



ENROLLED

CS for CS/CS/HB 307 & HB 1313, Engrossed 1

2016 Leg

1
2 An act relating to the medical use of cannabis;
3 amending s. 381.986, F.S.; providing and revising
4 definitions; revising requirements for physicians
5 ordering low-THC cannabis, medical cannabis, or a
6 cannabis delivery device; revising the information a
7 physician must update on the registry; requiring a
8 physician to update the registry within a specified
9 timeframe; requiring a physician to obtain certain
10 written consent; providing that a physician commits a
11 misdemeanor of the first degree under certain
12 circumstances; providing that an eligible patient who
13 uses medical cannabis, and such patient's legal
14 representative, who administers medical cannabis in
15 specified prohibited locations commits a misdemeanor
16 of the first degree; providing that a physician who
17 orders low-THC cannabis or medical cannabis and
18 receives related compensation from a dispensing
19 organization is subject to disciplinary action;
20 revising requirements relating to physician education;
21 providing that the appropriate board must require the
22 medical director of each dispensing organization to
23 hold a certain license; revising the information that
24 the Department of Health is required to include in its
25 online compassionate use registry; revising
26 performance bond requirements for certain dispensing



ENROLLED

CS for CS/CS/HB 307 & HB 1313, Engrossed 1

2016 Leg

27 organizations; requiring the department to approve
28 three dispensing organizations, including specified
29 applicants, under certain circumstances; providing
30 requirements for the three dispensing organizations;
31 requiring the department to allow a dispensing
32 organization to make certain wholesale purchases from
33 or distributions to another dispensing organization;
34 revising standards to be met and maintained by
35 dispensing organizations; authorizing dispensing
36 organizations to use certain pesticides after
37 consultation with the Department of Agriculture and
38 Consumer Services; providing requirements for
39 dispensing organizations when they are growing and
40 processing low-THC cannabis or medical cannabis;
41 requiring dispensing organizations to inspect seeds
42 and growing plants for certain pests and perform
43 certain fumigation and treatment of plants; providing
44 that dispensing organizations may not dispense low-THC
45 cannabis and medical cannabis unless they meet certain
46 testing requirements; requiring dispensing
47 organizations to maintain certain records; requiring
48 dispensing organizations to contract with an
49 independent testing laboratory to perform certain
50 audits; providing packaging requirements for low-THC
51 and medical cannabis; requiring dispensing
52 organizations to retain certain samples for specified



ENROLLED

CS for CS/CS/HB 307 & HB 1313, Engrossed 1

2016 Leg

53 | purposes; providing delivery requirements for
54 | dispensing organizations when dispensing low-THC
55 | cannabis and medical cannabis; providing certain
56 | safety and security requirements for dispensing
57 | organizations; providing certain safety and security
58 | requirements for the transport of low-THC cannabis and
59 | medical cannabis; authorizing the department to
60 | conduct certain inspections; providing inspection
61 | requirements; authorizing the department to enter into
62 | certain interagency agreements; requiring the
63 | department to make certain information available on
64 | its website; authorizing the department to establish a
65 | system for issuing and renewing registration cards;
66 | providing requirements for the registration cards;
67 | authorizing the department to impose certain fines;
68 | authorizing the department to suspend, revoke, or
69 | refuse to renew a dispensing organization's approval
70 | under certain circumstances; requiring the department
71 | to renew the dispensing organization biennially under
72 | certain conditions; providing applicability;
73 | authorizing an approved independent testing laboratory
74 | to possess, test, transport, and lawfully dispose of
75 | low-THC cannabis or medical cannabis by department
76 | rule ; providing that a dispensing organization is
77 | presumed to be registered with the department under
78 | certain circumstances; providing that a person is not



ENROLLED

CS for CS/CS/HB 307 & HB 1313, Engrossed 1

2016 Leg

79 exempt from prosecution for certain offenses and is
80 not relieved from certain requirements of law under
81 certain circumstances; amending s. 499.0295, F.S.;
82 revising definitions; authorizing certain
83 manufacturers to dispense cannabis delivery devices;
84 requiring the department to authorize certain
85 dispensing organizations or applicants to provide low-
86 THC cannabis, medical cannabis, and cannabis delivery
87 devices to eligible patients; providing for dispensing
88 organizations or applicants meeting specified criteria
89 to be granted authorization to cultivate certain
90 cannabis and operate as dispensing organizations;
91 requiring the department to grant approval as a
92 dispensing organization to certain qualified
93 applicants by a specified date; authorizing two
94 dispensing organizations in the same region under
95 certain circumstances; authorizing the Department of
96 Health to enforce certain rules; providing
97 applicability; authorizing certain colleges and
98 universities to conduct certain cannabis research;
99 providing an effective date.

100
101 Be It Enacted by the Legislature of the State of Florida:

102
103 Section 1. Section 381.986, Florida Statutes, is amended
104 to read:



ENROLLED

CS for CS/CS/HB 307 & HB 1313, Engrossed 1

2016 Leg

381.986 Compassionate use of low-THC and medical
cannabis.—

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

(a) "Cannabis delivery device" means an object used,
intended for use, or designed for use in preparing, storing,
ingesting, inhaling, or otherwise introducing low-THC cannabis
or medical cannabis into the human body.

