

By the Committees on Health Policy; and 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; authorizing a retail facility

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59 to be established in a municipality only after such an
60 ordinance has been created; authorizing a retail
61 facility to be established in the unincorporated areas
62 of a county only after such an ordinance has been
63 created; requiring retail facilities to have all
64 utilities and resources necessary to store and
65 dispense low-THC and low-THC cannabis products;
66 requiring retail facilities to be secured with
67 specified theft-prevention systems; requiring a
68 dispensing organization to provide the department with
69 specified updated information within a specified
70 period; authorizing a dispensing organization to
71 transport low-THC cannabis or low-THC cannabis
72 products in vehicles in certain circumstances;
73 requiring such vehicles to be operated by specified
74 persons in certain circumstances; requiring a fee for
75 a vehicle permit; requiring the signature of the
76 designated driver with a vehicle permit application;
77 providing for expiration of the permit in certain
78 circumstances; requiring the department to cancel a
79 vehicle permit upon the request of specified persons;
80 providing that the licensee authorizes the inspection
81 and search of his or her vehicle without a search
82 warrant by specified persons; requiring all low-THC
83 cannabis and low-THC cannabis products to be tested by
84 an independent testing laboratory before the
85 dispensing organization may dispense it; requiring the
86 independent testing laboratory to provide the lab
87 results to the dispensing organization for a specified

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88 determination; requiring all low-THC cannabis and low-
89 THC cannabis products to be labeled with specified
90 information before dispensing; requiring the
91 University of Florida College of Pharmacy to establish
92 and maintain a specified safety and efficacy research
93 program; providing program requirements; requiring the
94 department to provide information from the
95 prescription drug monitoring program to the University
96 of Florida as needed; requiring the Agency for Health
97 Care Administration to provide access to specified
98 patient records under certain circumstances; providing
99 that the act does not provide an exception to the
100 prohibition against driving under the influence;
101 authorizing specified individuals to manufacture,
102 possess, sell, deliver, distribute, dispense, and
103 lawfully dispose of reasonable quantities of low-THC
104 cannabis; authorizing a licensed laboratory and its
105 employees to receive and possess low-THC cannabis in
106 certain circumstances; providing that specified rules
107 adopted by the department are exempt from the
108 requirement to be ratified by the Legislature;
109 amending s. 381.987, F.S.; requiring the department to
110 allow specified persons engaged in research to access
111 the compassionate use registry; amending s. 893.055,
112 F.S.; providing that persons engaged in research at
113 the University of Florida shall have access to
114 specified information; amending s. 893.0551, F.S.;
115 providing a specified public records exemption for
116 persons engaged in research at the University of

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117 Florida; providing an effective date.

118
119 Be It Enacted by the Legislature of the State of Florida:

120
121 Section 1. Section 381.986, Florida Statutes, is amended to
122 read:

123 381.986 Compassionate use of low-THC cannabis.—

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

125 (a) "Applicant" means a person that has submitted an
126 application to the department for licensure or renewal as a
127 dispensing organization.

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

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

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

139 (e) ~~(b)~~ "Low-THC cannabis" means a plant of the genus
140 Cannabis, the dried flowers of which contain 0.8 percent or less
141 of tetrahydrocannabinol and more than 10 percent of cannabidiol
142 weight for weight; the seeds thereof; the resin extracted from
143 any part of such plant; or any compound, manufacture, salt,
144 derivative, mixture, or preparation of such plant or its seeds
145 or resin that is dispensed only from a dispensing organization.

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146 (f) "Low-THC cannabis product" means any product derived
147 from low-THC cannabis, including the resin extracted from any
148 part of such plant or any compound, manufacture, salt,
149 derivative, mixture, or preparation of such plant or its seeds
150 or resin which is dispensed from a dispensing organization. Low-
151 THC cannabis products include, but are not limited to, oils,
152 tinctures, creams, encapsulations, and food products. All low-
153 THC cannabis products must maintain concentrations, weight for
154 weight, of 0.8 percent or less of tetrahydrocannabinol and more
155 than 10 percent of cannabidiol.

