

By the Committees on Rules; 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; requiring the department to select two
20 applicants in specified regions for licensure as a
21 dispensing organization; requiring the department to
22 issue 10 additional licenses to qualified applicants
23 by lottery; authorizing applicants to operate in any
24 region of the state; prohibiting a dispensing
25 organization from having cultivation or processing
26 facilities outside the region in which it is licensed;
27 requiring the department to select by lottery another
28 applicant in certain circumstances; requiring the
29 department to conduct a new lottery after the

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30 revocation or the denial of renewal of a license;
31 requiring the department to conduct a lottery at
32 specified intervals if there are available dispensing
33 organization licenses; providing an exemption for the
34 application process; requiring the department to use
35 an application form that requires specified
36 information from the applicant; requiring the
37 department to impose specified application fees;
38 requiring the department to inspect each dispensing
39 organization's properties, cultivation facilities,
40 processing facilities, and retail facilities before
41 those facilities may operate; authorizing followup
42 inspections at reasonable hours; providing that
43 licensure constitutes permission for the department to
44 enter and inspect the premises and facilities of any
45 dispensing organization; authorizing the department to
46 inspect any licensed dispensing organization;
47 requiring dispensing organizations to make all
48 facility premises, equipment, documents, low-THC
49 cannabis, and low-THC cannabis products available to
50 the department upon inspection; authorizing the
51 department to test low-THC cannabis or low-THC
52 cannabis products; authorizing the department to
53 suspend or revoke a license, deny or refuse to renew a
54 license, or impose a maximum administrative penalty
55 for specified acts or omissions; requiring the
56 department to create a permitting process for vehicles
57 used for the transportation of low-THC cannabis or
58 low-THC cannabis products; authorizing the department

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59 to adopt rules as necessary for implementation of
60 specified provisions and procedures, and to provide
61 specified guidance; providing procedures and
62 requirements for an applicant seeking licensure as a
63 dispensing organization or the renewal of its license;
64 requiring the dispensing organization to verify
65 specified information of specified persons in certain
66 circumstances; authorizing a dispensing organization
67 to have cultivation facilities, processing facilities,
68 and retail facilities; authorizing a retail facility
69 to be established in a municipality only after such an
70 ordinance has been created; authorizing a retail
71 facility to be established in the unincorporated areas
72 of a county only after such an ordinance has been
73 created; requiring retail facilities to have all
74 utilities and resources necessary to store and
75 dispense low-THC and low-THC cannabis products;
76 requiring retail facilities to be secured with
77 specified theft-prevention systems; requiring a
78 dispensing organization to provide the department with
79 specified updated information within a specified
80 period; authorizing a dispensing organization to
81 transport low-THC cannabis or low-THC cannabis
82 products in vehicles in certain circumstances;
83 requiring such vehicles to be operated by specified
84 persons in certain circumstances; requiring a fee for
85 a vehicle permit; requiring the signature of the
86 designated driver with a vehicle permit application;
87 providing for expiration of the permit in certain

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88 circumstances; requiring the department to cancel a
89 vehicle permit upon the request of specified persons;
90 providing that the licensee authorizes the inspection
91 and search of his or her vehicle without a search
92 warrant by specified persons; requiring all low-THC
93 cannabis and low-THC cannabis products to be tested by
94 an independent testing laboratory before the
95 dispensing organization may dispense it; requiring the
96 independent testing laboratory to provide the lab
97 results to the dispensing organization for a specified
98 determination; requiring all low-THC cannabis and low-
99 THC cannabis products to be labeled with specified
100 information before dispensing; requiring the
101 University of Florida College of Pharmacy to establish
102 and maintain a specified safety and efficacy research
103 program; providing program requirements; requiring the
104 department to provide information from the
105 prescription drug monitoring program to the University
106 of Florida as needed; requiring the Agency for Health
107 Care Administration to provide access to specified
108 patient records under certain circumstances;
109 prohibiting persons who have direct or indirect
110 interest in a dispensing organization and the
111 dispensing organization's managers, employees, and
112 contractors who directly interact with low-THC
113 cannabis and low-THC cannabis products from making
114 recommendations, offering prescriptions, or providing
115 medical advice to qualified patients; providing that
116 the act does not provide an exception to the

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117 prohibition against driving under the influence;
118 authorizing specified individuals to manufacture,
119 possess, sell, deliver, distribute, dispense, and
120 lawfully dispose of reasonable quantities of low-THC
121 cannabis; authorizing a licensed laboratory and its
122 employees to receive and possess low-THC cannabis in
123 certain circumstances; providing that specified rules
124 adopted by the department are exempt from the
125 requirement to be ratified by the Legislature;
126 amending s. 381.987, F.S.; requiring the department to
127 allow specified persons engaged in research to access
128 the compassionate use registry; amending s. 893.055,
129 F.S.; providing that persons engaged in research at
130 the University of Florida shall have access to
131 specified information; amending s. 893.0551, F.S.;
132 providing a specified public records exemption for
133 persons engaged in research at the University of
134 Florida; providing an effective date.

