

By the Committee on Regulated Industries

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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,

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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

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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

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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.

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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

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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,

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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

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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.~~

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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

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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.

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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.~~

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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~~

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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

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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

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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

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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

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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

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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.

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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

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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.

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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.

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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

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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.

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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

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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

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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:

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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

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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.