

121 (c) "Dispensing organization" means an applicant licensed  
122 ~~organization approved~~ by the department to cultivate, process,  
123 and dispense low-THC cannabis pursuant to this section.

124 (d) "Harvest" means a specifically identified and numbered  
125 quantity of low-THC cannabis cultivated using the same  
126 herbicides, pesticides, and fungicides and harvested at the same  
127 time from a single facility.

128 (e)~~(b)~~ "Low-THC cannabis" means a plant of the genus  
129 *Cannabis*, the dried flowers of which contain 0.8 percent or less  
130 of tetrahydrocannabinol and more than 10 percent of cannabidiol  
131 weight for weight; the seeds thereof; the resin extracted from  
132 any part of such plant; or any compound, manufacture, salt,  
133 derivative, mixture, or preparation of such plant or its seeds  
134 or resin that is dispensed only from a dispensing organization.

135 (f) "Low-THC cannabis product" means any product derived  
136 from low-THC cannabis, including the resin extracted from any  
137 part of such plant or any compound, manufacture, salt,  
138 derivative, mixture, or preparation of such plant or its seeds  
139 or resin which is dispensed from a dispensing organization. Low-  
140 THC cannabis products include, but are not limited to, oils,  
141 tinctures, creams, encapsulations, and food products. All low-  
142 THC cannabis products must maintain concentrations, weight for  
143 weight, of 0.8 percent or less of tetrahydrocannabinol and more  
144 than 10 percent of cannabidiol.

145 (g)~~(e)~~ "Medical use" means administration of the ordered

580-02582A-15

20157066pb

146 amount of low-THC cannabis. The term does not include:

147 1. The possession, use, or administration by smoking;~~—~~

148 2. ~~The term also does not include~~ The transfer of low-THC  
149 cannabis to a person other than the qualified patient for whom  
150 it was ordered or the qualified patient's legal representative  
151 who is registered in the compassionate use registry on behalf of  
152 the qualified patient; ~~or—~~

153 3. The use or administration of medical-grade marijuana:

154 a. On any form of public transportation.

155 b. In any public place.

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

158 d. In a correctional facility.

159 e. On the grounds of any preschool, primary school, or  
160 secondary school.

161 f. On a school bus.

162 (h) ~~(d)~~ "Qualified patient" means a resident of this state  
163 who has been added to the compassionate use registry by a  
164 physician licensed under chapter 458 or chapter 459 to receive  
165 low-THC cannabis from a dispensing organization.

166 (i) ~~(e)~~ "Smoking" means burning or igniting a substance and  
167 inhaling the smoke. Smoking does not include the use of a  
168 vaporizer.

169 (2) PHYSICIAN ORDERING.—

170 (a) ~~Effective January 1, 2015,~~ A physician licensed under  
171 chapter 458 or chapter 459 who has examined and is treating a  
172 patient suffering from cancer, human immunodeficiency virus,  
173 acquired immune deficiency syndrome, epilepsy, amyotrophic  
174 lateral sclerosis, multiple sclerosis, Crohn's disease,

580-02582A-15

20157066pb

175 Parkinson's disease, paraplegia, quadriplegia, or terminal  
176 illness ~~a physical medical condition that chronically produces~~  
177 ~~symptoms of seizures or severe and persistent muscle spasms~~ may  
178 order for the patient's medical use low-THC cannabis to treat  
179 such disease, disorder, or condition; ~~or~~ to alleviate symptoms  
180 of such disease, disorder, or condition; ~~or~~ or to alleviate  
181 symptoms caused by a treatment for such disease, disorder, or  
182 condition if no other satisfactory alternative treatment options  
183 exist for that patient and all of the following ~~conditions~~  
184 apply:

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

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

192 3. ~~(c)~~ The physician registers the patient, the patient's  
193 legal representative if requested by the patient, and himself or  
194 herself as the orderer of low-THC cannabis for the named patient  
195 on the compassionate use registry maintained by the department  
196 and updates the registry to reflect the contents of the order.  
197 If the patient is a minor, the physician must register a legal  
198 representative on the compassionate use registry. The physician  
199 shall deactivate the patient's registration when treatment is  
200 discontinued.

