1 A bill to be entitled 2 An act relating to low-THC cannabis for medical use; 3 amending s. 381.986, F.S.; providing and revising 4 definitions; revising requirements for physicians 5 ordering low-THC cannabis; providing that a physician 6 who orders low-THC cannabis and receives related 7 compensation from a dispensing organization is subject 8 to disciplinary action; revising requirements relating 9 to physician education; requiring the Department of 10 Health to include caregiver information in the online compassionate use registry; revising requirements for 11 12 dispensing organizations; specifying duties and 13 responsibilities of the department; authorizing an approved laboratory and its employees to possess, 14 15 test, transport, and lawfully dispose of low-THC 16 cannabis or paraphernalia in certain circumstances; exempting an approved dispensing organization and 17 related persons from the Florida Drug and Cosmetic 18 19 Act; providing an effective date. 20 21 Be It Enacted by the Legislature of the State of Florida: 2.2 23 Section 381.986, Florida Statutes, is amended Section 1. 24 to read: 25 Compassionate use of low-THC cannabis.-381.986 26 DEFINITIONS.-As used in this section, the term: (1)

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27 <u>(a) "Caregiver" means an individual who is 21 years of age</u> 28 <u>or older, a permanent resident of the state, and registered with</u> 29 <u>the department to assist a patient with the medical use of low-</u> 30 THC cannabis.

31 <u>(b) (a)</u> "Dispensing organization" means an organization 32 approved by the department to cultivate, process, and dispense 33 low-THC cannabis pursuant to this section.

34 <u>(c) (b)</u> "Low-THC cannabis" means a plant of the genus 35 Cannabis, the dried flowers of which contain 0.8 percent or less 36 of tetrahydrocannabinol and more than 10 percent of cannabidiol 37 weight for weight; the seeds thereof; the resin extracted from 38 any part of such plant; or any compound, manufacture, salt, 39 derivative, mixture, or preparation of such plant or its seeds 40 or resin that is dispensed only from a dispensing organization.

(d) (c) "Medical use" means administration of the ordered 41 42 amount of low-THC cannabis. The term does not include the possession, use, or administration by smoking. The term also 43 44 does not include the transfer of low-THC cannabis to a person 45 other than the qualified patient for whom it was ordered, or the qualified patient's legal guardian if the guardian is a 46 47 registered caregiver, or other registered caregiver 48 representative on behalf of the qualified patient.

49 (e) "Paraphernalia" means objects used, intended for use, 50 or designed for use in preparing, storing, ingesting, inhaling, 51 or otherwise introducing low-THC cannabis into the human body. 52 (f) (d) "Qualified patient" means a permanent resident of

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53 this state who has been added to the compassionate use registry 54 by a physician licensed under chapter 458 or chapter 459 to 55 receive low-THC cannabis from a dispensing organization.

56 <u>(g) (e)</u> "Smoking" means burning or igniting a substance and 57 inhaling the smoke. Smoking does not include the use of a 58 vaporizer.

59 (2) PHYSICIAN ORDERING. -Effective January 1, 2015, A 60 physician is authorized to licensed under chapter 458 or chapter 61 459 who has examined and is treating a patient suffering from 62 cancer or a physical medical condition that chronically produces 63 symptoms of seizures or severe and persistent muscle spasms may 64 order for the patient's medical use low-THC cannabis to treat a patient suffering from cancer or a physical medical condition 65 that chronically produces symptoms of seizures or severe and 66 persistent muscle spasms; such disease, disorder, or condition 67 68 or to order low-THC cannabis to alleviate symptoms of such 69 disease, disorder, or condition, if no other satisfactory 70 alternative treatment options exist for the that patient; or 71 order paraphernalia for the medical use of low-THC cannabis, 72 only if the physician and all of the following conditions apply: (a) Holds an active, unrestricted license as a physician 73 74 under chapter 458 or an osteopathic physician under chapter 459; 75 Is board-certified as an oncologist, neurologist, or (b) 76 epileptologist or specializes in the treatment of cancer, 77 epilepsy, or physical medical conditions that chronically 78 produce symptoms of seizures or severe and persistent muscle