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

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

159 2. The transfer of low-THC~~term also does not include~~ The transfer of low-THC
160 cannabis to a person other than the qualified patient for whom
161 it was ordered or the qualified patient's legal representative
162 who is registered in the compassionate use registry on behalf of
163 the qualified patient; ~~or~~

164 3. The use or administration of low-THC cannabis or low-THC
165 cannabis products:

166 a. On any form of public transportation.

167 b. In any public place.

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

170 d. In a correctional facility.

171 e. On the grounds of any preschool, primary school, or
172 secondary school.

173 f. On a school bus.

174 (h)~~(d)~~ "Qualified patient" means a resident of this state

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175 who has been added to the compassionate use registry by a
176 physician licensed under chapter 458 or chapter 459 to receive
177 low-THC cannabis from a dispensing organization.

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

181 (2) PHYSICIAN ORDERING.—

182 (a) ~~Effective January 1, 2015,~~ A physician licensed under
183 chapter 458 or chapter 459 who has examined and is treating a
184 patient suffering from cancer, human immunodeficiency virus,
185 acquired immune deficiency syndrome, epilepsy, amyotrophic
186 lateral sclerosis, multiple sclerosis, Crohn's disease,
187 Parkinson's disease, paraplegia, quadriplegia, or terminal
188 illness ~~a physical medical condition that chronically produces~~
189 ~~symptoms of seizures or severe and persistent muscle spasms~~ may
190 order for the patient's medical use low-THC cannabis to treat
191 such disease, disorder, or condition; ~~or~~ to alleviate symptoms
192 of such disease, disorder, or condition; ~~or~~ to alleviate
193 symptoms caused by a treatment for such disease, disorder, or
194 condition if no other satisfactory alternative treatment options
195 exist for that patient and all of the following ~~conditions~~
196 apply:

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

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

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204 ~~3.(e)~~ The physician registers the patient, the patient's
205 legal representative if requested by the patient, and himself or
206 herself as the orderer of low-THC cannabis for the named patient
207 on the compassionate use registry maintained by the department
208 and updates the registry to reflect the contents of the order.
209 If the patient is a minor, the physician must register a legal
210 representative on the compassionate use registry. The physician
211 shall deactivate the patient's registration when treatment is
212 discontinued.

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

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

222 ~~6.(f)~~ The physician obtains the voluntary informed consent
223 of the patient or the patient's legal guardian to treatment with
224 low-THC cannabis after sufficiently explaining the current state
225 of knowledge in the medical community of the effectiveness of
226 treatment of the patient's conditions or symptoms ~~condition~~ with
227 low-THC cannabis, the medically acceptable alternatives, and the
228 potential risks and side effects.

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

232 (3) PENALTIES.—

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233 (a) A physician commits a misdemeanor of the first degree,
234 punishable as provided in s. 775.082 or s. 775.083, if the
235 physician orders low-THC cannabis for a patient without a
236 reasonable belief that the patient is suffering from at least
237 one of the conditions listed in subsection (2).~~±~~

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

241 ~~2. Symptoms of cancer or a physical medical condition that~~
242 ~~chronically produces symptoms of seizures or severe and~~
243 ~~persistent muscle spasms that can be alleviated with low-THC~~
244 ~~cannabis.~~

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

252 (4) PHYSICIAN EDUCATION.—

253 (a) Before ordering low-THC cannabis for use by a patient
254 in this state, the appropriate board shall require the ordering
255 physician licensed under chapter 458 or chapter 459 to
256 successfully complete an 8-hour course and subsequent
257 examination offered by the Florida Medical Association or the
258 Florida Osteopathic Medical Association that encompasses the
259 clinical indications for the appropriate use of low-THC
260 cannabis, the appropriate delivery mechanisms, the
261 contraindications for such use, as well as the relevant state

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262 and federal laws governing the ordering, dispensing, and
263 possessing of this substance. The first course and examination
264 shall be presented by October 1, 2014, and shall be administered
265 at least annually thereafter. Successful completion of the
266 course may be used by a physician to satisfy 8 hours of the
267 continuing medical education requirements required by his or her
268 respective board for licensure renewal. This course may be
269 offered in a distance learning format.