201 4. ~~(d)~~ The physician maintains a patient treatment plan that  
202 includes the dose, route of administration, planned duration,  
203 and monitoring of the patient's symptoms and other indicators of

580-02582A-15

20157066pb

204 tolerance or reaction to the low-THC cannabis.

205 5.(e) The physician submits the patient treatment plan, as  
206 well as any other requested medical records, quarterly to the  
207 University of Florida College of Pharmacy for research on the  
208 safety and efficacy of low-THC cannabis on patients pursuant to  
209 subsection (8).

210 6.(f) The physician obtains the voluntary informed consent  
211 of the patient or the patient's legal guardian to treatment with  
212 low-THC cannabis after sufficiently explaining the current state  
213 of knowledge in the medical community of the effectiveness of  
214 treatment of the patient's conditions or symptoms ~~condition~~ with  
215 low-THC cannabis, the medically acceptable alternatives, and the  
216 potential risks and side effects.

217 (b) A physician who improperly orders low-THC cannabis is  
218 subject to disciplinary action under the applicable practice act  
219 and under s. 456.072(1)(k).

220 (3) PENALTIES.—

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

226 ~~1. Cancer or a physical medical condition that chronically~~  
227 ~~produces symptoms of seizures or severe and persistent muscle~~  
228 ~~spasms that can be treated with low-THC cannabis; or~~

229 ~~2. Symptoms of cancer or a physical medical condition that~~  
230 ~~chronically produces symptoms of seizures or severe and~~  
231 ~~persistent muscle spasms that can be alleviated with low-THC~~  
232 ~~cannabis.~~



580-02582A-15

20157066pb

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

240 (4) PHYSICIAN EDUCATION.—

241 (a) Before ordering low-THC cannabis for use by a patient  
242 in this state, the appropriate board shall require the ordering  
243 physician licensed under chapter 458 or chapter 459 to  
244 successfully complete an 8-hour course and subsequent  
245 examination offered by the Florida Medical Association or the  
246 Florida Osteopathic Medical Association that encompasses the  
247 clinical indications for the appropriate use of low-THC  
248 cannabis, the appropriate delivery mechanisms, the  
249 contraindications for such use, as well as the relevant state  
250 and federal laws governing the ordering, dispensing, and  
251 possessing of this substance. The first course and examination  
252 shall be presented by October 1, 2014, and shall be administered  
253 at least annually thereafter. Successful completion of the  
254 course may be used by a physician to satisfy 8 hours of the  
255 continuing medical education requirements required by his or her  
256 respective board for licensure renewal. This course may be  
257 offered in a distance learning format.

258 (b) The appropriate board shall require the medical  
259 director of each dispensing organization approved under  
260 subsection (5) to successfully complete a 2-hour course and  
261 subsequent examination offered by the Florida Medical

580-02582A-15

20157066pb

262 Association or the Florida Osteopathic Medical Association that  
263 encompasses appropriate safety procedures and knowledge of low-  
264 THC cannabis.

265 (c) Successful completion of the course and examination  
266 specified in paragraph (a) is required for every physician who  
267 orders low-THC cannabis each time such physician renews his or  
268 her license. In addition, successful completion of the course  
269 and examination specified in paragraph (b) is required for the  
270 medical director of each dispensing organization each time such  
271 physician renews his or her license.

272 (d) A physician who fails to comply with this subsection  
273 and who orders low-THC cannabis may be subject to disciplinary  
274 action under the applicable practice act and under s.  
275 456.072(1)(k).

276 (5) DUTIES AND POWERS OF THE DEPARTMENT. ~~By January 1,~~  
277 ~~2015, The department shall:~~

278 (a) The department shall create a secure, electronic, and  
279 online compassionate use registry for the registration of  
280 physicians and patients as provided under this section. The  
281 registry must be accessible to law enforcement agencies and to a  
282 dispensing organization in order to verify patient authorization  
283 for low-THC cannabis and record the low-THC cannabis dispensed.  
284 The registry must prevent an active registration of a patient by  
285 multiple physicians.