(b) ~~(a)~~ "Dispensing organization" means an organization
approved by the department to cultivate, process, transport, and
dispense low-THC cannabis or medical cannabis pursuant to this
section.

(c) "Independent testing laboratory" means a laboratory,
including the managers, employees, or contractors of the
laboratory, which has no direct or indirect interest in a
dispensing organization.

(d) "Legal representative" means the qualified patient's
parent, legal guardian acting pursuant to a court's
authorization as required under s. 744.3215(4), health care
surrogate acting pursuant to the qualified patient's written
consent or a court's authorization as required under s. 765.113,
or an individual who is authorized under a power of attorney to
make health care decisions on behalf of the qualified patient.

(e) ~~(b)~~ "Low-THC cannabis" means a plant of the genus
Cannabis, the dried flowers of which contain 0.8 percent or less
of tetrahydrocannabinol and more than 10 percent of cannabidiol
weight for weight; the seeds thereof; the resin extracted from



ENROLLED

CS for CS/CS/HB 307 & HB 1313, Engrossed 1

2016 Leg

any part of such plant; or any compound, manufacture, salt, derivative, mixture, or preparation of such plant or its seeds or resin that is dispensed only from a dispensing organization.

(f) "Medical cannabis" means all parts of any plant of the genus *Cannabis*, whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, sale, derivative, mixture, or preparation of the plant or its seeds or resin that is dispensed only from a dispensing organization for medical use by an eligible patient as defined in s. 499.0295.

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

1. Possession, use, or administration of low-THC cannabis or medical cannabis by smoking.

2. ~~The term also does not include the~~ Transfer of low-THC cannabis or medical cannabis to a person other than the qualified patient for whom it was ordered or the qualified patient's legal representative on behalf of the qualified patient.

3. Use or administration of low-THC cannabis or medical cannabis:

a. On any form of public transportation.

b. In any public place.

c. In a qualified patient's place of employment, if restricted by his or her employer.



ENROLLED

CS for CS/CS/HB 307 & HB 1313, Engrossed 1

2016 Leg

157 d. In a state correctional institution as defined in s.
158 944.02 or a correctional institution as defined in s. 944.241.

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

161 f. On a school bus or in a vehicle, aircraft, or
162 motorboat.

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

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

171 (2) PHYSICIAN ORDERING. ~~Effective January 1, 2015, A~~
172 ~~physician is authorized to order licensed under chapter 458 or~~
173 ~~chapter 459 who has examined and is treating a patient suffering~~
174 ~~from cancer or a physical medical condition that chronically~~
175 ~~produces symptoms of seizures or severe and persistent muscle~~
176 ~~spasms may order for the patient's medical use low-THC cannabis~~
177 ~~to treat a~~ qualified patient suffering from cancer or a physical
178 medical condition that chronically produces symptoms of seizures
179 or severe and persistent muscle spasms; order low-THC cannabis
180 ~~such disease, disorder, or condition or to alleviate symptoms of~~
181 ~~such disease, disorder, or condition, if no other satisfactory~~
182 ~~alternative treatment options exist for~~ the qualified that



ENROLLED

CS for CS/CS/HB 307 & HB 1313, Engrossed 1

2016 Leg

183 patient; order medical cannabis to treat an eligible patient as
184 defined in s. 499.0295; or order a cannabis delivery device for
185 the medical use of low-THC cannabis or medical cannabis, only if
186 the physician and all of the following conditions apply:

187 (a) Holds an active, unrestricted license as a physician
188 under chapter 458 or an osteopathic physician under chapter 459;

189 (b) Has treated the patient for at least 3 months
190 immediately preceding the patient's registration in the
191 compassionate use registry;

192 (c) Has successfully completed the course and examination
193 required under paragraph (4) (a);

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

195 ~~(d) (b)~~ Has determined ~~The physician determines~~ that the
196 risks of treating the patient with ~~ordering~~ low-THC cannabis or
197 medical cannabis are reasonable in light of the potential
198 benefit to the ~~for that~~ patient. If a patient is younger than 18
199 years of age, a second physician must concur with this
200 determination, and such determination must be documented in the
201 patient's medical record; ~~:-~~

202 ~~(e) (c)~~ ~~The physician~~ Registers as the orderer of low-THC
203 cannabis or medical cannabis for the named patient on the
204 compassionate use registry maintained by the department and
205 updates the registry to reflect the contents of the order,
206 including the amount of low-THC cannabis or medical cannabis
207 that will provide the patient with not more than a 45-day supply
208 and a cannabis delivery device needed by the patient for the



ENROLLED

CS for CS/CS/HB 307 & HB 1313, Engrossed 1

2016 Leg

209 medical use of low-THC cannabis or medical cannabis. The
210 physician must also update the registry within 7 days after any
211 change is made to the original order to reflect the change. The
212 physician shall deactivate the registration of the patient and
213 the patient's legal representative ~~patient's registration~~ when
214 treatment is discontinued;