270 (b) The appropriate board shall require the medical
271 director of each dispensing organization approved under
272 subsection (5) to successfully complete a 2-hour course and
273 subsequent examination offered by the Florida Medical
274 Association or the Florida Osteopathic Medical Association that
275 encompasses appropriate safety procedures and knowledge of low-
276 THC cannabis.

277 (c) Successful completion of the course and examination
278 specified in paragraph (a) is required for every physician who
279 orders low-THC cannabis each time such physician renews his or
280 her license. In addition, successful completion of the course
281 and examination specified in paragraph (b) is required for the
282 medical director of each dispensing organization each time such
283 physician renews his or her license.

284 (d) A physician who fails to comply with this subsection
285 and who orders low-THC cannabis may be subject to disciplinary
286 action under the applicable practice act and under s.
287 456.072(1)(k).

288 (5) DUTIES AND POWERS OF THE DEPARTMENT. ~~By January 1,~~
289 ~~2015, The department shall:~~

290 (a) The department shall create a secure, electronic, and

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291 online compassionate use registry for the registration of
292 physicians and patients as provided under this section. The
293 registry must be accessible to law enforcement agencies and to a
294 dispensing organization in order to verify patient authorization
295 for low-THC cannabis and record the low-THC cannabis dispensed.
296 The registry must prevent an active registration of a patient by
297 multiple physicians.

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

303 2. Within 10 days after receiving an application for
304 licensure, the department shall examine the application, notify
305 the applicant of any apparent errors or omissions, and request
306 any additional information the department is allowed by law to
307 require. An application for licensure must be filed with the
308 department no later than 5 p.m. on the 30th day after the
309 effective date of this act, and all applications must be
310 complete no later than 5 p.m. on the 60th day after the
311 effective date of this act.

312 3. If fewer than 20 applicants meet the criteria specified
313 in subsection (6), the department shall, by the 75th day after
314 the effective date of this act, license each such applicant. If
315 more than 20 applicants meet these criteria, licensure shall be
316 determined by lottery.

317 4. Beginning March 15, 2016, and every 6 months thereafter,
318 if fewer than 20 dispensing organization licenses have been
319 issued in this state, the department may issue additional

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320 licenses to qualified applicants up to the 20-organization
321 maximum. The department shall use the same timeframes as set
322 forth in subparagraphs 1.-3., beginning 75 days before the date
323 specified for issuing additional licenses. If the number of
324 qualified applicants under this subparagraph exceeds the number
325 of dispensing organization licenses available for issuance,
326 licensure shall be determined by lottery.

327 5. This section is exempt from s. 120.60 ~~Authorize the~~
328 ~~establishment of five dispensing organizations to ensure~~
329 ~~reasonable statewide accessibility and availability as necessary~~
330 ~~for patients registered in the compassionate use registry and~~
331 ~~who are ordered low-THC cannabis under this section, one in each~~
332 ~~of the following regions: northwest Florida, northeast Florida,~~
333 ~~central Florida, southeast Florida, and southwest Florida.~~

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

336 1. Whether the application is for initial licensure or
337 renewal licensure;

338 2. The name, the physical address, the mailing address, the
339 address listed on the Department of Agriculture and Consumer
340 Services certificate required in paragraph (6) (b), and the
341 contact information for the applicant and for the nursery that
342 holds the Department of Agriculture and Consumer Services
343 certificate, if different from the applicant;

344 3. The name, address, and contact information for the
345 operating nurseryman of the organization that holds the
346 Department of Agriculture and Consumer Services certificate;

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

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349 5. All information required to be included by subsection
350 (6).