135

136 Be It Enacted by the Legislature of the State of Florida:

137

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

140 381.986 Compassionate use of low-THC cannabis.—

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

142 (a) "Applicant" means a person that has submitted an
143 application to the department for licensure or renewal as a
144 dispensing organization.

145 (b) "Batch" means a specific quantity of low-THC cannabis

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146 product that is intended to have uniform character and quality,
147 within specified limits, and is produced at the same time from
148 one or more harvests.

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

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

156 (e) "Independent testing laboratory" means a laboratory,
157 and the managers, employees, or contractors of the laboratory,
158 which have no direct or indirect interest in a dispensing
159 organization.

160 (f) ~~(b)~~ "Low-THC cannabis" means a plant of the genus
161 Cannabis, the dried flowers of which contain 0.8 percent or less
162 of tetrahydrocannabinol and more than 10 percent of cannabidiol
163 weight for weight; the seeds thereof; the resin extracted from
164 any part of such plant; or any compound, manufacture, salt,
165 derivative, mixture, or preparation of such plant or its seeds
166 or resin that is dispensed only from a dispensing organization.

167 (g) "Low-THC cannabis product" means any product derived
168 from low-THC cannabis, including the resin extracted from any
169 part of such plant or any compound, manufacture, salt,
170 derivative, mixture, or preparation of such plant or its seeds
171 or resin which is dispensed from a dispensing organization. Low-
172 THC cannabis products include, but are not limited to, oils,
173 tinctures, creams, encapsulations, and food products. Low-THC
174 cannabis food products may not include candy or similar

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175 confectionary products that appeal to children. All low-THC
176 cannabis products must maintain concentrations, weight for
177 weight, of 0.8 percent or less of tetrahydrocannabinol and more
178 than 10 percent of cannabidiol.

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

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

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

187 3. The use or administration of low-THC cannabis or low-THC
188 cannabis products:

189 a. On any form of public transportation.

190 b. In any public place.

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

193 d. In a correctional facility.

194 e. On the grounds of any preschool, primary school, or
195 secondary school.

196 f. On a school bus.

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

201 (j)~~(e)~~ "Smoking" means burning or igniting a substance and
202 inhaling the smoke. Smoking does not include the use of a
203 vaporizer.

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204 (2) PHYSICIAN ORDERING.—

205 (a) ~~Effective January 1, 2015,~~ A physician licensed under
206 chapter 458 or chapter 459 who has examined and is treating a
207 patient suffering from cancer, human immunodeficiency virus,
208 acquired immune deficiency syndrome, epilepsy, amyotrophic
209 lateral sclerosis, autism, multiple sclerosis, Crohn's disease,
210 Parkinson's disease, paraplegia, quadriplegia, or terminal
211 illness ~~a physical medical condition that chronically produces~~
212 ~~symptoms of seizures or severe and persistent muscle spasms~~ may
213 order for the patient's medical use low-THC cannabis to treat
214 such disease, disorder, or condition; ~~or~~ to alleviate symptoms
215 of such disease, disorder, or condition; or to alleviate
216 symptoms caused by a treatment for such disease, disorder, or
217 condition, if no other satisfactory alternative treatment
218 options exist for that patient and all of the following
219 ~~conditions~~ apply:

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

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

227 3. ~~(c)~~ The physician registers the patient, the patient's
228 legal representative if requested by the patient, and himself or
229 herself as the orderer of low-THC cannabis for the named patient
230 on the compassionate use registry maintained by the department
231 and updates the registry to reflect the contents of the order.
232 If the patient is a minor, the physician must register a legal

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233 representative on the compassionate use registry. The physician
234 shall deactivate the patient's registration when treatment is
235 discontinued.