215 (f)(d) ~~The physician~~ Maintains a patient treatment plan
216 that includes the dose, route of administration, planned
217 duration, and monitoring of the patient's symptoms and other
218 indicators of tolerance or reaction to the low-THC cannabis or
219 medical cannabis;

220 (g)(e) ~~The physician~~ Submits the patient treatment plan
221 quarterly to the University of Florida College of Pharmacy for
222 research on the safety and efficacy of low-THC cannabis and
223 medical cannabis on patients;

224 (h)(f) ~~The physician~~ Obtains the voluntary written
225 informed consent of the patient or the patient's legal
226 representative ~~guardian~~ to treatment with low-THC cannabis after
227 sufficiently explaining the current state of knowledge in the
228 medical community of the effectiveness of treatment of the
229 patient's condition with low-THC cannabis, the medically
230 acceptable alternatives, and the potential risks and side
231 effects;

232 (i) Obtains written informed consent as defined in and
233 required under s. 499.0295, if the physician is ordering medical
234 cannabis for an eligible patient pursuant to that section; and



ENROLLED

CS for CS/CS/HB 307 & HB 1313, Engrossed 1

2016 Leg

235 (j) Is not a medical director employed by a dispensing
236 organization.

237 (3) PENALTIES.—

238 (a) A physician commits a misdemeanor of the first degree,
239 punishable as provided in s. 775.082 or s. 775.083, if the
240 physician orders low-THC cannabis for a patient without a
241 reasonable belief that the patient is suffering from:

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

245 2. Symptoms of cancer or a physical medical condition that
246 chronically produces symptoms of seizures or severe and
247 persistent muscle spasms that can be alleviated with low-THC
248 cannabis.

249 (b) A physician commits a misdemeanor of the first degree,
250 punishable as provided in s. 775.082 or s. 775.083, if the
251 physician orders medical cannabis for a patient without a
252 reasonable belief that the patient has a terminal condition as
253 defined in s. 499.0295.

254 (c) ~~(b)~~ A ~~Any~~ person who fraudulently represents that he or
255 she has cancer, ~~or~~ a physical medical condition that chronically
256 produces symptoms of seizures or severe and persistent muscle
257 spasms, or a terminal condition to a physician for the purpose
258 of being ordered low-THC cannabis, medical cannabis, or a
259 cannabis delivery device by such physician commits a misdemeanor
260 of the first degree, punishable as provided in s. 775.082 or s.



ENROLLED

CS for CS/CS/HB 307 & HB 1313, Engrossed 1

2016 Leg

775.083.

(d) An eligible patient as defined in s. 499.0295 who uses medical cannabis, and such patient's legal representative who administers medical cannabis, in plain view of or in a place open to the general public, on the grounds of a school, or in a school bus, vehicle, aircraft, or motorboat, commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(e) A physician who orders low-THC cannabis, medical cannabis, or a cannabis delivery device and receives compensation from a dispensing organization related to the ordering of low-THC cannabis, medical cannabis, or a cannabis delivery device is subject to disciplinary action under the applicable practice act and s. 456.072(1)(n).

(4) PHYSICIAN EDUCATION.—

(a) Before ordering low-THC cannabis, medical cannabis, or a cannabis delivery device for medical use by a patient in this state, the appropriate board shall require the ordering physician licensed under chapter 458 or chapter 459 to successfully complete an 8-hour course and subsequent examination offered by the Florida Medical Association or the Florida Osteopathic Medical Association that encompasses the clinical indications for the appropriate use of low-THC cannabis and medical cannabis, the appropriate cannabis delivery devices mechanisms, the contraindications for such use, and as well as the relevant state and federal laws governing the ordering,



ENROLLED

CS for CS/CS/HB 307 & HB 1313, Engrossed 1

2016 Leg

287 dispensing, and possessing of these substances and devices ~~this~~
288 ~~substance~~. The ~~first~~ course and examination shall ~~be presented~~
289 ~~by October 1, 2014, and shall~~ be administered at least annually
290 ~~thereafter~~. Successful completion of the course may be used by a
291 physician to satisfy 8 hours of the continuing medical education
292 requirements required by his or her respective board for
293 licensure renewal. This course may be offered in a distance
294 learning format.

295 (b) The appropriate board shall require the medical
296 director of each dispensing organization to hold an active,
297 unrestricted license as a physician under chapter 458 or as an
298 osteopathic physician under chapter 459 and ~~approved under~~
299 ~~subsection (5) to~~ successfully complete a 2-hour course and
300 subsequent examination offered by the Florida Medical
301 Association or the Florida Osteopathic Medical Association that
302 encompasses appropriate safety procedures and knowledge of low-
303 THC cannabis, medical cannabis, and cannabis delivery devices.

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

312 (d) A physician who fails to comply with this subsection



ENROLLED

CS for CS/CS/HB 307 & HB 1313, Engrossed 1

2016 Leg

and who orders low-THC cannabis, medical cannabis, or a cannabis delivery device may be subject to disciplinary action under the applicable practice act and under s. 456.072(1)(k).

