

LEGISLATIVE ACTION

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Senate

House

| Senator Clemens moved the following: |
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| Senate Amendment (with title amendment) |
| Delete everything after the enacting clause |
| and insert: |
| Section 1. Section 381.986, Florida Statutes, is amended to |
| read: |
| 381.986 Compassionate use of low-THC cannabis |
| (1) DEFINITIONS.—As used in this section, the term: |
| (a) "Applicant" means a person that has submitted an |
| application to the department for licensure or renewal as a |
| dispensing organization. |

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| 12 | (b) "Batch" means a specific quantity of low-THC cannabis |
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| 13 | product that is intended to have uniform character and quality, |
| 14 | within specified limits, and is produced at the same time from |
| 15 | one or more harvests. |
| 16 | (c) "Dispensing organization" means an applicant licensed |
| 17 | organization approved by the department to cultivate <u>or</u> $	au$ |
| 18 | process <u>low-THC cannabis, and</u> or dispense low-THC cannabis |
| 19 | through a retail facility pursuant to this section. |
| 20 | (d) "Harvest" means a specifically identified and numbered |
| 21 | quantity of low-THC cannabis cultivated using the same |
| 22 | herbicides, pesticides, and fungicides and harvested at the same |
| 23 | time from a single facility. |
| 24 | (e) "Independent testing laboratory" means a laboratory, |
| 25 | and the managers, employees, or contractors of the laboratory, |
| 26 | which have no direct or indirect interest in a dispensing |
| 27 | organization. |
| 28 | <u>(f)</u> "Low-THC cannabis" means a plant of the genus |
| 29 | Cannabis, the dried flowers of which contain 0.8 percent or less |
| 30 | of tetrahydrocannabinol and more than 10 percent of cannabidiol |
| 31 | weight for weight; the seeds thereof; the resin extracted from |
| 32 | any part of such plant; or any compound, manufacture, salt, |
| 33 | derivative, mixture, or preparation of such plant or its seeds |
| 34 | or resin that is dispensed only from a dispensing organization. |
| 35 | (g) "Low-THC cannabis product" means any product derived |
| 36 | from low-THC cannabis, including the resin extracted from any |
| 37 | part of such plant or any compound, manufacture, salt, |
| 38 | derivative, mixture, or preparation of such plant or its seeds |
| 39 | or resin which is dispensed from a dispensing organization. Low- |
| 40 | THC cannabis products include, but are not limited to, oils, |
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| 41 | tinctures, creams, encapsulations, and food products. Low-THC |
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| 42 | cannabis food products may not include candy or similar |
| 43 | confectionary products that appeal to children. All low-THC |
| 44 | cannabis products must maintain concentrations, weight for |
| 45 | weight, of 0.8 percent or less of tetrahydrocannabinol and more |
| 46 | than 10 percent of cannabidiol. |
| 47 | (h) (c) "Medical use" means administration of the ordered |
| 48 | amount of low-THC cannabis. The term does not include: |
| 49 | <u>1.</u> The possession, use, or administration by smoking. |
| 50 | 2. The term also does not include The transfer of low-THC |
| 51 | cannabis to a person other than the qualified patient for whom |
| 52 | it was ordered or the qualified patient's legal representative |
| 53 | who is registered in the compassionate use registry on behalf of |
| 54 | the qualified patient. |
| 55 | 3. The use or administration of low-THC cannabis or low-THC |
| 56 | cannabis products: |
| 57 | a. On any form of public transportation. |
| 58 | b. In any public place. |
| 59 | c. In a registered qualified patient's place of work, if |
| 60 | restricted by his or her employer. |
| 61 | d. In a correctional facility. |
| 62 | e. On the grounds of any preschool, primary school, or |
| 63 | secondary school. |
| 64 | <u>f. On a school bus.</u> |
| 65 | <u>(i)</u> "Qualified patient" means a resident of this state |
| 66 | who has been added to the compassionate use registry by a |
| 67 | physician licensed under chapter 458 or chapter 459 to receive |
| 68 | low-THC cannabis from a dispensing organization. |
| 69 | (j) "Retail facility" means a facility that is used by an |
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70 applicant licensed to dispense low-THC cannabis.

71 (k) (c) "Smoking" means burning or igniting a substance and 72 inhaling the smoke. Smoking does not include the use of a 73 vaporizer.

74 75 76 (2) PHYSICIAN ORDERING.-

(a) Effective January 1, 2015, A physician licensed under chapter 458 or chapter 459 who has examined and is treating a 77 patient suffering from cancer, human immunodeficiency virus, acquired immune deficiency syndrome, epilepsy, amyotrophic 78 79 lateral sclerosis, autism, multiple sclerosis, Crohn's disease, Parkinson's disease, paraplegia, quadriplegia, or terminal 80 81 illness a physical medical condition that chronically produces 82 symptoms of seizures or severe and persistent muscle spasms may 83 order for the patient's medical use low-THC cannabis to treat 84 such disease, disorder, or condition; or to alleviate symptoms 85 of such disease, disorder, or condition; or to alleviate 86 symptoms caused by a treatment for such disease, disorder, or 87 condition τ if no other satisfactory alternative treatment 88 options exist for that patient and all of the following conditions apply:

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1.(a) The patient is a permanent resident of this state. 2.(b) The physician determines that the risks of ordering low-THC cannabis are reasonable in light of the potential benefit for that patient. If a patient is younger than 18 years of age, a second physician must concur with this determination, and such determination must be documented in the patient's

medical record.