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

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

245 6.(f) The physician obtains the voluntary informed consent
246 of the patient or the patient's legal guardian to treatment with
247 low-THC cannabis after sufficiently explaining the current state
248 of knowledge in the medical community of the effectiveness of
249 treatment of the patient's conditions or symptoms ~~condition~~ with
250 low-THC cannabis, the medically acceptable alternatives, and the
251 potential risks and side effects.

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

255 (3) PENALTIES.—

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

261 ~~1. Cancer or a physical medical condition that chronically~~

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262 ~~produces symptoms of seizures or severe and persistent muscle~~
263 ~~spasms that can be treated with low-THC cannabis; or~~

264 ~~2. Symptoms of cancer or a physical medical condition that~~
265 ~~chronically produces symptoms of seizures or severe and~~
266 ~~persistent muscle spasms that can be alleviated with low-THC~~
267 ~~cannabis.~~

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

275 (4) PHYSICIAN EDUCATION.—

276 (a) Before ordering low-THC cannabis for use by a patient
277 in this state, the appropriate board shall require the ordering
278 physician licensed under chapter 458 or chapter 459 to
279 successfully complete an 8-hour course and subsequent
280 examination offered by the Florida Medical Association or the
281 Florida Osteopathic Medical Association that encompasses the
282 clinical indications for the appropriate use of low-THC
283 cannabis, the appropriate delivery mechanisms, the
284 contraindications for such use, as well as the relevant state
285 and federal laws governing the ordering, dispensing, and
286 possessing of this substance. The first course and examination
287 shall be presented by October 1, 2014, and shall be administered
288 at least annually thereafter. Successful completion of the
289 course may be used by a physician to satisfy 8 hours of the
290 continuing medical education requirements required by his or her

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291 respective board for licensure renewal. This course may be
292 offered in a distance learning format.

293 (b) The appropriate board shall require the medical
294 director of each dispensing organization approved under
295 subsection (5) to successfully complete a 2-hour course and
296 subsequent examination offered by the Florida Medical
297 Association or the Florida Osteopathic Medical Association that
298 encompasses appropriate safety procedures and knowledge of low-
299 THC cannabis.

300 (c) Successful completion of the course and examination
301 specified in paragraph (a) is required for every physician who
302 orders low-THC cannabis each time such physician renews his or
303 her license. In addition, successful completion of the course
304 and examination specified in paragraph (b) is required for the
305 medical director of each dispensing organization each time such
306 physician renews his or her license.

307 (d) A physician who fails to comply with this subsection
308 and who orders low-THC cannabis may be subject to disciplinary
309 action under the applicable practice act and under s.
310 456.072(1)(k).

311 (5) DUTIES AND POWERS OF THE DEPARTMENT. ~~By January 1,~~
312 ~~2015, The department shall:~~

313 (a) The department shall create a secure, electronic, and
314 online compassionate use registry for the registration of
315 physicians and patients as provided under this section. The
316 registry must be accessible to law enforcement agencies and to a
317 dispensing organization in order to verify patient authorization
318 for low-THC cannabis and record the low-THC cannabis dispensed.
319 The registry must prevent an active registration of a patient by

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320 multiple physicians.

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

326 2. Within 10 days after receiving an application for
327 licensure, the department shall examine the application, notify
328 the applicant of any apparent errors or omissions, and request
329 any additional information the department is allowed by law to
330 require. An application for licensure must be filed with the
331 department no later than 5 p.m. on the 30th day after the
332 effective date of this act, and all applications must be
333 complete no later than 5 p.m. on the 60th day after the
334 effective date of this act.

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

339 a. Northwest Florida, consisting of Bay, Calhoun, Escambia,
340 Franklin, Gadsden, Gulf, Holmes, Jackson, Jefferson, Leon,
341 Liberty, Madison, Santa Rosa, Okaloosa, Taylor, Wakulla, Walton,
342 and Washington Counties.

343 b. Northeast Florida, consisting of Alachua, Baker,
344 Bradford, Clay, Columbia, Dixie, Duval, Flagler, Gilchrist,
345 Hamilton, Lafayette, Levy, Marion, Nassau, Putnam, St. Johns,
346 Suwannee, and Union Counties.

347 c. Central Florida, consisting of Brevard, Citrus, Hardee,
348 Hernando, Hillsborough, Indian River, Lake, Orange, Osceola,

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349 Pasco, Pinellas, Polk, Seminole, St. Lucie, Sumter, and Volusia
350 Counties.