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

(a) Create and maintain a secure, electronic, and online compassionate use registry for the registration of physicians, and patients, and the legal representatives of patients as provided under this section. The registry must be accessible to law enforcement agencies and to a dispensing organization ~~in order~~ to verify the authorization of a patient or a patient's legal representative to possess ~~patient authorization for low-~~ THC cannabis, medical cannabis, or a cannabis delivery device and record the low-THC cannabis, medical cannabis, or cannabis delivery device dispensed. The registry must prevent an active registration of a patient by multiple physicians.

(b) Authorize the establishment of five dispensing organizations to ensure reasonable statewide accessibility and availability as necessary for patients registered in the compassionate use registry and who are ordered low-THC cannabis, medical cannabis, or a cannabis delivery device under this section, one in each of the following regions: northwest Florida, northeast Florida, central Florida, southeast Florida, and southwest Florida. The department shall develop an application form and impose an initial application and biennial renewal fee that is sufficient to cover the costs of



ENROLLED

CS for CS/CS/HB 307 & HB 1313, Engrossed 1

2016 Leg

administering this section. An applicant for approval as a dispensing organization must be able to demonstrate:

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

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

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

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

5. The financial ability to maintain operations for the duration of the 2-year approval cycle, including the provision of certified financials to the department. Upon approval, the applicant must post a \$5 million performance bond. However, upon a dispensing organization's serving at least 1,000 qualified patients, the dispensing organization is only required to maintain a \$2 million performance bond.



ENROLLED

CS for CS/CS/HB 307 & HB 1313, Engrossed 1

2016 Leg

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

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

371 (c) Upon the registration of 250,000 active qualified
372 patients in the compassionate use registry, approve three
373 dispensing organizations, including, but not limited to, an
374 applicant that is a recognized class member of *Pigford v.*
375 *Glickman*, 185 F.R.D. 82 (D.D.C. 1999), or *In Re Black Farmers*
376 *Litig.*, 856 F. Supp. 2d 1 (D.D.C. 2011), and a member of the
377 Black Farmers and Agriculturalists Association, which must meet
378 the requirements of subparagraphs (b)2.-7. and demonstrate the
379 technical and technological ability to cultivate and produce
380 low-THC cannabis.

381 (d) Allow a dispensing organization to make a wholesale
382 purchase of low-THC cannabis or medical cannabis from, or a
383 distribution of low-THC cannabis or medical cannabis to, another
384 dispensing organization.

385 (e)-(e) Monitor physician registration and ordering of low-
386 THC cannabis, medical cannabis, or a cannabis delivery device
387 for ordering practices that could facilitate unlawful diversion
388 or misuse of low-THC cannabis, medical cannabis, or a cannabis
389 delivery device and take disciplinary action as indicated.

390 ~~(d) Adopt rules necessary to implement this section.~~



ENROLLED

CS for CS/CS/HB 307 & HB 1313, Engrossed 1

2016 Leg

391 (6) DISPENSING ORGANIZATION.—An approved dispensing
392 organization must, at all times, ~~shall~~ maintain compliance with
393 the criteria demonstrated for selection and approval as a
394 dispensing organization under subsection (5) and the criteria
395 required in this subsection ~~at all times~~.

396 (a) When growing low-THC cannabis or medical cannabis, a
397 dispensing organization:

398 1. May use pesticides determined by the department, after
399 consultation with the Department of Agriculture and Consumer
400 Services, to be safely applied to plants intended for human
401 consumption, but may not use pesticides designated as
402 restricted-use pesticides pursuant to s. 487.042.

403 2. Must grow low-THC cannabis or medical cannabis within
404 an enclosed structure and in a room separate from any other
405 plant.

406 3. Must inspect seeds and growing plants for plant pests
407 that endanger or threaten the horticultural and agricultural
408 interests of the state, notify the Department of Agriculture and
409 Consumer Services within 10 calendar days after a determination
410 that a plant is infested or infected by such plant pest, and
411 implement and maintain phytosanitary policies and procedures.

412 4. Must perform fumigation or treatment of plants, or the
413 removal and destruction of infested or infected plants, in
414 accordance with chapter 581 and any rules adopted thereunder.

415 (b) When processing low-THC cannabis or medical cannabis,
416 a dispensing organization must:



ENROLLED

CS for CS/CS/HB 307 & HB 1313, Engrossed 1

2016 Leg

417 1. Process the low-THC cannabis or medical cannabis within
418 an enclosed structure and in a room separate from other plants
419 or products.

420 2. Test the processed low-THC cannabis and medical
421 cannabis before they are dispensed. Results must be verified and
422 signed by two dispensing organization employees. Before
423 dispensing low-THC cannabis, the dispensing organization must
424 determine that the test results indicate that the low-THC
425 cannabis meets the definition of low-THC cannabis and, for
426 medical cannabis and low-THC cannabis, that all medical cannabis
427 and low-THC cannabis is safe for human consumption and free from
428 contaminants that are unsafe for human consumption. The
429 dispensing organization must retain records of all testing and
430 samples of each homogenous batch of cannabis and low-THC
431 cannabis for at least 9 months. The dispensing organization must
432 contract with an independent testing laboratory to perform
433 audits on the dispensing organization's standard operating
434 procedures, testing records, and samples and provide the results
435 to the department to confirm that the low-THC cannabis or
436 medical cannabis meets the requirements of this section and that
437 the medical cannabis and low-THC cannabis is safe for human
438 consumption.