3.(c) The physician registers the patient, the patient's legal representative if requested by the patient, and himself or

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99 <u>herself</u> as the orderer of low-THC cannabis for the named patient 100 on the compassionate use registry maintained by the department 101 and updates the registry to reflect the contents of the order. 102 <u>If the patient is a minor, the physician must register a legal</u> 103 <u>representative on the compassionate use registry.</u> The physician 104 shall deactivate the patient's registration when treatment is 105 discontinued.

106 <u>4.(d)</u> The physician maintains a patient treatment plan that 107 includes the dose, route of administration, planned duration, 108 and monitoring of the patient's symptoms and other indicators of 109 tolerance or reaction to the low-THC cannabis.

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

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

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

(3) PENALTIES.-

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(a) A physician commits a misdemeanor of the first degree,punishable as provided in s. 775.082 or s. 775.083, if the

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128 physician orders low-THC cannabis for a patient without a 129 reasonable belief that the patient is suffering from <u>at least</u> 130 one of the conditions listed in subsection (2).÷

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

134 2. Symptoms of cancer or a physical medical condition that 135 chronically produces symptoms of seizures or severe and 136 persistent muscle spasms that can be alleviated with low-THC 137 cannabis.

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

(4) PHYSICIAN EDUCATION.-

(a) Before ordering low-THC cannabis for use by a patient 146 147 in this state, the appropriate board shall require the ordering 148 physician licensed under chapter 458 or chapter 459 to 149 successfully complete an 8-hour course and subsequent 150 examination offered by the Florida Medical Association or the 151 Florida Osteopathic Medical Association that encompasses the 152 clinical indications for the appropriate use of low-THC 153 cannabis, the appropriate delivery mechanisms, the 154 contraindications for such use, as well as the relevant state 155 and federal laws governing the ordering, dispensing, and 156 possessing of this substance. The first course and examination

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157 shall be presented by October 1, 2014, and shall be administered 158 at least annually thereafter. Successful completion of the 159 course may be used by a physician to satisfy 8 hours of the 160 continuing medical education requirements required by his or her 161 respective board for licensure renewal. This course may be 162 offered in a distance learning format.

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

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

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

(5) DUTIES <u>AND POWERS</u> OF THE DEPARTMENT. By January 1, 2015, The department shall:

(a) <u>The department shall</u> create a secure, electronic, and
online compassionate use registry for the registration of
physicians and patients as provided under this section. The

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186 registry must be accessible to law enforcement agencies and to a 187 dispensing organization in order to verify patient authorization 188 for low-THC cannabis and record the low-THC cannabis dispensed. 189 The registry must prevent an active registration of a patient by 190 multiple physicians.

(b)<u>1. Beginning 7 days after the effective date of this</u> act, the department shall accept applications for licensure as a dispensing organization. A dispensing organization may be licensed to cultivate or process low-THC cannabis or dispense low-THC cannabis through a retail facility. A dispensing organization may be licensed to conduct one or more of these activities. The department shall review each application to determine whether the applicant meets the criteria in subsection (6) and qualifies for licensure.

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

3. Once licensed, applicants are authorized to operate in any region in the state, but a dispensing organization licensed to cultivate or process low-THC cannabis may not have cultivation or processing facilities outside the region in which it is licensed. 4. The department shall license a selected applicant unless

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the applicant fails to pay the licensure fee within 10 days of 215 216 selection. 5. This section is exempt from s. 120.60(1) Authorize the 217 218 establishment of five dispensing organizations to ensure 219 reasonable statewide accessibility and availability as necessary for patients registered in the compassionate use registry and 220 221 who are ordered low-THC cannabis under this section, one in each 222 of the following regions: northwest Florida, northeast Florida, 223 central Florida, southeast Florida, and southwest Florida. 224 (c) The department shall use develop an application form 225 that requires the applicant to state, as applicable: 226 1. Whether the application is for initial licensure or 227 renewal licensure; 228 2. Whether the application is for licensure as a 229 cultivator, processor, or dispenser of low-THC cannabis; 230 3. The name, the physical address, and the mailing address 231 of the applicant; 232 4. For a cultivating or processing license, the address 233 listed on the Department of Agriculture and Consumer Services 234 certificate required in paragraph (6)(b); 235 5. The name, address, license number, and contact 236 information for the applicant's medical director; and 237 6. All information required to be included by subsection 2.38 (6). 239 (d) The department shall and impose an initial application 240 fee of \$10,000, an initial licensure fee of \$25,000, and a biennial renewal fee of \$25,000 that is sufficient to cover the 241 242 costs of administering this section. An applicant for approval 243 as a dispensing organization must be able to demonstrate:

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| 244 | 1. The technical and technological ability to cultivate and |
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| 245 | produce low-THC cannabis. The applicant must possess a valid |
| 246 | certificate of registration issued by the Department of |
| 247 | Agriculture and Consumer Services pursuant to s. 581.131 that is |
| 248 | issued for the cultivation of more than 400,000 plants, be |
| 249 | operated by a nurseryman as defined in s. 581.011, and have been |
| 250 | operated as a registered nursery in this state for at least 30 |
| 251 | continuous years. |
| 252 | 2. The ability to secure the premises, resources, and |
| 253 | personnel necessary to operate as a dispensing organization. |
| 254 | 3. The ability to maintain accountability of all raw |
| 255 | materials, finished products, and any byproducts to prevent |
| 256 | diversion or unlawful access to or possession of these |
| 257 | substances. |
| 258 | 4. An infrastructure reasonably located to dispense low-THC |
| 259 | cannabis to registered patients statewide or regionally as |
| 260 | determined by the department. |
| 261 | 5. The financial ability to maintain operations for the |
| 262 | duration of the 2-year approval cycle, including the provision |
| 263 | of certified financials to the department. Upon approval, the |
| 264 | applicant must post a \$5 million performance bond. |
| 265 | 6. That all owners and managers have been fingerprinted and |
| 266 | have successfully passed a level 2 background screening pursuant |
| 267 | to s. 435.04. |
| 268 | 7. The employment of a medical director who is a physician |
| 269 | licensed under chapter 458 or chapter 459 to supervise the |
| 270 | activities of the dispensing organization. |
| 271 | (e) The department shall inspect each dispensing |
| 272 | organization's properties, cultivation facilities, processing |
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273 facilities, or retail facilities according to its licensure 274 before they begin operations and at least once every 2 years thereafter. The department may conduct additional announced or 275 276 unannounced inspections, including followup inspections, at 277 reasonable hours in order to ensure that such properties or 278 facilities maintain compliance with all applicable requirements 279 in subsections (6) and (7) and to ensure that the dispensing 280 organization has not committed any act that would endanger the 2.81 health, safety, or security of a qualified patient, a dispensing 282 organization staff member, or the community in which the 283 dispensing organization is located. Licensure under this section 284 constitutes permission for the department to enter and inspect 285 the premises or facilities of any dispensing organization. A 286 dispensing organization must make all facility premises, 287 equipment, documents, low-THC cannabis, and low-THC cannabis 288 products available, as applicable, to the department upon 289 inspection. The department may test any low-THC cannabis or low-290 THC cannabis product in order to ensure that it is safe for 291 human consumption and that it meets the requirements in this 292 section. 293 (f) The department may suspend or revoke a license, deny or refuse to renew a license, or impose an administrative penalty 294 295 not to exceed \$10,000 for the following acts or omissions: 296 1. Violating this section or department rule. 297 2. Failing to maintain qualifications for licensure. 298 3. Endangering the health, safety, or security of a 299 qualified patient. 300 4. Improperly disclosing personal and confidential 301 information of a qualified patient.