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

356 1. The technical and technological ability to cultivate and
357 produce low-THC cannabis. The applicant must possess a valid
358 certificate of registration issued by the Department of
359 Agriculture and Consumer Services pursuant to s. 581.131 that is
360 issued for the cultivation of more than 400,000 plants, be
361 operated by a nurseryman as defined in s. 581.011, and have been
362 operated as a registered nursery in this state for at least 30
363 continuous years.

364 2. The ability to secure the premises, resources, and
365 personnel necessary to operate as a dispensing organization.

366 3. The ability to maintain accountability of all raw
367 materials, finished products, and any byproducts to prevent
368 diversion or unlawful access to or possession of these
369 substances.

370 4. An infrastructure reasonably located to dispense low-THC
371 cannabis to registered patients statewide or regionally as
372 determined by the department.

373 5. The financial ability to maintain operations for the
374 duration of the 2-year approval cycle, including the provision
375 of certified financials to the department. Upon approval, the
376 applicant must post a \$5 million performance bond.

377 6. That all owners and managers have been fingerprinted and

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378 ~~have successfully passed a level 2 background screening pursuant~~
379 ~~to s. 435.04.~~

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

383 (e) The department shall inspect each dispensing
384 organization's properties, cultivation facilities, processing
385 facilities, and retail facilities before they begin operations
386 and at least once every 2 years thereafter. The department may
387 conduct additional announced or unannounced inspections,
388 including followup inspections, at reasonable hours in order to
389 ensure that such property and facilities maintain compliance
390 with all applicable requirements in subsections (6) and (7) and
391 to ensure that the dispensing organization has not committed any
392 other act that would endanger the health, safety, or security of
393 a qualified patient, dispensing organization staff, or the
394 community in which the dispensing organization is located.
395 Licensure under this section constitutes permission for the
396 department to enter and inspect the premises and facilities of
397 any dispensing organization. The department may inspect any
398 licensed dispensing organization, and a dispensing organization
399 must make all facility premises, equipment, documents, low-THC
400 cannabis, and low-THC cannabis products available to the
401 department upon inspection. The department may test any low-THC
402 cannabis or low-THC cannabis product in order to ensure that it
403 is safe for human consumption and that it meets the requirements
404 in this section.

405 (f) The department may suspend or revoke a license, deny or
406 refuse to renew a license, or impose an administrative penalty

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407 not to exceed \$10,000 for the following acts or omissions:

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

409 2. Failing to maintain qualifications for licensure.

410 3. Endangering the health, safety, or security of a
411 qualified patient.

412 4. Improperly disclosing personal and confidential
413 information of the qualified patient.

414 5. Attempting to procure a license by bribery or fraudulent
415 misrepresentation.

416 6. Being convicted or found guilty of, or entering a plea
417 of nolo contendere to, regardless of adjudication, a crime in
418 any jurisdiction which directly relates to the business of a
419 dispensing organization.

420 7. Making or filing a report or record that the licensee
421 knows to be false.

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

424 9. Willfully impeding or obstructing an employee or agent
425 of the department in the furtherance of his or her official
426 duties.

427 10. Engaging in fraud or deceit, negligence, incompetence,
428 or misconduct in the business practices of a dispensing
429 organization.

430 11. Making misleading, deceptive, or fraudulent
431 representations in or related to the business practices of a
432 dispensing organization.

433 12. Having a license or the authority to engage in any
434 regulated profession, occupation, or business that is related to
435 the business practices of a dispensing organization revoked,

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436 suspended, or otherwise acted against, including the denial of
437 licensure, by the licensing authority of any jurisdiction,
438 including its agencies or subdivisions, for a violation that
439 would constitute a violation under state law. A licensing
440 authority's acceptance of a relinquishment of licensure or a
441 stipulation, consent order, or other settlement, offered in
442 response to or in anticipation of the filing of charges against
443 the license, shall be construed as an action against the
444 license.

445 13. Violating a lawful order of the department or an agency
446 of the state, or failing to comply with a lawfully issued
447 subpoena of the department or an agency of the state.