439 3. Package the low-THC cannabis or medical cannabis in
440 compliance with the United States Poison Prevention Packaging
441 Act of 1970, 15 U.S.C. ss. 1471 et seq.

442 4. Package the low-THC cannabis or medical cannabis in a



ENROLLED

CS for CS/CS/HB 307 & HB 1313, Engrossed 1

2016 Leg

443 receptacle that has a firmly affixed and legible label stating
444 the following information:

445 a. A statement that the low-THC cannabis or medical
446 cannabis meets the requirements of subparagraph 2.;

447 b. The name of the dispensing organization from which the
448 medical cannabis or low-THC cannabis originates; and

449 c. The batch number and harvest number from which the
450 medical cannabis or low-THC cannabis originates.

451 5. Reserve two processed samples from each batch and
452 retain such samples for at least 9 months for the purpose of
453 testing pursuant to the audit required under subparagraph 2.

454 (c) When dispensing low-THC cannabis, medical cannabis, or
455 a cannabis delivery device, a dispensing organization:

456 1. May not dispense more than a 45-day supply of low-THC
457 cannabis or medical cannabis to a patient or the patient's legal
458 representative.

459 2. Must have the dispensing organization's employee who
460 dispenses the low-THC cannabis, medical cannabis, or a cannabis
461 delivery device enter into the compassionate use registry his or
462 her name or unique employee identifier.

463 3. Must verify in the compassionate use registry that a
464 physician has ordered the low-THC cannabis, medical cannabis, or
465 a specific type of a cannabis delivery device for the patient.

466 4. May not dispense or sell any other type of cannabis,
467 alcohol, or illicit drug-related product, including pipes,
468 bongs, or wrapping papers, other than a physician-ordered



ENROLLED

CS for CS/CS/HB 307 & HB 1313, Engrossed 1

2016 Leg

469 cannabis delivery device required for the medical use of low-THC
470 cannabis or medical cannabis, while dispensing low-THC cannabis
471 or medical cannabis.

472 5. Must ~~Before dispensing low-THC cannabis to a qualified~~
473 ~~patient, the dispensing organization shall~~ verify that the
474 patient has an active registration in the compassionate use
475 registry, the patient or patient's legal representative holds a
476 valid and active registration card, the order presented matches
477 the order contents as recorded in the registry, and the order
478 has not already been filled.

479 6. Must, upon dispensing the low-THC cannabis, medical
480 cannabis, or cannabis delivery device, ~~the dispensing~~
481 ~~organization shall~~ record in the registry the date, time,
482 quantity, and form of low-THC cannabis or medical cannabis
483 dispensed and the type of cannabis delivery device dispensed.

484 (d) To ensure the safety and security of its premises and
485 any off-site storage facilities, and to maintain adequate
486 controls against the diversion, theft, and loss of low-THC
487 cannabis, medical cannabis, or cannabis delivery devices, a
488 dispensing organization shall:

489 1.a. Maintain a fully operational security alarm system
490 that secures all entry points and perimeter windows and is
491 equipped with motion detectors; pressure switches; and duress,
492 panic, and hold-up alarms; or

493 b. Maintain a video surveillance system that records
494 continuously 24 hours each day and meets at least one of the



ENROLLED

CS for CS/CS/HB 307 & HB 1313, Engrossed 1

2016 Leg

495 following criteria:

496 (I) Cameras are fixed in a place that allows for the clear
497 identification of persons and activities in controlled areas of
498 the premises. Controlled areas include grow rooms, processing
499 rooms, storage rooms, disposal rooms or areas, and point-of-sale
500 rooms;

501 (II) Cameras are fixed in entrances and exits to the
502 premises, which shall record from both indoor and outdoor, or
503 ingress and egress, vantage points;

504 (III) Recorded images must clearly and accurately display
505 the time and date; or

506 (IV) Retain video surveillance recordings for a minimum of
507 45 days or longer upon the request of a law enforcement agency.

508 2. Ensure that the organization's outdoor premises have
509 sufficient lighting from dusk until dawn.

510 3. Establish and maintain a tracking system approved by
511 the department that traces the low-THC cannabis or medical
512 cannabis from seed to sale. The tracking system shall include
513 notification of key events as determined by the department,
514 including when cannabis seeds are planted, when cannabis plants
515 are harvested and destroyed, and when low-THC cannabis or
516 medical cannabis is transported, sold, stolen, diverted, or
517 lost.

518 4. Not dispense from its premises low-THC cannabis,
519 medical cannabis, or a cannabis delivery device between the
520 hours of 9 p.m. and 7 a.m., but may perform all other operations



ENROLLED

CS for CS/CS/HB 307 & HB 1313, Engrossed 1

2016 Leg

521 and deliver low-THC cannabis and medical cannabis to qualified
522 patients 24 hours each day.