351 d. Southwest Florida, consisting of Charlotte, Collier,
352 DeSoto, Glades, Hendry, Highlands, Lee, Manatee, Okeechobee, and
353 Sarasota Counties.

354 e. Southeast Florida, consisting of Broward, Miami-Dade,
355 Martin, Monroe, and Palm Beach Counties.

356 4. After the department has selected by lottery the 10
357 dispensing organizations pursuant to subparagraph 3., the
358 department shall select by lottery 10 more applicants who meet
359 the criteria in subsection (6) for licensure. Once licensed,
360 those applicants are authorized to operate in any region in the
361 state, but a dispensing organization may not have cultivation or
362 processing facilities outside the region in which it is
363 licensed.

364 5. The department shall license an applicant selected
365 pursuant to subparagraph 3. or subparagraph 4. unless the
366 applicant fails to pay the licensure fee within 10 days of
367 selection. If a selected applicant fails to timely pay the
368 licensure fee, the department shall select by lottery another
369 applicant from the existing pool of eligible applicants.

370 6. If the department revokes a license or denies the
371 renewal of a license pursuant to paragraph (f), the department
372 shall conduct a new lottery using the selection process outlined
373 in this paragraph. The selection process must begin 24 hours
374 after such revocation or denial.

375 7. If the department does not have a sufficient pool of
376 qualified applicants to issue 2 licenses in each region, or to
377 license 10 dispensing organizations pursuant to subparagraph 4.,

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378 the department shall conduct a lottery using the process in this
379 paragraph every 6 months until each region has 2 licensed
380 dispensing organizations and 10 additional dispensing
381 organizations are licensed, totaling 20 licensed dispensing
382 organizations in this state.

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

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

392 1. Whether the application is for initial licensure or
393 renewal licensure;

394 2. The name, the physical address, the mailing address, the
395 address listed on the Department of Agriculture and Consumer
396 Services certificate required in paragraph (6) (b), and the
397 contact information for the applicant and for the nursery that
398 holds the Department of Agriculture and Consumer Services
399 certificate, if different from the applicant;

400 3. The name, address, and contact information for the
401 operating nurseryman of the organization that holds the
402 Department of Agriculture and Consumer Services certificate;

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

405 5. All information required to be included by subsection
406 (6).

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

412 1. ~~The technical and technological ability to cultivate and~~
413 ~~produce low-THC cannabis. The applicant must possess a valid~~
414 ~~certificate of registration issued by the Department of~~
415 ~~Agriculture and Consumer Services pursuant to s. 581.131 that is~~
416 ~~issued for the cultivation of more than 400,000 plants, be~~
417 ~~operated by a nurseryman as defined in s. 581.011, and have been~~
418 ~~operated as a registered nursery in this state for at least 30~~
419 ~~continuous years.~~

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

422 3. ~~The ability to maintain accountability of all raw~~
423 ~~materials, finished products, and any byproducts to prevent~~
424 ~~diversion or unlawful access to or possession of these~~
425 ~~substances.~~

426 4. ~~An infrastructure reasonably located to dispense low-THC~~
427 ~~cannabis to registered patients statewide or regionally as~~
428 ~~determined by the department.~~

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

433 6. ~~That all owners and managers have been fingerprinted and~~
434 ~~have successfully passed a level 2 background screening pursuant~~
435 ~~to s. 435.04.~~

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

439 (e) The department shall inspect each dispensing
440 organization's properties, cultivation facilities, processing
441 facilities, and retail facilities before they begin operations
442 and at least once every 2 years thereafter. The department may
443 conduct additional announced or unannounced inspections,
444 including followup inspections, at reasonable hours in order to
445 ensure that such property and facilities maintain compliance
446 with all applicable requirements in subsections (6) and (7) and
447 to ensure that the dispensing organization has not committed any
448 other act that would endanger the health, safety, or security of
449 a qualified patient, dispensing organization staff, or the
450 community in which the dispensing organization is located.
451 Licensure under this section constitutes permission for the
452 department to enter and inspect the premises and facilities of
453 any dispensing organization. The department may inspect any
454 licensed dispensing organization, and a dispensing organization
455 must make all facility premises, equipment, documents, low-THC
456 cannabis, and low-THC cannabis products available to the
457 department upon inspection. The department may test any low-THC
458 cannabis or low-THC cannabis product in order to ensure that it
459 is safe for human consumption and that it meets the requirements
460 in this section.

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

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

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465 2. Failing to maintain qualifications for licensure.

466 3. Endangering the health, safety, or security of a
467 qualified patient.