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79 spasms;

80 (c) Has treated the patient for cancer or a physical 81 medical condition that chronically produces symptoms of seizures 82 or severe and persistent muscle spasms for at least 3 months 83 immediately preceding the patient's registration in the 84 compassionate use registry;

85 (d) Has successfully completed the course and examination 86 required under paragraph (4)(a);

87 (e) (b) Has determined The physician determines that the 88 risks of treating the patient with ordering low-THC cannabis are 89 reasonable in light of the potential benefit to the for that 90 patient. If a patient is younger than 18 years of age, a second physician having a board certification or specialization 91 described in paragraph (b) must concur with this determination, 92 93 and such determination must be documented in the patient's 94 medical record; -

95 (f) (c) The physician Registers as the orderer of low-THC 96 cannabis for the named patient on the compassionate use registry 97 maintained by the department and updates the registry to reflect 98 the contents of the order, including the amount of low-THC 99 cannabis that will provide the patient with not more than a 30-100 day supply and any paraphernalia needed by the patient for the 101 medical use of low-THC cannabis. The physician must also update 102 the registry within 7 days after any change is made to the 103 original order to reflect the change. The physician shall 104 deactivate the patient's and caregiver's registration when

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105 treatment is discontinued; -

106 (g) (d) The physician Maintains a patient treatment plan 107 that includes the dose, route of administration, planned 108 duration, and monitoring of the patient's symptoms and other 109 indicators of tolerance or reaction to the low-THC cannabis;-

110 (h) (e) The physician Submits the patient treatment plan 111 quarterly to the University of Florida College of Pharmacy for 112 research on the safety and efficacy of low-THC cannabis on 113 patients;-

114 <u>(i)(f)</u> The physician Obtains the voluntary informed 115 consent of the patient or the patient's legal guardian to 116 treatment with low-THC cannabis after sufficiently explaining 117 the current state of knowledge in the medical community of the 118 effectiveness of treatment of the patient's condition with low-119 THC cannabis, the medically acceptable alternatives, and the 120 potential risks and side effects; and

121 (j) Is not a medical director employed by a dispensing 122 organization.

123

124

(a) The patient is a permanent resident of this state.(3) PENALTIES.-

(a) A physician commits a misdemeanor of the first degree,
punishable as provided in s. 775.082 or s. 775.083, if the
physician orders low-THC cannabis <u>or paraphernalia</u> for a patient
without a reasonable belief that the patient is suffering from:
1. Cancer or a physical medical condition that chronically
produces symptoms of seizures or severe and persistent muscle

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131 spasms that can be treated with low-THC cannabis; or

132 2. Symptoms of cancer or a physical medical condition that 133 chronically produces symptoms of seizures or severe and 134 persistent muscle spasms that can be alleviated with low-THC 135 cannabis.

(b) Any person who fraudulently represents that he or she
has 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 <u>or paraphernalia</u> by such physician commits a
misdemeanor of the first degree, punishable as provided in s.
775.082 or s. 775.083.

143 (c) A physician who orders low-THC cannabis or 144 paraphernalia and receives compensation from a dispensing 145 organization related to the ordering of low-THC cannabis is 146 subject to disciplinary action under the applicable practice act 147 and s. 456.072(1)(n).

148

(4) PHYSICIAN EDUCATION.-

149 Before ordering low-THC cannabis or paraphernalia for (a) 150 medical use by a patient in this state, the appropriate board 151 shall require the ordering physician <del>licensed under chapter 458</del> or chapter 459 to successfully complete an 8-hour course and 152 153 subsequent examination offered by the Florida Medical 154 Association or the Florida Osteopathic Medical Association that 155 encompasses the clinical indications for the appropriate use of 156 low-THC cannabis, the appropriate delivery mechanisms, the

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157 contraindications for such use, as well as the relevant state and federal laws governing the ordering, dispensing, and 158 159 possessing of this substance. The first course and examination 160 shall be presented by October 1, 2014, and shall be administered 161 at least annually thereafter. Successful completion of the 162 course may be used by a physician to satisfy 8 hours of the 163 continuing medical education requirements required by his or her 164 respective board for licensure renewal. This course may be 165 offered in a distance learning format.