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

580-02582A-15

20157066pb

291 2. Within 10 days after receiving an application for  
292 licensure, the department shall examine the application, notify  
293 the applicant of any apparent errors or omissions, and request  
294 any additional information the department is allowed by law to  
295 require. An application for licensure must be filed with the  
296 department no later than 5 p.m. on the 30th day after the  
297 effective date of this act, and all applications must be  
298 complete no later than 5 p.m. on the 60th day after the  
299 effective date of this act.

300 3. If fewer than 20 applicants meet the criteria specified  
301 in subsection (6), the department shall, by the 75th day after  
302 the effective date of this act, license each such applicant. If  
303 more than 20 applicants meet these criteria, licensure shall be  
304 determined by lottery.

305 4. Beginning March 15, 2016, and every 6 months thereafter,  
306 if fewer than 20 dispensing organization licenses have been  
307 issued in this state, the department may issue additional  
308 licenses to qualified applicants up to the 20-organization  
309 maximum. If the number of qualified applicants under this  
310 subparagraph exceeds the number of dispensing organization  
311 licenses available for issuance, licensure shall be determined  
312 by lottery.

313 5. This section is exempt from s. 120.60 ~~Authorize the~~  
314 ~~establishment of five dispensing organizations to ensure~~  
315 ~~reasonable statewide accessibility and availability as necessary~~  
316 ~~for patients registered in the compassionate use registry and~~  
317 ~~who are ordered low-THC cannabis under this section, one in each~~  
318 ~~of the following regions: northwest Florida, northeast Florida,~~  
319 ~~central Florida, southeast Florida, and southwest Florida.~~

580-02582A-15

20157066pb

320       (c) The department shall use develop an application form  
321 that requires the applicant to state:

322           1. Whether the application is for initial licensure or  
323 renewal licensure;

324           2. The name, the physical address, the mailing address, the  
325 address listed on the Department of Agriculture and Consumer  
326 Services certificate required in paragraph (6) (b), and the  
327 contact information for the applicant and for the nursery that  
328 holds the Department of Agriculture and Consumer Services  
329 certificate, if different from the applicant;

330           3. The name, address, and contact information for the  
331 operating nurseryman of the organization that holds the  
332 Department of Agriculture and Consumer Services certificate;

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

335           5. All information required to be included by subsection  
336 (6).

337       (d) The department shall and impose an initial application  
338 fee of \$50,000, an initial licensure fee of \$125,000, and a  
339 biennial renewal fee of \$125,000 that is sufficient to cover the  
340 costs of administering this section. An applicant for approval  
341 as a dispensing organization must be able to demonstrate:

342           ~~1. The technical and technological ability to cultivate and~~  
343 ~~produce low-THC cannabis. The applicant must possess a valid~~  
344 ~~certificate of registration issued by the Department of~~  
345 ~~Agriculture and Consumer Services pursuant to s. 581.131 that is~~  
346 ~~issued for the cultivation of more than 400,000 plants, be~~  
347 ~~operated by a nurseryman as defined in s. 581.011, and have been~~  
348 ~~operated as a registered nursery in this state for at least 30~~

580-02582A-15

20157066pb

349 ~~continuous years.~~

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

352 ~~3. The ability to maintain accountability of all raw~~  
353 ~~materials, finished products, and any byproducts to prevent~~  
354 ~~diversion or unlawful access to or possession of these~~  
355 ~~substances.~~

356 ~~4. An infrastructure reasonably located to dispense low-THC~~  
357 ~~cannabis to registered patients statewide or regionally as~~  
358 ~~determined by the department.~~

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

363 ~~6. That all owners and managers have been fingerprinted and~~  
364 ~~have successfully passed a level 2 background screening pursuant~~  
365 ~~to s. 435.04.~~