468 4. Improperly disclosing personal and confidential
469 information of the qualified patient.

470 5. Attempting to procure a license by bribery or fraudulent
471 misrepresentation.

472 6. Being convicted or found guilty of, or entering a plea
473 of nolo contendere to, regardless of adjudication, a crime in
474 any jurisdiction which directly relates to the business of a
475 dispensing organization.

476 7. Making or filing a report or record that the licensee
477 knows to be false.

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

480 9. Willfully impeding or obstructing an employee or agent
481 of the department in the furtherance of his or her official
482 duties.

483 10. Engaging in fraud or deceit, negligence, incompetence,
484 or misconduct in the business practices of a dispensing
485 organization.

486 11. Making misleading, deceptive, or fraudulent
487 representations in or related to the business practices of a
488 dispensing organization.

489 12. Having a license or the authority to engage in any
490 regulated profession, occupation, or business that is related to
491 the business practices of a dispensing organization revoked,
492 suspended, or otherwise acted against, including the denial of
493 licensure, by the licensing authority of any jurisdiction,

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494 including its agencies or subdivisions, for a violation that
495 would constitute a violation under state law. A licensing
496 authority's acceptance of a relinquishment of licensure or a
497 stipulation, consent order, or other settlement, offered in
498 response to or in anticipation of the filing of charges against
499 the license, shall be construed as an action against the
500 license.

501 13. Violating a lawful order of the department or an agency
502 of the state, or failing to comply with a lawfully issued
503 subpoena of the department or an agency of the state.

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

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

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

513 (6) DISPENSING ORGANIZATION.—

514 (a) An applicant seeking licensure as a dispensing
515 organization, or the renewal of its license, must submit an
516 application to the department. The department must review all
517 applications for completeness, including an appropriate
518 inspection of the applicant's property and facilities to verify
519 the authenticity of the information provided in, or in
520 connection with, the application. An applicant authorizes the
521 department to inspect his or her property and facilities for
522 licensure by applying under this subsection.

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523 (b) In order to receive or maintain licensure as a
524 dispensing organization, an applicant must provide proof that:
525 1. The applicant, or a separate entity that is owned solely
526 by the same persons or entities in the same ratio as the
527 applicant, possesses a valid certificate of registration issued
528 by the Department of Agriculture and Consumer Services pursuant
529 to s. 581.131 for the cultivation of more than 400,000 plants,
530 is operated by a nurseryman as defined in s. 581.011, and has
531 been operated as a registered nursery in this state for at least
532 30 continuous years.

533 2. The personnel on staff or under contract for the
534 applicant have experience cultivating and introducing multiple
535 varieties of plants in this state, including plants that are not
536 native to Florida; experience with propagating plants; and
537 experience with genetic modification or breeding of plants.

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

540 a. Has at least 5 years' experience with United States
541 Department of Agriculture Good Agricultural Practices and Good
542 Handling Practices;

543 b. Has at least 5 years' experience with United States Food
544 and Drug Administration Good Manufacturing Practices for food
545 production;

546 c. Has a doctorate degree in organic chemistry or
547 microbiology;

548 d. Has at least 5 years' of experience with laboratory
549 procedures which includes analytical laboratory quality control
550 measures, chain of custody procedures, and analytical laboratory
551 methods;

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552 e. Has experience with cannabis cultivation and processing,
553 including cannabis extraction techniques and producing cannabis
554 products;

555 f. Has experience and qualifications in chain of custody or
556 other tracking mechanisms;

557 g. Works solely on inventory control; and

558 h. Works solely for security purposes.

559 4. The persons who have a direct or indirect interest in
560 the dispensing organization and the applicant's managers,
561 employees, and contractors who directly interact with low-THC
562 cannabis or low-THC cannabis products have been fingerprinted
563 and have successfully passed a level 2 background screening
564 pursuant to s. 435.04.

565 5. The applicant owns, or has at least a 2-year lease of,
566 all properties, facilities, and equipment necessary for the
567 cultivation and processing of low-THC cannabis. The applicant
568 must provide a detailed description of each facility and its
569 equipment, a cultivation and processing plan, and a detailed
570 floor plan. The description must include proof that:

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

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

578 c. Each facility is secured and has theft-prevention
579 systems including an alarm system, cameras, and 24-hour security
580 personnel.