166 The appropriate board shall require the medical (b) 167 director of each dispensing organization to hold an active, 168 unrestricted license as a physician under chapter 458 or an osteopathic physician under chapter 459 and be board-certified 169 as an oncologist, neurologist, or epileptologist or provide 170 171 proof that he or she specializes in the treatment of cancer, 172 epilepsy, or physical medical conditions that chronically 173 produce symptoms of seizures or severe and persistent muscle 174 spasms. Additionally, the medical director must approved under 175 subsection (5) to successfully complete a 2-hour course and 176 subsequent examination offered by the Florida Medical 177 Association or the Florida Osteopathic Medical Association that 178 encompasses appropriate safety procedures and knowledge of low-179 THC cannabis.

(c) Successful completion of the course and examination
 specified in paragraph (a) is required for every physician who
 orders low-THC cannabis <u>or paraphernalia</u> each time such

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183 physician renews his or her license. In addition, successful 184 completion of the course and examination specified in paragraph 185 (b) is required for the medical director of each dispensing 186 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 <u>or paraphernalia</u> may be subject
to disciplinary action under the applicable practice act and
under s. 456.072(1)(k).

191 (5) DUTIES OF THE DEPARTMENT.-By January 1, 2015, The 192 department shall:

193 Create and maintain a secure, electronic, and online (a) compassionate use registry for the registration of physicians, 194 195 and patients, and caregivers as provided under this section. The registry must be accessible to law enforcement agencies and to a 196 197 dispensing organization in order to verify patient and caregiver 198 authorization for low-THC cannabis and paraphernalia and record 199 the low-THC cannabis and paraphernalia dispensed. The registry 200 must prevent an active registration of a patient by multiple 201 physicians.

(b) Authorize the establishment of five dispensing organizations to ensure reasonable statewide accessibility and availability as necessary for patients registered in the compassionate use registry and who are ordered low-THC cannabis or paraphernalia under this section, one in each of the following regions: northwest Florida, northeast Florida, central Florida, southeast Florida, and southwest Florida. The

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209 department shall develop an application form and impose an 210 initial application and biennial renewal fee that is sufficient 211 to cover the costs of administering this section. An applicant 212 for approval as a dispensing organization must be able to 213 demonstrate:

214 The technical and technological ability to cultivate 1. 215 and produce low-THC cannabis. The applicant must possess a valid certificate of registration issued by the Department of 216 217 Agriculture and Consumer Services pursuant to s. 581.131 that is 218 issued for the cultivation of more than 400,000 plants, be 219 operated by a nurseryman as defined in s. 581.011, and have been 220 operated as a registered nursery in this state for at least 30 221 continuous years.

222 2. The ability to secure the premises, resources, and 223 personnel necessary to operate as a dispensing organization.

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

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

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

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235	6. That all owners and managers have been fingerprinted
236	and have successfully passed a level 2 background screening
237	pursuant to s. 435.04.
238	7. The employment of a medical director who meets the
239	qualifications of paragraph (4)(b) is a physician licensed under
240	<del>chapter 458 or chapter 459</del> to supervise the activities of the
241	dispensing organization.
242	(c) Monitor physician registration and ordering of low-THC
243	cannabis or paraphernalia for ordering practices that could
244	facilitate unlawful diversion or misuse of low-THC cannabis and
245	take disciplinary action as indicated.
246	(d) Adopt rules necessary to implement this section.
247	(6) DISPENSING ORGANIZATIONAn approved dispensing
248	organization, at all times, must shall maintain compliance with
249	the criteria demonstrated for selection and approval as a
250	dispensing organization under subsection (5) and the criteria
251	required in this subsection at all times.
252	(a) When growing low-THC cannabis, a dispensing
253	organization:
254	1. May use pesticides determined by the department, after
255	consultation with the Department of Agriculture and Consumer
256	Services, to be safely applied to plants intended for human
257	consumption, but may not use pesticides designated as
258	restricted-use pesticides pursuant to s. 487.042.
259	2. Must grow and process low-THC cannabis within an
260	enclosed structure and in a room separate from any other plant.