366 ~~7. The employment of a medical director who is a physician~~  
367 ~~licensed under chapter 458 or chapter 459 to supervise the~~  
368 ~~activities of the dispensing organization.~~

369 (e) The department shall inspect each dispensing  
370 organization's properties, cultivation facilities, processing  
371 facilities, and retail facilities before they begin operations  
372 and at least once every 2 years thereafter. The department may  
373 conduct additional announced or unannounced inspections,  
374 including followup inspections, at reasonable hours in order to  
375 ensure that such property and facilities maintain compliance  
376 with all applicable requirements in subsections (6) and (7) and  
377 to ensure that the dispensing organization has not committed any

580-02582A-15

20157066pb

378 other act that would endanger the health, safety, or security of  
379 a qualified patient, dispensing organization staff, or the  
380 community in which the dispensing organization is located.  
381 Licensure under this section constitutes permission for the  
382 department to enter and inspect the premises and facilities of  
383 any dispensing organization. The department may inspect any  
384 licensed dispensing organization, and a dispensing organization  
385 must make all facility premises, equipment, documents, low-THC  
386 cannabis, and low-THC cannabis products available to the  
387 department upon inspection. The department may test any low-THC  
388 cannabis or low-THC cannabis product in order to ensure that it  
389 is safe for human consumption and that it meets the requirements  
390 in this section.

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

394 1. A violation of this section or department rule.

395 2. Failing to maintain qualifications for licensure.

396 3. Endangering the health, safety, or security of a  
397 qualified patient.

398 4. Improperly disclosing personal and confidential  
399 information of the qualified patient.

400 5. Attempting to procure a license by bribery or fraudulent  
401 misrepresentation.

402 6. Being convicted or found guilty of, or entering a plea  
403 of nolo contendere to, regardless of adjudication, a crime in  
404 any jurisdiction which directly relates to the business of a  
405 dispensing organization.

406 7. Making or filing a report or record that the licensee

580-02582A-15

20157066pb

407 knows to be false.

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

410 9. Willfully impeding or obstructing an employee or agent  
411 of the department in the furtherance of his or her official  
412 duties.

413 10. Engaging in fraud or deceit, negligence, incompetence,  
414 or misconduct in the business practices of a dispensing  
415 organization.

416 11. Making misleading, deceptive, or fraudulent  
417 representations in or related to the business practices of a  
418 dispensing organization.

419 12. Having a license or the authority to engage in any  
420 regulated profession, occupation, or business that is related to  
421 the business practices of a dispensing organization revoked,  
422 suspended, or otherwise acted against, including the denial of  
423 licensure, by the licensing authority of any jurisdiction,  
424 including its agencies or subdivisions, for a violation that  
425 would constitute a violation under state law. A licensing  
426 authority's acceptance of a relinquishment of licensure or a  
427 stipulation, consent order, or other settlement, offered in  
428 response to or in anticipation of the filing of charges against  
429 the license, shall be construed as an action against the  
430 license.

431 13. Violating a lawful order of the department or an agency  
432 of the state, or failing to comply with a lawfully issued  
433 subpoena of the department or an agency of the state.

434 (g) The department shall create a permitting process for  
435 all dispensing organization vehicles used for the transportation

580-02582A-15

20157066pb

436 of low-THC cannabis or low-THC cannabis products.

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

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

443 (6) DISPENSING ORGANIZATION.—

444 (a) An applicant seeking licensure as a dispensing  
445 organization, or the renewal of its license, must submit an  
446 application to the department. The department must review all  
447 applications for completeness, including an appropriate  
448 inspection of the applicant's property and facilities to verify  
449 the authenticity of the information provided in, or in  
450 connection with, the application. An applicant authorizes the  
451 department to inspect his or her property and facilities for  
452 licensure by applying under this subsection.

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

455 1. The applicant, or a separate entity that is owned solely  
456 by the same persons or entities in the same ratio as the  
457 applicant, possesses a valid certificate of registration issued  
458 by the Department of Agriculture and Consumer Services pursuant  
459 to s. 581.131 for the cultivation of more than 400,000 plants,  
460 the applicant's land is operated by a nurseryman as defined in  
461 s. 581.011, and the land has been operated as a registered  
462 nursery in this state for at least 30 continuous years.