448 (g) The department shall create a permitting process for
449 all dispensing organization vehicles used for the transportation
450 of low-THC cannabis or low-THC cannabis products.

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

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

457 (6) DISPENSING ORGANIZATION.—

458 (a) An applicant seeking licensure as a dispensing
459 organization, or the renewal of its license, must submit an
460 application to the department. The department must review all
461 applications for completeness, including an appropriate
462 inspection of the applicant's property and facilities to verify
463 the authenticity of the information provided in, or in
464 connection with, the application. An applicant authorizes the

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465 department to inspect his or her property and facilities for
466 licensure by applying under this subsection.

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

469 1. The applicant, or a separate entity that is owned solely
470 by the same persons or entities in the same ratio as the
471 applicant, possesses a valid certificate of registration issued
472 by the Department of Agriculture and Consumer Services pursuant
473 to s. 581.131 for the cultivation of more than 400,000 plants,
474 is operated by a nurseryman as defined in s. 581.011, and has
475 been operated as a registered nursery in this state for at least
476 30 continuous years.

477 2. The personnel on staff or under contract for the
478 applicant have experience cultivating and introducing multiple
479 varieties of plants in this state, including plants that are not
480 native to Florida; experience with propagating plants; and
481 experience with genetic modification or breeding of plants.

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

484 a. Has at least 5 years' experience with United States
485 Department of Agriculture Good Agricultural Practices and Good
486 Handling Practices;

487 b. Has at least 5 years' experience with United States Food
488 and Drug Administration Good Manufacturing Practices for food
489 production;

490 c. Has a doctorate degree in organic chemistry or
491 microbiology;

492 d. Has at least 5 years of experience with laboratory
493 procedures which includes analytical laboratory quality control

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494 measures, chain of custody procedures, and analytical laboratory
495 methods;

496 e. Has experience with cannabis cultivation and processing,
497 including cannabis extraction techniques and producing cannabis
498 products;

499 f. Has experience and qualifications in chain of custody or
500 other tracking mechanisms;

501 g. Works solely on inventory control; and

502 h. Works solely for security purposes.

503 4. The persons who have a direct or indirect interest in
504 the dispensing organization and the applicant's managers,
505 employees, and contractors who directly interact with low-THC
506 cannabis or low-THC cannabis products have been fingerprinted
507 and have successfully passed a level 2 background screening
508 pursuant to s. 435.04.

509 5. The applicant owns, or has at least a 2-year lease of,
510 all properties, facilities, and equipment necessary for the
511 cultivation and processing of low-THC cannabis. The applicant
512 must provide a detailed description of each facility and its
513 equipment, a cultivation and processing plan, and a detailed
514 floor plan. The description must include proof that:

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

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

522 c. Each facility is secured and has theft-prevention

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523 systems including an alarm system, cameras, and 24-hour security
524 personnel.

525 6. The applicant has diversion and tracking prevention
526 procedures, including:

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

530 b. An inventory control system for low-THC cannabis and
531 low-THC cannabis products;

532 c. A vehicle tracking and security system; and

533 d. A cannabis waste-disposal plan.

534 7. The applicant has recordkeeping policies and procedures
535 in place.

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

537 9. The applicant has a plan for dispensing low-THC cannabis
538 throughout the state. This plan must include planned retail
539 facilities and a delivery plan for providing low-THC cannabis
540 and low-THC cannabis products to qualified patients who cannot
541 travel to a retail facility.

542 10. The applicant has financial documentation, including:

543 a. Documentation that demonstrates the applicant's
544 financial ability to operate. If the applicant's assets, credit,
545 and projected revenues meet or exceed projected liabilities and
546 expenses and the applicant provides independent evidence that
547 the funds necessary for startup costs, working capital, and
548 contingency financing exist and are available as needed, the
549 applicant has demonstrated the financial ability to operate.