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- 581 6. The applicant has diversion and tracking prevention
582 procedures, including:
- 583 a. A system for tracking low-THC material through
584 cultivation, processing, and dispensing, including the use of
585 batch and harvest numbers;
- 586 b. An inventory control system for low-THC cannabis and
587 low-THC cannabis products;
- 588 c. A vehicle tracking and security system; and
- 589 d. A cannabis waste-disposal plan.
- 590 7. The applicant has recordkeeping policies and procedures
591 in place.
- 592 8. The applicant has a facility emergency management plan.
- 593 9. The applicant has a plan for dispensing low-THC cannabis
594 throughout the state. This plan must include planned retail
595 facilities and a delivery plan for providing low-THC cannabis
596 and low-THC cannabis products to qualified patients who cannot
597 travel to a retail facility.
- 598 10. The applicant has financial documentation, including:
- 599 a. Documentation that demonstrates the applicant's
600 financial ability to operate. If the applicant's assets, credit,
601 and projected revenues meet or exceed projected liabilities and
602 expenses and the applicant provides independent evidence that
603 the funds necessary for startup costs, working capital, and
604 contingency financing exist and are available as needed, the
605 applicant has demonstrated the financial ability to operate.
606 Financial ability to operate must be documented by:
- 607 I. The applicant's audited financial statements. If the
608 applicant is a newly formed entity and does not have a financial
609 history of business upon which audited financial statements may

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610 be submitted, the applicant must provide audited financial
611 statements for the separate entity that is owned solely by the
612 same persons or entities in the same ratio as the applicant that
613 possesses the valid certificate of registration issued by the
614 Department of Agriculture and Consumer Services;

615 II. The applicant's projected financial statements,
616 including a balance sheet, an income and expense statement, and
617 a statement of cash flow for the first 2 years of operation,
618 which provides evidence that the applicant has sufficient
619 assets, credit, and projected revenues to cover liabilities and
620 expenses; and

621 III. A statement of the applicant's estimated startup costs
622 and sources of funds, including a break-even projection and
623 documentation demonstrating that the applicant has the ability
624 to fund all startup costs, working capital costs, and
625 contingency financing requirements.

626

627 All documents required under this sub-subparagraph shall be
628 prepared in accordance with generally accepted accounting
629 principles and signed by a certified public accountant. The
630 statements required by sub-sub-subparagraphs II. and III. may be
631 presented as a compilation.

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

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

635 d. Proof of a \$1 million performance and compliance bond,
636 or other equivalent means of security deemed equivalent by the
637 department, such as an irrevocable letter of credit or a deposit
638 in a trust account or financial institution, payable to the

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639 department, which must be posted once the applicant is approved
640 as a dispensing organization. The purpose of the bond is to
641 secure payment of any administrative penalties imposed by the
642 department and any fees and costs incurred by the department
643 regarding the dispensing organization license, such as the
644 dispensing organization failing to pay 30 days after the fine or
645 costs become final. The department may make a claim against such
646 bond or security until 1 year after the dispensing
647 organization's license ceases to be valid or until 60 days after
648 any administrative or legal proceeding authorized in this
649 section involving the dispensing organization concludes,
650 including any appeal, whichever occurs later.

651 11. The employment of a medical director who is a physician
652 licensed under chapter 458 or chapter 459 to supervise the
653 activities of the dispensing organization.

654 (c) An approved dispensing organization shall maintain
655 compliance with the criteria in paragraphs (b), (d), and (e) and
656 subsection (7) ~~demonstrated for selection and approval as a~~
657 ~~dispensing organization under subsection (5)~~ at all times.
658 Before dispensing low-THC cannabis or low-THC cannabis products
659 to a qualified patient or to the qualified patient's legal
660 representative, the dispensing organization shall verify the
661 identity of the qualified patient or the qualified patient's
662 legal representative by requiring the qualified patient or the
663 qualified patient's legal representative to produce a
664 government-issued identification card and shall verify that the
665 qualified patient and the qualified patient's legal
666 representative have ~~has~~ an active registration in the
667 compassionate use registry, that the order presented matches the

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668 order contents as recorded in the registry, and that the order
669 has not already been filled. Upon dispensing the low-THC
670 cannabis, the dispensing organization shall record in the
671 registry the date, time, quantity, and form of low-THC cannabis
672 dispensed.

673 (d) A dispensing organization may have cultivation
674 facilities, processing facilities, and retail facilities.