463 2. The personnel on staff or under contract for the  
464 applicant have experience cultivating and introducing multiple



580-02582A-15

20157066pb

465 varieties of plants in this state, including plants that are not  
466 native to Florida; experience with propagating plants; and  
467 experience with genetic modification or breeding of plants.

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

470 a. Has at least 5 years' experience with United States  
471 Department of Agriculture Good Agricultural Practices and Good  
472 Handling Practices;

473 b. Has at least 5 years' experience with United States Food  
474 and Drug Administration Good Manufacturing Practices for food  
475 production;

476 c. Has a doctorate degree in organic chemistry or  
477 microbiology;

478 d. Has at least 5 years of experience with laboratory  
479 procedures which includes analytical laboratory quality control  
480 measures, chain of custody procedures, and analytical laboratory  
481 methods;

482 e. Has experience with cannabis cultivation and processing,  
483 including cannabis extraction techniques and producing cannabis  
484 products;

485 f. Has experience and qualifications in chain of custody or  
486 other tracking mechanisms;

487 g. Works solely on inventory control; and

488 h. Works solely for security purposes.

489 4. The persons who have a direct or indirect interest in  
490 the dispensing organization and the applicant's managers,  
491 employees, and contractors who directly interact with low-THC  
492 cannabis or low-THC cannabis products have been fingerprinted  
493 and have successfully passed a level 2 background screening

580-02582A-15

20157066pb

494 pursuant to s. 435.04.

495 5. The applicant owns, or has at least a 2-year lease of,  
496 all properties, facilities, and equipment necessary for the  
497 cultivation and processing of low-THC cannabis. The applicant  
498 must provide a detailed description of each facility and its  
499 equipment, a cultivation and processing plan, and a detailed  
500 floor plan. The description must include proof that:

501 a. The applicant is capable of sufficient cultivation and  
502 processing to serve at least 15,000 patients with an assumed  
503 daily use of 1,000 mg per patient per day of low-THC cannabis or  
504 low-THC cannabis product;

505 b. The applicant has arranged for access to all utilities  
506 and resources necessary to cultivate or process low-THC cannabis  
507 at each listed facility; and

508 c. Each facility is secured and has theft-prevention  
509 systems including an alarm system, cameras, and 24-hour security  
510 personnel.

511 6. The applicant has diversion and tracking prevention  
512 procedures, including:

513 a. A system for tracking low-THC material through  
514 cultivation, processing, and dispensing, including the use of  
515 batch and harvest numbers;

516 b. An inventory control system for low-THC cannabis and  
517 low-THC cannabis products;

518 c. A vehicle tracking and security system; and

519 d. A cannabis waste-disposal plan.

520 7. The applicant has recordkeeping policies and procedures  
521 in place.

522 8. The applicant has a facility emergency management plan.

580-02582A-15

20157066pb

523 9. The applicant has a plan for dispensing low-THC cannabis  
524 throughout the state. This plan must include planned retail  
525 facilities and a delivery plan for providing low-THC cannabis  
526 and low-THC cannabis products to qualified patients who cannot  
527 travel to a retail facility.

528 10. The applicant has financial documentation, including:

529 a. Documentation that demonstrates the applicant's  
530 financial ability to operate. If the applicant's assets, credit,  
531 and projected revenues meet or exceed projected liabilities and  
532 expenses and the applicant provides independent evidence that  
533 the funds necessary for startup costs, working capital, and  
534 contingency financing exist and are available as needed, the  
535 applicant has demonstrated the financial ability to operate.  
536 Financial ability to operate must be documented by:

537 I. The applicant's audited financial statements. If the  
538 applicant is a newly formed entity and does not have a financial  
539 history of business upon which audited financial statements may  
540 be submitted, the applicant must provide audited financial  
541 statements for the separate entity that is owned solely by the  
542 same persons or entities in the same ratio as the applicant that  
543 possesses the valid certificate of registration issued by the  
544 Department of Agriculture and Consumer Services;