550 Financial ability to operate must be documented by:

551 I. The applicant's audited financial statements. If the

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552 applicant is a newly formed entity and does not have a financial
553 history of business upon which audited financial statements may
554 be submitted, the applicant must provide audited financial
555 statements for the separate entity that is owned solely by the
556 same persons or entities in the same ratio as the applicant that
557 possesses the valid certificate of registration issued by the
558 Department of Agriculture and Consumer Services;

559 II. The applicant's projected financial statements,
560 including a balance sheet, an income and expense statement, and
561 a statement of cash flow for the first 2 years of operation,
562 which provides evidence that the applicant has sufficient
563 assets, credit, and projected revenues to cover liabilities and
564 expenses; and

565 III. A statement of the applicant's estimated startup costs
566 and sources of funds, including a break-even projection and
567 documentation demonstrating that the applicant has the ability
568 to fund all startup costs, working capital costs, and
569 contingency financing requirements.

570
571 All documents required under this sub-subparagraph shall be
572 prepared in accordance with generally accepted accounting
573 principles and signed by a certified public accountant. The
574 statements required by sub-sub-subparagraph II. and III. may be
575 presented as a compilation.

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

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

579 d. Proof of a \$1 million performance and compliance bond,
580 or other equivalent means of security deemed equivalent by the

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581 department, such as an irrevocable letter of credit or a deposit
582 in a trust account or financial institution, payable to the
583 department, which must be posted once the applicant is approved
584 as a dispensing organization. The purpose of the bond is to
585 secure payment of any administrative penalties imposed by the
586 department and any fees and costs incurred by the department
587 regarding the dispensing organization license, such as the
588 dispensing organization failing to pay 30 days after the fine or
589 costs become final. The department may make a claim against such
590 bond or security until 1 year after the dispensing
591 organization's license ceases to be valid or until 60 days after
592 any administrative or legal proceeding authorized in this
593 section involving the dispensing organization concludes,
594 including any appeal, whichever occurs later.

595 11. The employment of a medical director who is a physician
596 licensed under chapter 458 or chapter 459 to supervise the
597 activities of the dispensing organization.

598 (c) An approved dispensing organization shall maintain
599 compliance with the criteria in paragraphs (b), (d), and (e) and
600 subsection (7) demonstrated for selection and approval as a
601 dispensing organization under subsection (5) at all times.
602 Before dispensing low-THC cannabis or low-THC cannabis products
603 to a qualified patient or to the qualified patient's legal
604 representative, the dispensing organization shall verify the
605 identity of the qualified patient or the qualified patient's
606 legal representative by requiring the qualified patient or the
607 qualified patient's legal representative to produce a
608 government-issued identification card and shall verify that the
609 qualified patient and the qualified patient's legal

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610 representative have ~~has~~ an active registration in the
611 compassionate use registry, that the order presented matches the
612 order contents as recorded in the registry, and that the order
613 has not already been filled. Upon dispensing the low-THC
614 cannabis, the dispensing organization shall record in the
615 registry the date, time, quantity, and form of low-THC cannabis
616 dispensed.

617 (d) A dispensing organization may have cultivation
618 facilities, processing facilities, and retail facilities.

619 1. All matters regarding the location of cultivation
620 facilities and processing facilities are preempted to the state.
621 Cultivation facilities and processing facilities must be closed
622 to the public, and low-THC cannabis may not be dispensed on the
623 premises of such facilities.

624 2. A municipality must determine by ordinance the criteria
625 for the number, location, and other permitting requirements for
626 all retail facilities located within its municipal boundaries. A
627 retail facility may be established in a municipality only after
628 such an ordinance has been created. A county must determine by
629 ordinance the criteria for the number, location, and other
630 permitting requirements for all retail facilities located within
631 the unincorporated areas of that county. A retail facility may
632 be established in the unincorporated areas of a county only
633 after such an ordinance has been created. Retail facilities must
634 have all utilities and resources necessary to store and dispense
635 low-THC cannabis and low-THC cannabis products. Retail
636 facilities must be secured and have theft-prevention systems,
637 including an alarm system, cameras, and 24-hour security
638 personnel. Retail facilities may not sell, or contract for the

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639 sale of, anything other than low-THC cannabis or low-THC
640 cannabis products on the property of the retail facility. Before
641 a retail facility may dispense low-THC cannabis or a low-THC
642 cannabis product, the dispensing organization must have a
643 computer network compliant with the federal Health Insurance
644 Portability and Accountability Act of 1996 which is able to
645 access and upload data to the compassionate use registry and
646 which shall be used by all retail facilities.