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261 3. Must inspect seeds and growing plants for plant pests 262 that endanger or threaten the horticultural and agricultural 263 interests of the state, notify the Department of Agriculture and 264 Consumer Services within 10 calendar days after a determination 265 that a plant is infested or infected by such plant pest, and 266 implement and maintain phytosanitary policies and procedures. 267 4. Must perform fumigation or treatment of plants, or the 268 removal and destruction of infested or infected plants, in 269 accordance with chapter 581 and any rules adopted thereunder. 270 When processing low-THC cannabis, a dispensing (b) 271 organization must: 272 1. Process the low-THC cannabis in an enclosure separate 273 from other plants or products. 274 2. Package the low-THC cannabis in compliance with the 275 United States Poison Prevention Packaging Act, 15 U.S.C. ss. 276 1471-1477. 277 3. Package the low-THC cannabis in a receptacle that has a 278 firmly affixed and legible label stating the following 279 information: 280 a. The name of the dispensing organization. 281 b. The quantity of low-THC cannabis contained in the 282 receptacle. с. 283 The cannabinoid profile of the low-THC cannabis, 284 including the THC level. 285 d. Any ingredient other than low-THC cannabis contained in 286 the receptacle.

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287	e. The date that the low-THC is dispensed.
288	f. The patient's name and registration identification
289	number.
290	g. A statement that the low-THC cannabis is for medical
291	use and not for resale or transfer to another person.
292	h. A unique serial number corresponding to the original
293	batch of low-THC cannabis from which the low-THC cannabis
294	contained in the receptacle was made, to facilitate necessary
295	warnings or recalls by the department.
296	i. A recommended "use by" date or expiration date.
297	4. Reserve two processed samples from each batch, retain
298	such samples for at least 1 year, and make such samples
299	available for testing.
300	(c) When dispensing low-THC cannabis or paraphernalia, a
301	dispensing organization:
302	1. May not dispense more than a 30-day supply of low-THC
303	cannabis to a patient or the patient's caregiver.
304	2. Must have the dispensing organization's employee who
305	dispenses the low-THC cannabis or paraphernalia enter into the
306	compassionate use registry his or her name or unique employee
307	identifier.
308	3. Must verify in the compassionate use registry that a
309	physician has ordered the low-THC cannabis or a specific type of
310	paraphernalia for the patient.
311	4. May not dispense or sell any other type of retail
312	product, other than physician-ordered paraphernalia, while
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313	dispensing low-THC cannabis.
314	5. Must Before dispensing low-THC cannabis to a qualified
315	patient, the dispensing organization shall verify that the
316	patient has an active registration in the compassionate use
317	registry, the patient or patient's caregiver holds a valid and
318	active registration card, the order presented matches the order
319	contents as recorded in the registry, and the order has not
320	already been filled.
321	<u>6. Must,</u> upon dispensing the low-THC cannabis, <del>the</del>
322	dispensing organization shall record in the registry the date,
323	time, quantity, and form of low-THC cannabis and any
324	paraphernalia dispensed.
325	(d) To ensure the safety and security of its premises and
326	any off-site storage facilities, and to maintain adequate
327	controls against the diversion, theft, and loss of low-THC
328	cannabis, a dispensing organization must:
329	1. Maintain a fully operational security alarm system that
330	secures all entry points and perimeter windows and is equipped
331	with motion detectors; pressure switches; and duress, panic, and
332	hold-up alarms.
333	2. Maintain a video surveillance system that records
334	continuously 24 hours each day and meets the following minimum
335	criteria:
336	a. Cameras are fixed in a place that allows for the clear
337	identification of persons and activities in controlled areas of
338	the premises. Controlled areas include grow rooms, processing