675 1. All matters regarding the location of cultivation
676 facilities and processing facilities are preempted to the state.
677 Cultivation facilities and processing facilities must be closed
678 to the public, and low-THC cannabis may not be dispensed on the
679 premises of such facilities.

680 2. A municipality must determine by ordinance the criteria
681 for the number and location of, and other permitting
682 requirements for, all retail facilities located within its
683 municipal boundaries. A retail facility may be established in a
684 municipality only after such an ordinance has been created. A
685 county must determine by ordinance the criteria for the number,
686 location, and other permitting requirements for all retail
687 facilities located within the unincorporated areas of that
688 county. A retail facility may be established in the
689 unincorporated areas of a county only after such an ordinance
690 has been created. Retail facilities must have all utilities and
691 resources necessary to store and dispense low-THC cannabis and
692 low-THC cannabis products. Retail facilities must be secured and
693 have theft-prevention systems, including an alarm system,
694 cameras, and 24-hour security personnel. Retail facilities may
695 not sell, or contract for the sale of, anything other than low-
696 THC cannabis or low-THC cannabis products on the property of the

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697 retail facility. Before a retail facility may dispense low-THC
698 cannabis or a low-THC cannabis product, the dispensing
699 organization must have a computer network compliant with the
700 federal Health Insurance Portability and Accountability Act of
701 1996 which is able to access and upload data to the
702 compassionate use registry and which shall be used by all retail
703 facilities.

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

707 1. The location and a detailed description of any new or
708 proposed facilities.

709 2. The updated contact information, including electronic
710 and voice communication, for all dispensing organization
711 facilities.

712 3. The registration information for any vehicles used for
713 the transportation of low-THC cannabis and low-THC cannabis
714 products, including confirmation that all such vehicles have
715 tracking and security systems.

716 4. A plan for the recall of any or all low-THC cannabis or
717 low-THC cannabis products.

718 (f)1. A dispensing organization may transport low-THC
719 cannabis or low-THC cannabis products in vehicles departing from
720 their places of business only in vehicles that are owned or
721 leased by the licensee or by a person designated by the
722 dispensing organization, and for which a valid vehicle permit
723 has been issued for such vehicle by the department.

724 2. A vehicle owned or leased by the dispensing organization
725 or a person designated by the dispensing organization and

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726 approved by the department must be operated by such person when
727 transporting low-THC cannabis or low-THC products from the
728 licensee's place of business.

729 3. A vehicle permit may be obtained by a dispensing
730 organization upon application and payment of a fee of \$5 per
731 vehicle to the department. The signature of the person
732 designated by the dispensing organization to drive the vehicle
733 must be included on the vehicle permit application. Such permit
734 remains valid and does not expire unless the licensee or any
735 person designated by the dispensing organization disposes of his
736 or her vehicle, or the licensee's license is transferred,
737 canceled, not renewed, or is revoked by the department,
738 whichever occurs first. The department shall cancel a vehicle
739 permit upon request of the licensee or owner of the vehicle.

740 4. By acceptance of a license issued under this section,
741 the licensee agrees that the licensed vehicle is, at all times
742 it is being used to transport low-THC cannabis or low-THC
743 cannabis products, subject to inspection and search without a
744 search warrant by authorized employees of the department,
745 sheriffs, deputy sheriffs, police officers, or other law
746 enforcement officers to determine that the licensee is
747 transporting such products in compliance with this section.

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

749 (a) All low-THC cannabis and low-THC cannabis products must
750 be tested by an independent testing laboratory before the
751 dispensing organization may dispense them. The independent
752 testing laboratory shall provide the dispensing organization
753 with lab results. Before dispensing, the dispensing organization
754 must determine that the lab results indicate that the low-THC

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755 cannabis or low-THC cannabis product meets the definition of
756 low-THC cannabis or low-THC cannabis product, is safe for human
757 consumption, and is free from harmful contaminants.