523 5. Store low-THC cannabis or medical cannabis in a
524 secured, locked room or a vault.

525 6. Require at least two of its employees, or two employees
526 of a security agency with whom it contracts, to be on the
527 premises at all times.

528 7. Require each employee to wear a photo identification
529 badge at all times while on the premises.

530 8. Require each visitor to wear a visitor's pass at all
531 times while on the premises.

532 9. Implement an alcohol and drug-free workplace policy.

533 10. Report to local law enforcement within 24 hours after
534 it is notified or becomes aware of the theft, diversion, or loss
535 of low-THC cannabis or medical cannabis.

536 (e) To ensure the safe transport of low-THC cannabis or
537 medical cannabis to dispensing organization facilities,
538 independent testing laboratories, or patients, the dispensing
539 organization must:

540 1. Maintain a transportation manifest, which must be
541 retained for at least 1 year.

542 2. Ensure only vehicles in good working order are used to
543 transport low-THC cannabis or medical cannabis.

544 3. Lock low-THC cannabis or medical cannabis in a separate
545 compartment or container within the vehicle.

546 4. Require at least two persons to be in a vehicle



ENROLLED

CS for CS/CS/HB 307 & HB 1313, Engrossed 1

2016 Leg

547 transporting low-THC cannabis or medical cannabis, and require
548 at least one person to remain in the vehicle while the low-THC
549 cannabis or medical cannabis is being delivered.

550 5. Provide specific safety and security training to
551 employees transporting or delivering low-THC cannabis or medical
552 cannabis.

553 (7) DEPARTMENT AUTHORITY AND RESPONSIBILITIES.—

554 (a) The department may conduct announced or unannounced
555 inspections of dispensing organizations to determine compliance
556 with this section or rules adopted pursuant to this section.

557 (b) The department shall inspect a dispensing organization
558 upon complaint or notice provided to the department that the
559 dispensing organization has dispensed low-THC cannabis or
560 medical cannabis containing any mold, bacteria, or other
561 contaminant that may cause or has caused an adverse effect to
562 human health or the environment.

563 (c) The department shall conduct at least a biennial
564 inspection of each dispensing organization to evaluate the
565 dispensing organization's records, personnel, equipment,
566 processes, security measures, sanitation practices, and quality
567 assurance practices.

568 (d) The department may enter into interagency agreements
569 with the Department of Agriculture and Consumer Services, the
570 Department of Business and Professional Regulation, the
571 Department of Transportation, the Department of Highway Safety
572 and Motor Vehicles, and the Agency for Health Care



ENROLLED

CS for CS/CS/HB 307 & HB 1313, Engrossed 1

2016 Leg

Administration, and such agencies are authorized to enter into an interagency agreement with the department, to conduct inspections or perform other responsibilities assigned to the department under this section.

(e) The department must make a list of all approved dispensing organizations and qualified ordering physicians and medical directors publicly available on its website.

(f) The department may establish a system for issuing and renewing registration cards for patients and their legal representatives, establish the circumstances under which the cards may be revoked by or must be returned to the department, and establish fees to implement such system. The department must require, at a minimum, the registration cards to:

1. Provide the name, address, and date of birth of the patient or legal representative.

2. Have a full-face, passport-type, color photograph of the patient or legal representative taken within the 90 days immediately preceding registration.

3. Identify whether the cardholder is a patient or legal representative.

4. List a unique numeric identifier for the patient or legal representative that is matched to the identifier used for such person in the department's compassionate use registry.

5. Provide the expiration date, which shall be 1 year after the date of the physician's initial order of low-THC cannabis or medical cannabis.



ENROLLED

CS for CS/CS/HB 307 & HB 1313, Engrossed 1

2016 Leg

599 6. For the legal representative, provide the name and
600 unique numeric identifier of the patient that the legal
601 representative is assisting.

602 7. Be resistant to counterfeiting or tampering.

603 (g) The department may impose reasonable fines not to
604 exceed \$10,000 on a dispensing organization for any of the
605 following violations:

606 1. Violating this section, s. 499.0295, or department
607 rule.

608 2. Failing to maintain qualifications for approval.

609 3. Endangering the health, safety, or security of a
610 qualified patient.

611 4. Improperly disclosing personal and confidential
612 information of the qualified patient.

613 5. Attempting to procure dispensing organization approval
614 by bribery, fraudulent misrepresentation, or extortion.

615 6. Being convicted or found guilty of, or entering a plea
616 of guilty or nolo contendere to, regardless of adjudication, a
617 crime in any jurisdiction which directly relates to the business
618 of a dispensing organization.

619 7. Making or filing a report or record that the dispensing
620 organization knows to be false.

621 8. Willfully failing to maintain a record required by this
622 section or department rule.

623 9. Willfully impeding or obstructing an employee or agent
624 of the department in the furtherance of his or her official



ENROLLED

CS for CS/CS/HB 307 & HB 1313, Engrossed 1

2016 Leg

duties.