545 II. The applicant's projected financial statements,  
546 including a balance sheet, an income and expense statement, and  
547 a statement of cash flow for the first 2 years of operation,  
548 which provides evidence that the applicant has sufficient  
549 assets, credit, and projected revenues to cover liabilities and  
550 expenses; and

551 III. A statement of the applicant's estimated startup costs

580-02582A-15

20157066pb

552 and sources of funds, including a break-even projection and  
553 documentation demonstrating that the applicant has the ability  
554 to fund all startup costs, working capital costs, and  
555 contingency financing requirements.

556  
557 All documents required under this sub-subparagraph shall be  
558 prepared in accordance with generally accepted accounting  
559 principles and signed by a certified public accountant. The  
560 statements required by sub-sub-subparagraph II. and III. may be  
561 presented as a compilation.

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

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

565 d. Proof of a \$1 million performance and compliance bond,  
566 or other equivalent means of security deemed equivalent by the  
567 department, such as an irrevocable letter of credit or a deposit  
568 in a trust account or financial institution, payable to the  
569 department, which must be posted once the applicant is approved  
570 as a dispensing organization. The purpose of the bond is to  
571 secure payment of any administrative penalties imposed by the  
572 department and any fees and costs incurred by the department  
573 regarding the dispensing organization license, such as the  
574 dispensing organization failing to pay 30 days after the fine or  
575 costs become final. The department may make a claim against such  
576 bond or security until 1 year after the dispensing  
577 organization's license ceases to be valid or until 60 days after  
578 any administrative or legal proceeding authorized in this  
579 section involving the dispensing organization concludes,  
580 including any appeal, whichever occurs later.

580-02582A-15

20157066pb

581       11. The employment of a medical director who is a physician  
582 licensed under chapter 458 or chapter 459 to supervise the  
583 activities of the dispensing organization.

584       (c) An approved dispensing organization shall maintain  
585 compliance with the criteria in paragraphs (b), (d), and (e) and  
586 subsection (7) ~~demonstrated for selection and approval as a~~  
587 ~~dispensing organization under subsection (5)~~ at all times.  
588 Before dispensing low-THC cannabis or low-THC cannabis products  
589 to a qualified patient or to the qualified patient's legal  
590 representative, the dispensing organization shall verify the  
591 identity of the qualified patient or the qualified patient's  
592 legal representative by requiring the qualified patient or the  
593 qualified patient's legal representative to produce a  
594 government-issued identification card and shall verify that the  
595 qualified patient and the qualified patient's legal  
596 representative have ~~has~~ an active registration in the  
597 compassionate use registry, that the order presented matches the  
598 order contents as recorded in the registry, and that the order  
599 has not already been filled. Upon dispensing the low-THC  
600 cannabis, the dispensing organization shall record in the  
601 registry the date, time, quantity, and form of low-THC cannabis  
602 dispensed.

603       (d) A dispensing organization may have cultivation  
604 facilities, processing facilities, and retail facilities.

605       1. All matters regarding the location of cultivation  
606 facilities and processing facilities are preempted to the state.  
607 Cultivation facilities and processing facilities must be closed  
608 to the public, and low-THC cannabis may not be dispensed on the  
609 premises of such facilities.

580-02582A-15

20157066pb

610       2. A county must determine by ordinance the criteria for  
611 the number, location, and other permitting requirements for all  
612 retail facilities located within that county. A retail facility  
613 may be established in a county only after such an ordinance has  
614 been created. Retail facilities must meet the requirements in  
615 subparagraphs (b)5. and (b)7. Retail facilities may not sell, or  
616 contract for the sale of, anything other than low-THC cannabis  
617 or low-THC cannabis products on the property of the retail  
618 facility. Before a retail facility may dispense low-THC cannabis  
619 or a low-THC cannabis product, the dispensing organization must  
620 have a computer network compliant with the federal Health  
621 Insurance Portability and Accountability Act of 1996 which is  
622 able to access and upload data to the compassionate use registry  
623 and which shall be used by all retail facilities.