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

650 1. The location and a detailed description of any new or
651 proposed facilities.

652 2. The updated contact information, including electronic
653 and voice communication, for all dispensing organization
654 facilities.

655 3. The registration information for any vehicles used for
656 the transportation of low-THC cannabis and low-THC cannabis
657 product, including confirmation that all such vehicles have
658 tracking and security systems.

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

661 (f)1. A dispensing organization may transport low-THC
662 cannabis or low-THC cannabis products in vehicles departing from
663 their places of business only in vehicles that are owned or
664 leased by the licensee or by a person designated by the
665 dispensing organization, and for which a valid vehicle permit
666 has been issued for such vehicle by the department.

667 2. A vehicle owned or leased by the dispensing organization

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668 or a person designated by the dispensing organization and
669 approved by the department must be operated by such person when
670 transporting low-THC cannabis or low-THC products from the
671 licensee's place of business.

672 3. A vehicle permit may be obtained by a dispensing
673 organization upon application and payment of a fee of \$5 per
674 vehicle to the department. The signature of the person
675 designated by the dispensing organization to drive the vehicle
676 must be included on the vehicle permit application. Such permit
677 remains valid and does not expire unless the licensee or any
678 person designated by the dispensing organization disposes of his
679 or her vehicle, or the licensee's license is transferred,
680 canceled, not renewed, or is revoked by the department,
681 whichever occurs first. The department shall cancel a vehicle
682 permit upon request of the licensee or owner of the vehicle.

683 4. By acceptance of a license issued under this section,
684 the licensee agrees that the licensed vehicle is, at all times
685 it is being used to transport low-THC cannabis or low-THC
686 cannabis products, subject to inspection and search without a
687 search warrant by authorized employees of the department,
688 sheriffs, deputy sheriffs, police officers, or other law
689 enforcement officers to determine that the licensee is
690 transporting such products in compliance with this section.

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

692 (a) All low-THC cannabis and low-THC cannabis products must
693 be tested by an independent testing laboratory before the
694 dispensing organization may dispense them. The independent
695 testing laboratory shall provide the dispensing organization
696 with lab results. Before dispensing, the dispensing organization

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697 must determine that the lab results indicate that the low-THC
698 cannabis or low-THC cannabis product meets the definition of
699 low-THC cannabis or low-THC cannabis product, is safe for human
700 consumption, and is free from harmful contaminants.

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

704 1. A statement that the low-THC cannabis or low-THC
705 cannabis product meets the requirements in paragraph (a);

706 2. The name of the independent testing laboratory that
707 tested the low-THC cannabis or low-THC cannabis product;

708 3. The name of the cultivation and processing facility
709 where the low-THC cannabis or low-THC cannabis product
710 originates; and

711 4. The batch number and harvest number from which the low-
712 THC cannabis or low-THC cannabis product originates.

713 (8) SAFETY AND EFFICACY RESEARCH FOR LOW-THC CANNABIS.—The
714 University of Florida College of Pharmacy must establish and
715 maintain a safety and efficacy research program for the use of
716 low-THC cannabis or low-THC cannabis products to treat
717 qualifying conditions and symptoms. The program must include a
718 fully integrated electronic information system for the broad
719 monitoring of health outcomes and safety signal detection. The
720 electronic information system must include information from the
721 compassionate use registry; provider reports, including
722 treatment plans, adverse event reports, and treatment
723 discontinuation reports; patient reports of adverse impacts;
724 event-triggered interviews and medical chart reviews performed
725 by University of Florida clinical research staff; information