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

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

12. Having a license or the authority to engage in any regulated profession, occupation, or business that is related to the business practices of a dispensing organization suspended, revoked, or otherwise acted against by the licensing authority of any jurisdiction, including its agencies or subdivisions, for a violation that would constitute a violation under Florida law.

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

(h) The department may suspend, revoke, or refuse to renew a dispensing organization's approval if a dispensing organization commits any of the violations in paragraph (g).

(i) The department shall renew the approval of a dispensing organization biennially if the dispensing organization meets the requirements of this section and pays the biennial renewal fee.

(j) The department may adopt rules necessary to implement this section.

(8) PREEMPTION.—



ENROLLED

CS for CS/CS/HB 307 & HB 1313, Engrossed 1

2016 Leg

651 (a) All matters regarding the regulation of the
652 cultivation and processing of medical cannabis or low-THC
653 cannabis by dispensing organizations are preempted to the state.

654 (b) A municipality may determine by ordinance the criteria
655 for the number and location of, and other permitting
656 requirements that do not conflict with state law or department
657 rule for, dispensing facilities of dispensing organizations
658 located within its municipal boundaries. A county may determine
659 by ordinance the criteria for the number, location, and other
660 permitting requirements that do not conflict with state law or
661 department rule for all dispensing facilities of dispensing
662 organizations located within the unincorporated areas of that
663 county.

664 (9) ~~(7)~~ EXCEPTIONS TO OTHER LAWS.—

665 (a) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or
666 any other provision of law, but subject to the requirements of
667 this section, a qualified patient and the qualified patient's
668 legal representative may purchase and possess for the patient's
669 medical use up to the amount of low-THC cannabis or medical
670 cannabis ordered for the patient, but not more than a 45-day
671 supply, and a cannabis delivery device ordered for the patient.

672 (b) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or
673 any other provision of law, but subject to the requirements of
674 this section, an approved dispensing organization and its
675 owners, managers, and employees may manufacture, possess, sell,
676 deliver, distribute, dispense, and lawfully dispose of



ENROLLED

CS for CS/CS/HB 307 & HB 1313, Engrossed 1

2016 Leg

reasonable quantities, as established by department rule, of low-THC cannabis, medical cannabis, or a cannabis delivery device. For purposes of this subsection, the terms "manufacture," "possession," "deliver," "distribute," and "dispense" have the same meanings as provided in s. 893.02.

(c) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or any other provision of law, but subject to the requirements of this section, an approved independent testing laboratory may possess, test, transport, and lawfully dispose of low-THC cannabis or medical cannabis as provided by department rule.

(d) ~~(e)~~ An approved dispensing organization and its owners, managers, and employees are not subject to licensure or regulation under chapter 465 or chapter 499 for manufacturing, possessing, selling, delivering, distributing, dispensing, or lawfully disposing of reasonable quantities, as established by department rule, of low-THC cannabis, medical cannabis, or a cannabis delivery device.

(e) An approved dispensing organization that continues to meet the requirements for approval is presumed to be registered with the department and to meet the regulations adopted by the department or its successor agency for the purpose of dispensing medical cannabis or low-THC cannabis under Florida law. Additionally, the authority provided to a dispensing organization in s. 499.0295 does not impair the approval of a dispensing organization.

(f) This subsection does not exempt a person from



ENROLLED

CS for CS/CS/HB 307 & HB 1313, Engrossed 1

2016 Leg

prosecution for a criminal offense related to impairment or
intoxication resulting from the medical use of low-THC cannabis
or medical cannabis or relieve a person from any requirement
under law to submit to a breath, blood, urine, or other test to
detect the presence of a controlled substance.

Section 2. Subsections (2) and (3) of section 499.0295,
Florida Statutes, are amended to read:

499.0295 Experimental treatments for terminal conditions.—

(2) As used in this section, the term:

(a) "Dispensing organization" means an organization
approved by the Department of Health under s. 381.986(5) to
cultivate, process, transport, and dispense low-THC cannabis,
medical cannabis, and cannabis delivery devices.

(b)~~(a)~~ "Eligible patient" means a person who:

1. Has a terminal condition that is attested to by the
patient's physician and confirmed by a second independent
evaluation by a board-certified physician in an appropriate
specialty for that condition;

2. Has considered all other treatment options for the
terminal condition currently approved by the United States Food
and Drug Administration;

3. Has given written informed consent for the use of an
investigational drug, biological product, or device; and

4. Has documentation from his or her treating physician
that the patient meets the requirements of this paragraph.

(c)~~(b)~~ "Investigational drug, biological product, or



ENROLLED

CS for CS/CS/HB 307 & HB 1313, Engrossed 1

2016 Leg

729 device" means:

730 1. A drug, biological product, or device that has
731 successfully completed phase 1 of a clinical trial but has not
732 been approved for general use by the United States Food and Drug
733 Administration and remains under investigation in a clinical
734 trial approved by the United States Food and Drug
735 Administration; or

736 2. Medical cannabis that is manufactured and sold by a
737 dispensing organization.