624       (e) Within 15 days of such information becoming available,  
625 a dispensing organization must provide the department with  
626 updated information, as applicable, including:

627           1. The location and a detailed description of any new or  
628 proposed facilities.

629           2. The updated contact information, including electronic  
630 and voice communication, for all dispensing organization  
631 facilities.

632           3. The registration information for any vehicles used for  
633 the transportation of low-THC cannabis and low-THC cannabis  
634 product, including confirmation that all such vehicles have  
635 tracking and security systems.

636           4. A plan for the recall of any or all low-THC cannabis or  
637 low-THC cannabis product.

638       (f)1. A dispensing organization may transport low-THC

580-02582A-15

20157066pb

639 cannabis or low-THC cannabis products in vehicles departing from  
640 their places of business only in vehicles that are owned or  
641 leased by the licensee or by a person designated by the  
642 dispensing organization, and for which a valid vehicle permit  
643 has been issued for such vehicle by the department.

644 2. A vehicle owned or leased by the dispensing organization  
645 or a person designated by the dispensing organization and  
646 approved by the department must be operated by such person when  
647 transporting low-THC cannabis or low-THC products from the  
648 licensee's place of business.

649 3. A vehicle permit may be obtained by a dispensing  
650 organization upon application and payment of a fee of \$5 per  
651 vehicle to the department. The signature of the person  
652 designated by the dispensing organization to drive the vehicle  
653 must be included on the vehicle permit application. Such permit  
654 remains valid and does not expire unless the licensee or any  
655 person designated by the dispensing organization disposes of his  
656 or her vehicle, or the licensee's license is transferred,  
657 canceled, not renewed, or is revoked by the department,  
658 whichever occurs first. The department shall cancel a vehicle  
659 permit upon request of the licensee or owner of the vehicle.

660 4. By acceptance of a license issued under this section,  
661 the licensee agrees that the licensed vehicle is, at all times  
662 it is being used to transport low-THC cannabis or low-THC  
663 cannabis products, subject to inspection and search without a  
664 search warrant by authorized employees of the department,  
665 sheriffs, deputy sheriffs, or police officers to determine that  
666 the licensee is transporting such products in compliance with  
667 this section.

580-02582A-15

20157066pb

668 (7) TESTING AND LABELING OF LOW-THC CANNABIS.—

669 (a) All low-THC cannabis and low-THC cannabis products must  
670 be tested by an independent testing laboratory before the  
671 dispensing organization may dispense them. The independent  
672 testing laboratory shall provide the dispensing organization  
673 with lab results. Before dispensing, the dispensing organization  
674 must determine that the lab results indicate that the low-THC  
675 cannabis or low-THC cannabis product meets the definition of  
676 low-THC cannabis or low-THC cannabis product, is safe for human  
677 consumption, and is free from harmful contaminants.

678 (b) All low-THC cannabis and low-THC cannabis products must  
679 be labeled before dispensing. The label must include, at a  
680 minimum:

- 681 1. A statement that the low-THC cannabis or low-THC  
682 cannabis product meets the requirements in paragraph (a);  
683 2. The name of the independent testing laboratory that  
684 tested the low-THC cannabis or low-THC cannabis product;  
685 3. The name of the cultivation and processing facility  
686 where the low-THC cannabis or low-THC cannabis product  
687 originates; and  
688 4. The batch number and harvest number from which the low-  
689 THC cannabis or low-THC cannabis product originates.

