



ENROLLED

CS for CS/CS/HB 307 &amp; 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 &amp; 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 &amp; 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 &amp; 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

105 |           381.986 Compassionate use of low-THC and medical  
 106 | cannabis.—  
 107 |           (1) DEFINITIONS.—As used in this section, the term:  
 108 |           (a) "Cannabis delivery device" means an object used,  
 109 | intended for use, or designed for use in preparing, storing,  
 110 | ingesting, inhaling, or otherwise introducing low-THC cannabis  
 111 | or medical cannabis into the human body.  
 112 |           (b) ~~(a)~~ "Dispensing organization" means an organization  
 113 | approved by the department to cultivate, process, transport, and  
 114 | dispense low-THC cannabis or medical cannabis pursuant to this  
 115 | section.  
 116 |           (c) "Independent testing laboratory" means a laboratory,  
 117 | including the managers, employees, or contractors of the  
 118 | laboratory, which has no direct or indirect interest in a  
 119 | dispensing organization.  
 120 |           (d) "Legal representative" means the qualified patient's  
 121 | parent, legal guardian acting pursuant to a court's  
 122 | authorization as required under s. 744.3215(4), health care  
 123 | surrogate acting pursuant to the qualified patient's written  
 124 | consent or a court's authorization as required under s. 765.113,  
 125 | or an individual who is authorized under a power of attorney to  
 126 | make health care decisions on behalf of the qualified patient.  
 127 |           (e) ~~(b)~~ "Low-THC cannabis" means a plant of the genus  
 128 | Cannabis, the dried flowers of which contain 0.8 percent or less  
 129 | of tetrahydrocannabinol and more than 10 percent of cannabidiol  
 130 | weight for weight; the seeds thereof; the resin extracted from



ENROLLED

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

2016 Leg

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

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

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

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

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

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

153 a. On any form of public transportation.

154 b. In any public place.

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



ENROLLED

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

2016 Leg

261 775.083.

262 (d) An eligible patient as defined in s. 499.0295 who uses  
263 medical cannabis, and such patient's legal representative who  
264 administers medical cannabis, in plain view of or in a place  
265 open to the general public, on the grounds of a school, or in a  
266 school bus, vehicle, aircraft, or motorboat, commits a  
267 misdemeanor of the first degree, punishable as provided in s.  
268 775.082 or s. 775.083.

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

275 (4) PHYSICIAN EDUCATION.—

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



ENROLLED

CS for CS/CS/HB 307 &amp; 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

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

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

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

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



ENROLLED

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

2016 Leg

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

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

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

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

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

358 5. The financial ability to maintain operations for the  
359 duration of the 2-year approval cycle, including the provision  
360 of certified financials to the department. Upon approval, the  
361 applicant must post a \$5 million performance bond. However, upon  
362 a dispensing organization's serving at least 1,000 qualified  
363 patients, the dispensing organization is only required to  
364 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 &amp; 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 &amp; 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 &amp; 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 &amp; 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 &amp; 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 &amp; HB 1313, Engrossed 1

2016 Leg

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

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

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

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

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

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

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

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



ENROLLED

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

2016 Leg

625 duties.

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

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

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

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

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

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

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

650 (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)~~ 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

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

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

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

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

702 (f) This subsection does not exempt a person from



ENROLLED

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

2016 Leg

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

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

710 499.0295 Experimental treatments for terminal conditions.-

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

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

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

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

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

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

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

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



ENROLLED

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

2016 Leg

807 approved to operate as a dispensing organization for the full  
808 term of its original approval and all subsequent renewals  
809 pursuant to s. 381.986, Florida Statutes. Any applicant that  
810 qualifies under this subsection which has not previously been  
811 approved as a dispensing organization by the department must be  
812 given approval as a dispensing organization by the department  
813 within 10 days after the effective date of this act, and within  
814 10 days after receiving such approval must comply with the bond  
815 requirement in rule 64-4.002(5)(e), Florida Administrative Code,  
816 and must comply with all other applicable requirements of  
817 chapter 64-4, Florida Administrative Code.

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

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

831 Section 4. Any college or university in the state that has  
832 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.