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| 302 | 5. Attempting to procure a license by bribery or fraudulent |
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| 303 | misrepresentation. |
| 304 | 6. Being convicted or found guilty of, or entering a plea |
| 305 | of nolo contendere to, regardless of adjudication, a crime in |
| 306 | any jurisdiction which directly relates to the business of a |
| 307 | dispensing organization. |
| 308 | 7. Making or filing a report or record that the licensee |
| 309 | knows to be false. |
| 310 | 8. Willfully failing to maintain a record required by this |
| 311 | section or department rule. |
| 312 | 9. Willfully impeding or obstructing an employee or agent |
| 313 | of the department in the furtherance of his or her official |
| 314 | duties. |
| 315 | 10. Engaging in fraud or deceit, negligence, incompetence, |
| 316 | or misconduct in the business practices of a dispensing |
| 317 | organization. |
| 318 | 11. Making misleading, deceptive, or fraudulent |
| 319 | representations in or related to the business practices of a |
| 320 | dispensing organization. |
| 321 | 12. Having a license or the authority to engage in any |
| 322 | regulated profession, occupation, or business that is related to |
| 323 | the business practices of a dispensing organization revoked, |
| 324 | suspended, or otherwise acted against, including the denial of |
| 325 | licensure, by the licensing authority of any jurisdiction, |
| 326 | including its agencies or subdivisions, for a violation that |
| 327 | would constitute a violation under state law. A licensing |
| 328 | authority's acceptance of a relinquishment of licensure or a |
| 329 | stipulation, consent order, or other settlement, offered in |
| 330 | response to or in anticipation of the filing of charges against |
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| 331 | the license, shall be construed as an action against the |
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| 332 | license. |
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| | 13. Violating a lawful order of the department or an agency |
| 334 | of the state, or failing to comply with a lawfully issued |
| 335 | subpoena of the department or an agency of the state. |
| 336 | (g) The department shall create a permitting process for |
| 337 | all dispensing organization vehicles used for the transportation |
| 338 | of low-THC cannabis or low-THC cannabis products. |
| 339 | <u>(h) (c)</u> The department shall monitor physician registration |
| 340 | and ordering of low-THC cannabis for ordering practices that |
| 341 | could facilitate unlawful diversion or misuse of low-THC |
| 342 | cannabis and take disciplinary action as indicated. |
| 343 | <u>(i)(d) The department shall</u> adopt rules <u>as</u> necessary to |
| 344 | implement this section. |
| 345 | (6) DISPENSING ORGANIZATION |
| 346 | (a) An applicant seeking licensure as a dispensing |
| 347 | organization, or the renewal of its license, must submit an |
| 348 | application to the department. An applicant may seek licensure |
| 349 | as a dispensing organization to cultivate, process, or dispense |
| 350 | low-THC cannabis. Each function of the dispensing organization |
| 351 | requires separate licensure; however, an applicant may seek |
| 352 | licensure for more than one function. The department must review |
| 353 | all applications for completeness, including an appropriate |
| 354 | inspection of the applicant's property or facilities, as |
| 355 | applicable, to verify the authenticity of the information |
| 356 | provided in, or in connection with, the application. An |
| 357 | applicant authorizes the department to inspect his or her |
| 358 | property or facilities for licensure by applying under this |
| 359 | subsection. |
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| 360 | (b) In order to receive or maintain licensure as a |
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| 361 | dispensing organization, an applicant must provide proof that: |
| 362 | 1. For a cultivating or processing license, the applicant, |
| 363 | or a separate entity that is owned solely by the same persons or |
| 364 | entities in the same ratio as the applicant, possesses a valid |
| 365 | certificate of registration issued by the Department of |
| 366 | Agriculture and Consumer Services pursuant to s. 581.131 for the |
| 367 | cultivation of more than 400,000 plants. |
| 368 | 2. For a cultivating or processing license, the personnel |
| 369 | on staff or under contract for the applicant have experience |
| 370 | cultivating and introducing multiple varieties of plants in this |
| 371 | state, including plants that are not native to Florida; |
| 372 | experience with propagating plants; and experience with genetic |
| 373 | modification or breeding of plants. |
| 374 | 3. For a cultivating or processing license, the personnel |
| 375 | on staff or under contract for the applicant include at least |
| 376 | one person who: |
| 377 | a. Has at least 5 years' experience with United States |
| 378 | Department of Agriculture Good Agricultural Practices and Good |
| 379 | Handling Practices; |
| 380 | b. Has at least 5 years' experience with United States Food |
| 381 | and Drug Administration Good Manufacturing Practices for food |
| 382 | production; |
| 383 | <u>c. Has a doctorate degree in organic chemistry or</u> |
| 384 | microbiology; |
| 385 | d. Has at least 5 years' of experience with laboratory |
| 386 | procedures which includes analytical laboratory quality control |
| 387 | measures, chain of custody procedures, and analytical laboratory |
| 388 | methods; |
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| 389 | e. Has experience with cannabis cultivation and processing, |
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| 390 | including cannabis extraction techniques and producing cannabis |
| 391 | products; |
| 392 | f. Has experience and qualifications in chain of custody or |
| 393 | other tracking mechanisms; |
| 394 | g. Works solely on inventory control; and |
| 395 | h. Works solely for security purposes. |
| 396 | 4. The persons who have a direct or indirect interest in |
| 397 | any dispensing organization and the applicant's managers, |
| 398 | employees, and contractors who directly interact with low-THC |
| 399 | cannabis or low-THC cannabis products have been fingerprinted |
| 400 | and have successfully passed a level 2 background screening |
| 401 | pursuant to s. 435.04. |
| 402 | 5. For a cultivating or processing license, the applicant |
| 403 | owns, or has at least a 2-year lease of, all properties, |
| 404 | facilities, and equipment necessary for the cultivation and |
| 405 | processing of low-THC cannabis. The applicant must provide a |
| 406 | detailed description of each facility and its equipment, a |
| 407 | cultivation and processing plan, and a detailed floor plan. The |
| 408 | description must include proof that: |
| 409 | a. The applicant is capable of sufficient cultivation and |
| 410 | processing to serve at least 15,000 patients with an assumed |
| 411 | daily use of 1,000 mg per patient per day of low-THC cannabis or |
| 412 | low-THC cannabis product; |
| 413 | b. The applicant has arranged for access to all utilities |
| 414 | and resources necessary to cultivate or process low-THC cannabis |
| 415 | at each listed facility; and |
| 416 | c. Each facility is secured and has theft-prevention |
| 417 | systems including an alarm system, cameras, and 24-hour security |
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| 418 | personnel. |
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| 419 | 6. The applicant has diversion and tracking prevention |
| 420 | procedures, as applicable, including: |
| 421 | a. A system for tracking low-THC material through |
| 422 | cultivation, processing, or dispensing, including the use of |
| 423 | batch and harvest numbers; |
| 424 | b. An inventory control system for low-THC cannabis and |
| 425 | low-THC cannabis products; |
| 426 | c. A vehicle tracking and security system; and |
| 427 | d. A cannabis waste-disposal plan. |
| 428 | 7. The applicant has recordkeeping policies and procedures |
| 429 | in place. |
| 430 | 8. The applicant has a facility emergency management plan. |
| 431 | 9. For a dispensing license, the applicant has a plan for |
| 432 | dispensing low-THC cannabis throughout the state. This plan must |
| 433 | include planned retail facilities and a delivery plan for |
| 434 | providing low-THC cannabis and low-THC cannabis products to |
| 435 | qualified patients who cannot travel to a retail facility. |
| 436 | 10. The applicant has financial documentation, as |
| 437 | applicable, including: |
| 438 | a. Documentation that demonstrates the applicant's |
| 439 | financial ability to operate. If the applicant's assets, credit, |
| 440 | and projected revenues meet or exceed projected liabilities and |
| 441 | expenses and the applicant provides independent evidence that |
| 442 | the funds necessary for startup costs, working capital, and |
| 443 | contingency financing exist and are available as needed, the |
| 444 | applicant has demonstrated the financial ability to operate. |
| 445 | Financial ability to operate must be documented by: |
| 446 | I. The applicant's audited financial statements. If the |