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726 from external databases, including Medicaid billing reports and
727 information in the prescription drug monitoring database for
728 registered patients; and all other medical reports required by
729 the University of Florida to conduct the research required by
730 this subsection. The department must provide access to
731 information from the compassionate use registry and the
732 prescription drug monitoring database, established in s.
733 893.055, as needed by the University of Florida to conduct
734 research under this subsection. The Agency for Health Care
735 Administration must provide access to registered patient
736 Medicaid records, to the extent allowed under federal law, as
737 needed by the University of Florida to conduct research under
738 this subsection.

739 (9) ~~(7)~~ EXCEPTIONS TO OTHER LAWS.-

740 (a) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or
741 any other ~~provision of~~ law, but subject to the requirements of
742 this section, a qualified patient and the qualified patient's
743 legal representative who is registered with the department on
744 the compassionate use registry may purchase and possess for the
745 patient's medical use up to the amount of low-THC cannabis
746 ordered for the patient. Nothing in this section exempts any
747 person from the prohibition against driving under the influence
748 provided in s. 316.193.

749 (b) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or
750 any other provision of law, but subject to the requirements of
751 this section, an approved dispensing organization and its
752 owners, managers, ~~and~~ employees and the owners, managers, and
753 employees of contractors who have direct contact with low-THC
754 cannabis or low-THC cannabis product may manufacture, possess,

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755 sell, deliver, distribute, dispense, and lawfully dispose of
756 reasonable quantities, as established by department rule, of
757 low-THC cannabis. For purposes of this subsection, the terms
758 "manufacture," "possession," "deliver," "distribute," and
759 "dispense" have the same meanings as provided in s. 893.02.

760 (c) An approved dispensing organization and its owners,
761 managers, and employees are not subject to licensure or
762 regulation under chapter 465 or chapter 499 for manufacturing,
763 possessing, selling, delivering, distributing, dispensing, or
764 lawfully disposing of reasonable quantities, as established by
765 department rule, of low-THC cannabis.

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

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

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

776 381.987 Public records exemption for personal identifying
777 information in the compassionate use registry.—

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

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

782 Section 3. Paragraph (b) of subsection (7) of section
783 893.055, Florida Statutes, is amended to read:

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784 893.055 Prescription drug monitoring program.—
785 (7)
786 (b) A pharmacy, prescriber, or dispenser shall have access
787 to information in the prescription drug monitoring program's
788 database which relates to a patient of that pharmacy,
789 prescriber, or dispenser in a manner established by the
790 department as needed for the purpose of reviewing the patient's
791 controlled substance prescription history. Persons engaged in
792 research at the University of Florida pursuant to s. 381.986(8)
793 shall have access to information in the prescription drug
794 monitoring program's database which relates to qualified
795 patients as defined in s. 381.986(1) for the purpose of
796 conducting such research. Other access to the program's database
797 shall be limited to the program's manager and to the designated
798 program and support staff, who may act only at the direction of
799 the program manager or, in the absence of the program manager,
800 as authorized. Access by the program manager or such designated
801 staff is for prescription drug program management only or for
802 management of the program's database and its system in support
803 of the requirements of this section and in furtherance of the
804 prescription drug monitoring program. Confidential and exempt
805 information in the database shall be released only as provided
806 in paragraph (c) and s. 893.0551. The program manager,
807 designated program and support staff who act at the direction of
808 or in the absence of the program manager, and any individual who
809 has similar access regarding the management of the database from
810 the prescription drug monitoring program shall submit
811 fingerprints to the department for background screening. The
812 department shall follow the procedure established by the

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813 Department of Law Enforcement to request a statewide criminal
814 history record check and to request that the Department of Law
815 Enforcement forward the fingerprints to the Federal Bureau of
816 Investigation for a national criminal history record check.

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

819 893.0551 Public records exemption for the prescription drug
820 monitoring program.—

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

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

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