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

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

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

765 3. The name of the cultivation and processing facility
766 where the low-THC cannabis or low-THC cannabis product
767 originates; and

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

770 (8) SAFETY AND EFFICACY RESEARCH FOR LOW-THC CANNABIS.—The
771 University of Florida College of Pharmacy shall establish and
772 maintain a safety and efficacy research program for the use of
773 low-THC cannabis or low-THC cannabis products to treat
774 qualifying conditions and symptoms. The program must include a
775 fully integrated electronic information system for the broad
776 monitoring of health outcomes and safety signal detection. The
777 electronic information system must include information from the
778 compassionate use registry; provider reports, including
779 treatment plans, adverse event reports, and treatment
780 discontinuation reports; patient reports of adverse impacts;
781 event-triggered interviews and medical chart reviews performed
782 by University of Florida clinical research staff; information
783 from external databases, including Medicaid billing reports and

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784 information in the prescription drug monitoring database for
785 registered patients; and all other medical reports required by
786 the University of Florida to conduct the research required by
787 this subsection. The department must provide access to
788 information from the compassionate use registry and the
789 prescription drug monitoring database, established in s.
790 893.055, as needed by the University of Florida to conduct
791 research under this subsection. The Agency for Health Care
792 Administration must provide access to registered patient
793 Medicaid records, to the extent allowed under federal law, as
794 needed by the University of Florida to conduct research under
795 this subsection.

796 (9) The persons who have direct or indirect interest in the
797 dispensing organization and the dispensing organization's
798 managers, employees, and contractors who directly interact with
799 low-THC cannabis or low-THC cannabis products are prohibited
800 from making recommendations, offering prescriptions, or
801 providing medical advice to qualified patients.

802 (10) ~~(7)~~ EXCEPTIONS TO OTHER LAWS.-

803 (a) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or
804 any other ~~provision of~~ law, but subject to the requirements of
805 this section, a qualified patient and the qualified patient's
806 legal representative who is registered with the department on
807 the compassionate use registry may purchase and possess for the
808 patient's medical use up to the amount of low-THC cannabis
809 ordered for the patient. Nothing in this section exempts any
810 person from the prohibition against driving under the influence
811 provided in s. 316.193.

812 (b) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or

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813 any other provision of law, but subject to the requirements of
814 this section, an approved dispensing organization and its
815 owners, managers, ~~and employees~~ and the owners, managers, and
816 employees of contractors who have direct contact with low-THC
817 cannabis or low-THC cannabis product may manufacture, possess,
818 sell, deliver, distribute, dispense, and lawfully dispose of
819 reasonable quantities, as established by department rule, of
820 low-THC cannabis. For purposes of this subsection, the terms
821 "manufacture," "possession," "deliver," "distribute," and
822 "dispense" have the same meanings as provided in s. 893.02.

823 (c) An approved dispensing organization and its owners,
824 managers, and employees are not subject to licensure or
825 regulation under chapter 465 or chapter 499 for manufacturing,
826 possessing, selling, delivering, distributing, dispensing, or
827 lawfully disposing of reasonable quantities, as established by
828 department rule, of low-THC cannabis.

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

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

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

839 381.987 Public records exemption for personal identifying
840 information in the compassionate use registry.-

841 (3) The department shall allow access to the registry,

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842 including access to confidential and exempt information, to:

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

845 Section 3. Paragraph (b) of subsection (7) of section
846 893.055, Florida Statutes, is amended to read:

847 893.055 Prescription drug monitoring program.—

848 (7)

849 (b) A pharmacy, prescriber, or dispenser shall have access
850 to information in the prescription drug monitoring program's
851 database which relates to a patient of that pharmacy,
852 prescriber, or dispenser in a manner established by the
853 department as needed for the purpose of reviewing the patient's
854 controlled substance prescription history. Persons engaged in
855 research at the University of Florida pursuant to s. 381.986(8)
856 shall have access to information in the prescription drug
857 monitoring program's database which relates to qualified
858 patients as defined in s. 381.986(1) for the purpose of
859 conducting such research. Other access to the program's database
860 shall be limited to the program's manager and to the designated
861 program and support staff, who may act only at the direction of
862 the program manager or, in the absence of the program manager,
863 as authorized. Access by the program manager or such designated
864 staff is for prescription drug program management only or for
865 management of the program's database and its system in support
866 of the requirements of this section and in furtherance of the
867 prescription drug monitoring program. Confidential and exempt
868 information in the database shall be released only as provided
869 in paragraph (c) and s. 893.0551. The program manager,
870 designated program and support staff who act at the direction of

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871 or in the absence of the program manager, and any individual who
872 has similar access regarding the management of the database from
873 the prescription drug monitoring program shall submit
874 fingerprints to the department for background screening. The
875 department shall follow the procedure established by the
876 Department of Law Enforcement to request a statewide criminal
877 history record check and to request that the Department of Law
878 Enforcement forward the fingerprints to the Federal Bureau of
879 Investigation for a national criminal history record check.

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

882 893.0551 Public records exemption for the prescription drug
883 monitoring program.—

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

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

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