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| 447 | applicant is a newly formed entity and does not have a financial |
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| 448 | history of business upon which audited financial statements may |
| 449 | be submitted, the applicant must provide audited financial |
| 450 | statements for the separate entity that is owned solely by the |
| 451 | same persons or entities in the same ratio as the applicant; |
| 452 | II. The applicant's projected financial statements, |
| 453 | including a balance sheet, an income and expense statement, and |
| 454 | a statement of cash flow for the first 2 years of operation, |
| 455 | which provides evidence that the applicant has sufficient |
| 456 | assets, credit, and projected revenues to cover liabilities and |
| 457 | expenses; and |
| 458 | III. A statement of the applicant's estimated startup costs |
| 459 | and sources of funds, including a break-even projection and |
| 460 | documentation demonstrating that the applicant has the ability |
| 461 | to fund all startup costs, working capital costs, and |
| 462 | contingency financing requirements. |
| 463 | |
| 464 | All documents required under this sub-subparagraph shall be |
| 465 | prepared in accordance with generally accepted accounting |
| 466 | principles and signed by a certified public accountant. The |
| 467 | statements required by sub-sub-subparagraphs II. and III. may be |
| 468 | presented as a compilation; |
| 469 | b. A list of all subsidiaries of the applicant; |
| 470 | c. A list of all lawsuits pending and completed within the |
| 471 | past 7 years of which the applicant was a party; and |
| 472 | d. Proof of a \$1 million performance and compliance bond, |
| 473 | or other equivalent means of security deemed equivalent by the |
| 474 | department, such as an irrevocable letter of credit or a deposit |
| 475 | in a trust account or financial institution, payable to the |
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476 department, which must be posted once the applicant is approved 477 as a dispensing organization. The purpose of the bond is to secure payment of any administrative penalties imposed by the 478 479 department and any fees and costs incurred by the department 480 regarding the dispensing organization license, such as the 481 dispensing organization failing to pay 30 days after the fine or 482 costs become final. The department may make a claim against such 483 bond or security until 1 year after the dispensing 484 organization's license ceases to be valid or until 60 days after 485 any administrative or legal proceeding authorized in this 486 section involving the dispensing organization concludes, 487 including any appeal, whichever occurs later. 488 11. The employment of a medical director who is a physician 489 licensed under chapter 458 or chapter 459 to supervise the 490 activities of the dispensing organization. (c) An approved dispensing organization shall maintain 491 492 compliance with the criteria in paragraphs (b), (d), and (e) and subsection (7) demonstrated for selection and approval as a 493 494 dispensing organization under subsection (5) at all times. 495 Before dispensing low-THC cannabis or low-THC cannabis products 496 to a qualified patient or to the qualified patient's legal 497 representative, the dispensing organization shall verify the 498 identity of the qualified patient or the qualified patient's 499 legal representative by requiring the qualified patient or the 500 qualified patient's legal representative to produce a 501 government-issued identification card and shall verify that the 502 qualified patient and the qualified patient's legal 503 representative have has an active registration in the 504 compassionate use registry, that the order presented matches the

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505 order contents as recorded in the registry, and that the order 506 has not already been filled. Upon dispensing the low-THC 507 cannabis, the dispensing organization shall record in the registry the date, time, quantity, and form of low-THC cannabis 508 509 dispensed. 510 (d) A dispensing organization may have cultivation 511 facilities, processing facilities, or retail facilities. 512 1. All matters regarding the location of cultivation 513 facilities and processing facilities are preempted to the state. 514 Cultivation facilities and processing facilities must be closed 515 to the public, and low-THC cannabis may not be dispensed on the 516 premises of such facilities. 517 2. A municipality must determine by ordinance the criteria 518 for the number and location of, and other permitting 519 requirements for, all retail facilities located within its 520 municipal boundaries. A retail facility may be established in a 521 municipality only after such an ordinance has been created. A 522 county must determine by ordinance the criteria for the number, 523 location, and other permitting requirements for all retail 524 facilities located within the unincorporated areas of that 525 county. A retail facility may be established in the 526 unincorporated areas of a county only after such an ordinance 527 has been created. Retail facilities must have all utilities and 528 resources necessary to store and dispense low-THC cannabis and 529 low-THC cannabis products. Retail facilities must be secured and 530 have theft-prevention systems, including an alarm system, 531 cameras, and 24-hour security personnel. Retail facilities may 532 not sell, or contract for the sale of, anything other than low-533 THC cannabis or low-THC cannabis products on the property of the