690 (8) SAFETY AND EFFICACY RESEARCH FOR LOW-THC CANNABIS.—The  
691 University of Florida College of Pharmacy must establish and  
692 maintain a safety and efficacy research program for the use of  
693 low-THC cannabis or low-THC cannabis products to treat  
694 qualifying conditions and symptoms. The program must include a  
695 fully integrated electronic information system for the broad  
696 monitoring of health outcomes and safety signal detection. The



580-02582A-15

20157066pb

697 electronic information system must include information from the  
698 compassionate use registry; provider reports, including  
699 treatment plans, adverse event reports, and treatment  
700 discontinuation reports; patient reports of adverse impacts;  
701 event-triggered interviews and medical chart reviews performed  
702 by University of Florida clinical research staff; information  
703 from external databases, including Medicaid billing reports and  
704 information in the prescription drug monitoring database for  
705 registered patients; and all other medical reports required by  
706 the University of Florida to conduct the research required by  
707 this subsection. The department must provide access to  
708 information from the compassionate use registry and the  
709 prescription drug monitoring database, established in s.  
710 893.055, as needed by the University of Florida to conduct  
711 research under this subsection. The Agency for Health Care  
712 Administration must provide access to registered patient  
713 Medicaid records, to the extent allowed under federal law, as  
714 needed by the University of Florida to conduct research under  
715 this subsection.

716 (9) ~~(7)~~ EXCEPTIONS TO OTHER LAWS.—

717 (a) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or  
718 any other ~~provision of law~~, but subject to the requirements of  
719 this section, a qualified patient and the qualified patient's  
720 legal representative who is registered with the department on  
721 the compassionate use registry may purchase and possess for the  
722 patient's medical use up to the amount of low-THC cannabis  
723 ordered for the patient.

724 (b) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or  
725 any other provision of law, but subject to the requirements of

580-02582A-15

20157066pb

726 this section, an approved dispensing organization and its  
727 owners, managers, ~~and employees~~ and the owners, managers, and  
728 employees of contractors who have direct contact with low-THC  
729 cannabis or low-THC cannabis product may manufacture, possess,  
730 sell, deliver, distribute, dispense, and lawfully dispose of  
731 reasonable quantities, as established by department rule, of  
732 low-THC cannabis. For purposes of this subsection, the terms  
733 "manufacture," "possession," "deliver," "distribute," and  
734 "dispense" have the same meanings as provided in s. 893.02.

735 (c) An approved dispensing organization and its owners,  
736 managers, and employees are not subject to licensure or  
737 regulation under chapter 465 or chapter 499 for manufacturing,  
738 possessing, selling, delivering, distributing, dispensing, or  
739 lawfully disposing of reasonable quantities, as established by  
740 department rule, of low-THC cannabis.

741 (d) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or  
742 any other law, but subject to the requirements of this section,  
743 a licensed laboratory and its employees may receive and possess  
744 low-THC cannabis for the sole purpose of testing the low-THC  
745 cannabis to ensure compliance with this section.

746 (10) Rules adopted by the department under this section are  
747 exempt from the requirement that they be ratified by the  
748 Legislature pursuant to s. 120.541(3).

749 Section 2. Paragraph (g) is added to subsection (3) of  
750 section 381.987, Florida Statutes, to read:

751 381.987 Public records exemption for personal identifying  
752 information in the compassionate use registry.-

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

580-02582A-15

20157066pb

755 (g) Persons engaged in research at the University of  
756 Florida pursuant to s. 381.986(8).

757 Section 3. Paragraph (b) of subsection (7) of section  
758 893.055, Florida Statutes, is amended to read:

759 893.055 Prescription drug monitoring program.—

760 (7)

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

580-02582A-15

20157066pb

784 has similar access regarding the management of the database from  
785 the prescription drug monitoring program shall submit  
786 fingerprints to the department for background screening. The  
787 department shall follow the procedure established by the  
788 Department of Law Enforcement to request a statewide criminal  
789 history record check and to request that the Department of Law  
790 Enforcement forward the fingerprints to the Federal Bureau of  
791 Investigation for a national criminal history record check.

792 Section 4. Paragraph (h) is added to subsection (3) of  
793 section 893.0551, Florida Statutes, to read:

794 893.0551 Public records exemption for the prescription drug  
795 monitoring program.—

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

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

802 Section 5. This act shall take effect upon becoming a law.