738 (d)~~(e)~~ "Terminal condition" means a progressive disease or
739 medical or surgical condition that causes significant functional
740 impairment, is not considered by a treating physician to be
741 reversible even with the administration of available treatment
742 options currently approved by the United States Food and Drug
743 Administration, and, without the administration of life-
744 sustaining procedures, will result in death within 1 year after
745 diagnosis if the condition runs its normal course.

746 (e)~~(d)~~ "Written informed consent" means a document that is
747 signed by a patient, a parent of a minor patient, a court-
748 appointed guardian for a patient, or a health care surrogate
749 designated by a patient and includes:

750 1. An explanation of the currently approved products and
751 treatments for the patient's terminal condition.

752 2. An attestation that the patient concurs with his or her
753 physician in believing that all currently approved products and
754 treatments are unlikely to prolong the patient's life.



ENROLLED

CS for CS/CS/HB 307 & HB 1313, Engrossed 1

2016 Leg

755 3. Identification of the specific investigational drug,
756 biological product, or device that the patient is seeking to
757 use.

758 4. A realistic description of the most likely outcomes of
759 using the investigational drug, biological product, or device.
760 The description shall include the possibility that new,
761 unanticipated, different, or worse symptoms might result and
762 death could be hastened by the proposed treatment. The
763 description shall be based on the physician's knowledge of the
764 proposed treatment for the patient's terminal condition.

765 5. A statement that the patient's health plan or third-
766 party administrator and physician are not obligated to pay for
767 care or treatment consequent to the use of the investigational
768 drug, biological product, or device unless required to do so by
769 law or contract.

770 6. A statement that the patient's eligibility for hospice
771 care may be withdrawn if the patient begins treatment with the
772 investigational drug, biological product, or device and that
773 hospice care may be reinstated if the treatment ends and the
774 patient meets hospice eligibility requirements.

775 7. A statement that the patient understands he or she is
776 liable for all expenses consequent to the use of the
777 investigational drug, biological product, or device and that
778 liability extends to the patient's estate, unless a contract
779 between the patient and the manufacturer of the investigational
780 drug, biological product, or device states otherwise.



ENROLLED

CS for CS/CS/HB 307 & HB 1313, Engrossed 1

2016 Leg

781 (3) Upon the request of an eligible patient, a
782 manufacturer may, or upon a physician's order pursuant to s.
783 381.986, a dispensing organization may:

784 (a) Make its investigational drug, biological product, or
785 device available under this section.

786 (b) Provide an investigational drug, biological product,
787 ~~or device~~, or cannabis delivery device as defined in s. 381.986
788 to an eligible patient without receiving compensation.

789 (c) Require an eligible patient to pay the costs of, or
790 the costs associated with, the manufacture of the
791 investigational drug, biological product, ~~or device~~, or cannabis
792 delivery device as defined in s. 381.986.

793 Section 3. (1) Notwithstanding s. 381.986(5)(b), Florida
794 Statutes, a dispensing organization that receives notice from
795 the Department of Health that it is approved as a region's
796 dispensing organization, posts a \$5 million performance bond in
797 compliance with rule 64-4.002(5)(e), Florida Administrative
798 Code, meets the requirements of and requests cultivation
799 authorization pursuant to rule 64-4.005(2), Florida
800 Administrative Code, and expends at least \$100,000 to fulfill
801 its legal obligations as a dispensing organization; or any
802 applicant that received the highest aggregate score through the
803 department's evaluation process, notwithstanding any prior
804 determination by the department that the applicant failed to
805 meet the requirements of s. 381.986, Florida Statutes, must be
806 granted cultivation authorization by the department and is



ENROLLED

CS for CS/CS/HB 307 & HB 1313, Engrossed 1

2016 Leg

approved to operate as a dispensing organization for the full term of its original approval and all subsequent renewals pursuant to s. 381.986, Florida Statutes. Any applicant that qualifies under this subsection which has not previously been approved as a dispensing organization by the department must be given approval as a dispensing organization by the department within 10 days after the effective date of this act, and within 10 days after receiving such approval must comply with the bond requirement in rule 64-4.002(5)(e), Florida Administrative Code, and must comply with all other applicable requirements of chapter 64-4, Florida Administrative Code.

(2) If an organization that does not meet the criteria of subsection (1) receives a final determination from the Division of Administrative Hearings, the Department of Health, or a court of competent jurisdiction that it was entitled to be a dispensing organization under s. 381.986, Florida Statutes, and applicable rules, such organization and an organization that meets the criteria of subsection (1) shall both be dispensing organizations in the same region. During the operations of any dispensing organization that meets the criteria in this section, the Department of Health may enforce rule 64-4.005, Florida Administrative Code, as filed on June 17, 2015.

(3) This section does not apply to s. 381.986 (5)(c), Florida Statutes.

Section 4. Any college or university in the state that has a college of agriculture may conduct cannabis research



ENROLLED

CS for CS/CS/HB 307 & HB 1313, Engrossed 1

2016 Leg

833 | consistent with state and federal law.

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