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| 534 | retail facility. Before a retail facility may dispense low-THC |
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| 535 | cannabis or a low-THC cannabis product, the dispensing |
| 536 | organization must have a computer network compliant with the |
| 537 | federal Health Insurance Portability and Accountability Act of |
| 538 | 1996 which is able to access and upload data to the |
| 539 | compassionate use registry and which shall be used by all retail |
| 540 | facilities. |
| 541 | (e) Within 15 days after such information becoming |
| 542 | available, a dispensing organization must provide the department |
| 543 | with updated information, as applicable, including: |
| 544 | 1. The location and a detailed description of any new or |
| 545 | proposed facilities. |
| 546 | 2. The updated contact information, including electronic |
| 547 | and voice communication, for all dispensing organization |
| 548 | facilities. |
| 549 | 3. The registration information for any vehicles used for |
| 550 | the transportation of low-THC cannabis and low-THC cannabis |
| 551 | products, including confirmation that all such vehicles have |
| 552 | tracking and security systems. |
| 553 | 4. A plan for the recall of any or all low-THC cannabis or |
| 554 | low-THC cannabis products. |
| 555 | (f)1. A dispensing organization may transport low-THC |
| 556 | cannabis or low-THC cannabis products in vehicles departing from |
| 557 | their places of business only in vehicles that are owned or |
| 558 | leased by the licensee or by a person designated by the |
| 559 | dispensing organization, and for which a valid vehicle permit |
| 560 | has been issued for such vehicle by the department. |
| 561 | 2. A vehicle owned or leased by the dispensing organization |
| 562 | or a person designated by the dispensing organization and |
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563 <u>approved by the department must be operated by such person when</u> 564 <u>transporting low-THC cannabis or low-THC products from the</u> 565 <u>licensee's place of business.</u>

566 3. A vehicle permit may be obtained by a dispensing 567 organization upon application and payment of a fee of \$5 per 568 vehicle to the department. The signature of the person 569 designated by the dispensing organization to drive the vehicle 570 must be included on the vehicle permit application. Such permit 571 remains valid and does not expire unless the licensee or any 572 person designated by the dispensing organization disposes of his 573 or her vehicle, or the licensee's license is transferred, 574 canceled, not renewed, or is revoked by the department, 575 whichever occurs first. The department shall cancel a vehicle 576 permit upon request of the licensee or owner of the vehicle. 577 4. By acceptance of a license issued under this section, 578 the licensee agrees that the licensed vehicle is, at all times 579 it is being used to transport low-THC cannabis or low-THC 580 cannabis products, subject to inspection and search without a 581 search warrant by authorized employees of the department, 582 sheriffs, deputy sheriffs, police officers, or other law 583 enforcement officers to determine that the licensee is 584 transporting such products in compliance with this section. 585 (7) TESTING AND LABELING OF LOW-THC CANNABIS.-(a) All low-THC cannabis and low-THC cannabis products must 586 587 be tested by an independent testing laboratory before the 588 dispensing organization may dispense them. The independent 589 testing laboratory shall provide the dispensing organization 590 with lab results. Before dispensing, the dispensing organization 591 must determine that the lab results indicate that the low-THC

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| 592 | cannabis or low-THC cannabis product meets the definition of |
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| 593 | low-THC cannabis or low-THC cannabis product, is safe for human |
| 594 | consumption, and is free from harmful contaminants. |
| 595 | (b) All low-THC cannabis and low-THC cannabis products must |
| 596 | be labeled before dispensing. The label must include, at a |
| 597 | minimum: |
| 598 | 1. A statement that the low-THC cannabis or low-THC |
| 599 | cannabis product meets the requirements in paragraph (a); |
| 600 | 2. The name of the independent testing laboratory that |
| 601 | tested the low-THC cannabis or low-THC cannabis product; |
| 602 | 3. The name of the cultivation and processing facility |
| 603 | where the low-THC cannabis or low-THC cannabis product |
| 604 | originates; and |
| 605 | 4. The batch number and harvest number from which the low- |
| 606 | THC cannabis or low-THC cannabis product originates. |
| 607 | (8) SAFETY AND EFFICACY RESEARCH FOR LOW-THC CANNABISThe |
| 608 | University of Florida College of Pharmacy shall establish and |
| 609 | maintain a safety and efficacy research program for the use of |
| 610 | low-THC cannabis or low-THC cannabis products to treat |
| 611 | qualifying conditions and symptoms. The program must include a |
| 612 | fully integrated electronic information system for the broad |
| 613 | monitoring of health outcomes and safety signal detection. The |
| 614 | electronic information system must include information from the |
| 615 | compassionate use registry; provider reports, including |
| 616 | treatment plans, adverse event reports, and treatment |
| 617 | discontinuation reports; patient reports of adverse impacts; |
| 618 | event-triggered interviews and medical chart reviews performed |
| 619 | by University of Florida clinical research staff; information |
| 620 | from external databases, including Medicaid billing reports and |
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621 information in the prescription drug monitoring database for 622 registered patients; and all other medical reports required by 623 the University of Florida to conduct the research required by 624 this subsection. The department must provide access to 625 information from the compassionate use registry and the 626 prescription drug monitoring database, established in s. 627 893.055, as needed by the University of Florida to conduct 628 research under this subsection. The Agency for Health Care 629 Administration must provide access to registered patient 630 Medicaid records, to the extent allowed under federal law, as needed by the University of Florida to conduct research under 631 632 this subsection. 633 (9) The persons who have direct or indirect interest in the 634 dispensing organization and the dispensing organization's 635 managers, employees, and contractors who directly interact with low-THC cannabis or low-THC cannabis products are prohibited 636 637 from making recommendations, offering prescriptions, or 638 providing medical advice to qualified patients. 639 (10) (7) EXCEPTIONS TO OTHER LAWS.-640 (a) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or 641 any other provision of law, but subject to the requirements of 642 this section, a qualified patient and the qualified patient's 643 legal representative who is registered with the department on the compassionate use registry may purchase and possess for the 644 645 patient's medical use up to the amount of low-THC cannabis 646 ordered for the patient. Nothing in this section exempts any 647 person from the prohibition against driving under the influence 648 provided in s. 316.193. 649 (b) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or

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650 any other provision of law, but subject to the requirements of 651 this section, an approved dispensing organization and its 652 owners, managers, and employees and the owners, managers, and 653 employees of contractors who have direct contact with low-THC 654 cannabis or low-THC cannabis product may manufacture, possess, 655 sell, deliver, distribute, dispense, and lawfully dispose of 656 reasonable quantities, as established by department rule, of 657 low-THC cannabis in accordance with their licensure. For purposes of this subsection, the terms "manufacture," 658 659 "possession," "deliver," "distribute," and "dispense" have the 660 same meanings as provided in s. 893.02.

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

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

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

675 Section 2. Paragraph (g) is added to subsection (3) of 676 section 381.987, Florida Statutes, to read:

677 381.987 Public records exemption for personal identifying678 information in the compassionate use registry.-

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679 (3) The department shall allow access to the registry, 680 including access to confidential and exempt information, to: 681 (g) Persons engaged in research at the University of 682 Florida pursuant to s. 381.986(8). Section 3. Paragraph (b) of subsection (7) of section 683 684 893.055, Florida Statutes, is amended to read: 685 893.055 Prescription drug monitoring program.-686 (7)687 (b) A pharmacy, prescriber, or dispenser shall have access 688 to information in the prescription drug monitoring program's 689 database which relates to a patient of that pharmacy, 690 prescriber, or dispenser in a manner established by the 691 department as needed for the purpose of reviewing the patient's 692 controlled substance prescription history. Persons engaged in 693 research at the University of Florida pursuant to s. 381.986(8) 694 shall have access to information in the prescription drug 695 monitoring program's database which relates to qualified 696 patients as defined in s. 381.986(1) for the purpose of 697 conducting such research. Other access to the program's database 698 shall be limited to the program's manager and to the designated 699 program and support staff, who may act only at the direction of 700 the program manager or, in the absence of the program manager, 701 as authorized. Access by the program manager or such designated 702 staff is for prescription drug program management only or for 703 management of the program's database and its system in support 704 of the requirements of this section and in furtherance of the 705 prescription drug monitoring program. Confidential and exempt 706 information in the database shall be released only as provided 707 in paragraph (c) and s. 893.0551. The program manager,

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708 designated program and support staff who act at the direction of 709 or in the absence of the program manager, and any individual who 710 has similar access regarding the management of the database from 711 the prescription drug monitoring program shall submit 712 fingerprints to the department for background screening. The 713 department shall follow the procedure established by the 714 Department of Law Enforcement to request a statewide criminal 715 history record check and to request that the Department of Law 716 Enforcement forward the fingerprints to the Federal Bureau of 717 Investigation for a national criminal history record check.

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

893.0551 Public records exemption for the prescription drug monitoring program.-

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

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

Section 5. <u>The Division of Law Revision and Information is</u> <u>directed to replace the phrase "the effective date of this act"</u> <u>wherever it occurs in this act with the date the act becomes a</u> <u>law.</u>

Section 6. This act shall take effect upon becoming a law.

Delete everything before the enacting clause

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| 737 | and insert: |
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| 738 | A bill to be entitled |
| 739 | An act relating to low-THC cannabis; amending s. |
| 740 | 381.986, F.S.; defining terms; revising the illnesses |
| 741 | and symptoms for which a physician may order a patient |
| 742 | the medical use of low-THC cannabis in certain |
| 743 | circumstances; providing that a physician who |
| 744 | improperly orders low-THC cannabis is subject to |
| 745 | specified disciplinary action; revising the duties of |
| 746 | the Department of Health; requiring the department to |
| 747 | create a secure, electronic, and online compassionate |
| 748 | use registry; requiring the department to begin to |
| 749 | accept applications for licensure as a dispensing |
| 750 | organization according to a specified application |
| 751 | process; authorizing a dispensing organization to be |
| 752 | licensed to cultivate, to process, or to dispense low- |
| 753 | THC cannabis; requiring the department to review all |
| 754 | applications, notify applicants of deficient |
| 755 | applications, and request any additional information |
| 756 | within a specified period; requiring an application |
| 757 | for licensure to be filed and complete by specified |
| 758 | dates; authorizing licensed applicants to operate in |
| 759 | any region of the state; prohibiting a dispensing |
| 760 | organization licensed to cultivate or process low-THC |
| 761 | cannabis from having cultivation or processing |
| 762 | facilities outside the region in which it is licensed; |
| 763 | requiring licensure fees to be paid within a specified |
| 764 | timeframe; providing an exemption for the application |
| 765 | process; requiring the department to use an |

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766 application form that requires specified information 767 from the applicant; requiring the department to impose 768 specified application fees; requiring the department 769 to inspect each dispensing organization's properties, 770 cultivation facilities, processing facilities, or 771 retail facilities before those facilities may operate; 772 authorizing followup inspections at reasonable hours; 773 providing that licensure constitutes permission for 774 the department to enter and inspect the premises or 775 facilities of any dispensing organization; authorizing 776 the department to inspect any licensed dispensing 777 organization; requiring dispensing organizations to 778 make all facility premises, equipment, documents, low-779 THC cannabis, and low-THC cannabis products, as 780 applicable, available to the department upon 781 inspection; authorizing the department to test low-THC 782 cannabis or low-THC cannabis products; authorizing the 783 department to suspend or revoke a license, deny or 784 refuse to renew a license, or impose a maximum 785 administrative penalty for specified acts or 786 omissions; requiring the department to create a 787 permitting process for vehicles used for the 788 transportation of low-THC cannabis or low-THC cannabis 789 products; requiring the department to adopt rules as 790 necessary for implementation of specified provisions 791 and procedures, and to provide specified guidance; 792 providing procedures and requirements for an applicant 793 seeking licensure as a dispensing organization or the 794 renewal of its license; requiring the dispensing

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795 organization to verify specified information of 796 specified persons in certain circumstances; 797 authorizing a dispensing organization to have 798 cultivation facilities, processing facilities, or 799 retail facilities; authorizing a retail facility to be 800 established in a municipality only after such an 801 ordinance has been created; authorizing a retail 802 facility to be established in the unincorporated areas 803 of a county only after such an ordinance has been 804 created; requiring retail facilities to have all 805 utilities and resources necessary to store and 806 dispense low-THC and low-THC cannabis products; 807 requiring retail facilities to be secured with 808 specified theft-prevention systems; requiring a 809 dispensing organization to provide the department with 810 specified updated information within a specified 811 period; authorizing a dispensing organization to 812 transport low-THC cannabis or low-THC cannabis 813 products in vehicles in certain circumstances; requiring such vehicles to be operated by specified 814 815 persons in certain circumstances; requiring a fee for 816 a vehicle permit; requiring the signature of the 817 designated driver with a vehicle permit application; 818 providing for expiration of the permit in certain 819 circumstances; requiring the department to cancel a 820 vehicle permit upon the request of specified persons; 821 providing that the licensee authorizes the inspection 822 and search of his or her vehicle without a search 823 warrant by specified persons; requiring all low-THC

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824 cannabis and low-THC cannabis products to be tested by 825 an independent testing laboratory before the 826 dispensing organization may dispense it; requiring the 827 independent testing laboratory to provide the lab results to the dispensing organization for a specified 828 829 determination; requiring all low-THC cannabis and low-830 THC cannabis products to be labeled with specified 831 information before dispensing; requiring the 8.32 University of Florida College of Pharmacy to establish 833 and maintain a specified safety and efficacy research 834 program; providing program requirements; requiring the 835 department to provide information from the 836 prescription drug monitoring program to the University 837 of Florida as needed; requiring the Agency for Health 838 Care Administration to provide access to specified 839 patient records under certain circumstances; 840 prohibiting persons who have direct or indirect 841 interest in a dispensing organization and the 842 dispensing organization's managers, employees, and 843 contractors who directly interact with low-THC 844 cannabis and low-THC cannabis products from making 845 recommendations, offering prescriptions, or providing 846 medical advice to qualified patients; providing that 847 the act does not provide an exception to the 848 prohibition against driving under the influence; 849 authorizing specified individuals to manufacture, 850 possess, sell, deliver, distribute, dispense, and 851 lawfully dispose of reasonable quantities of low-THC 852 cannabis according to their licensure; authorizing a

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853 licensed laboratory and its employees to receive and 854 possess low-THC cannabis in certain circumstances; 855 providing that specified rules adopted by the 856 department are exempt from the requirement to be 857 ratified by the Legislature; amending s. 381.987, 858 F.S.; requiring the department to allow specified 859 persons engaged in research to access the 860 compassionate use registry; amending s. 893.055, F.S.; 861 providing that persons engaged in research at the 862 University of Florida shall have access to specified 863 information; amending s. 893.0551, F.S.; providing a 864 specified public records exemption for persons engaged 865 in research at the University of Florida; providing a 866 directive to the Division of Law Revision and 867 Information; providing an effective date.