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339	rooms, storage rooms, disposal rooms or areas, and point-of-sale
340	rooms.
341	b. Cameras are fixed in entrances and exits to the
342	premises, which shall record from both indoor and outdoor, or
343	ingress and egress, vantage points.
344	c. Recorded images must clearly and accurately display the
345	time and date.
346	3. Retain video surveillance recordings for a minimum of
347	45 days or longer upon the request of a law enforcement agency.
348	4. Enclose the perimeter of any buildings used in
349	cultivating, processing, or dispensing low-THC cannabis with a
350	fence or wall at least 6 feet in height.
351	5. Ensure that the organization's outdoor premises have
352	sufficient lighting from dusk until dawn.
353	6. Establish and maintain a tracking system approved by
354	the department that traces the low-THC cannabis from seed to
355	sale. The tracking system shall include notification of key
356	events as determined by the department, including when low-THC
357	cannabis seeds are planted, low-THC cannabis plants are
358	harvested, low-THC cannabis plants are destroyed, low-THC
359	cannabis is transported, low-THC cannabis is sold, or a theft,
360	diversion, or loss of low-THC cannabis occurs.
361	7. Not dispense low-THC cannabis or paraphernalia between
362	the hours of 9 p.m. and 7 a.m., but may perform all other
363	operations 24 hours each day.
364	8. Store low-THC cannabis in a secured, locked room or a

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365 vault.

Require at least two of its employees, or two employees 366 9. 367 of a security agency with whom it contracts, to be on the 368 organization's premises at all times. 369 10. Require each employee to wear a photo identification 370 badge at all times while on the premises. 11. Require each visitor to wear a visitor's pass at all 371 372 times while on the premises. 373 12. Implement an alcohol and drug-free workplace policy. 374 13. Report to local law enforcement within 24 hours after 375 it is notified or becomes aware of the theft, diversion, or loss 376 of low-THC cannabis. 377 (e) To ensure the safe transport of low-THC cannabis to dispensing organization facilities, laboratories, or patients, 378 379 the dispensing organization must: 380 1. Maintain a transportation manifest, which must be 381 retained for at least 1 year. 382 2. Ensure only vehicles in good working order are used to 383 transport low-THC cannabis. 384 3. Lock low-THC cannabis in a separate compartment or 385 container within the vehicle. 386 4. Require at least two persons to be in a vehicle 387 transporting low-THC cannabis, and require at least one person 388 to remain in the vehicle while the low-THC cannabis is being 389 delivered. 390 5. Provide specific safety and security training to Page 15 of 20

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391	employees transporting or delivering low-THC cannabis.
392	(f) A dispensing organization may only use an insignia or
393	logo approved by the department to advertise its product.
394	(g) A dispensing organization must contract with a
395	laboratory approved by the department for purposes of testing
396	low-THC cannabis for compliance with this section and to detect
397	any mold, bacteria, or other contaminant in the product that may
398	result in adverse effects to human health or the environment.
399	The contract must require the laboratory to report to the
400	dispensing organization, within 48 hours after a test, the
401	cannabinoid composition of the product and whether the
402	laboratory has detected any mold, bacteria, or other contaminant
403	in the product that may result in adverse effects to human
404	health or the environment.
405	(7) DEPARTMENT AUTHORITY AND RESPONSIBILITIES
406	(a) The department:
407	1. May conduct announced or unannounced inspections of
408	dispensing organizations to determine compliance with this
409	section or rules adopted pursuant to this section.
410	2. Must inspect a dispensing organization upon complaint
411	or notice provided to the department that the dispensing
412	organization has dispensed low-THC cannabis containing any mold,
413	bacteria, or other contaminant that may cause or has caused an
414	adverse effect to human health or the environment.
415	3. Must conduct at least a biennial inspection of each
416	dispensing organization to evaluate the dispensing
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417	organization's records, personnel, equipment, processes,
418	security measures, sanitation practices, and quality assurance
419	practices.
420	(b) The department may inspect laboratories to ensure they
421	are using standardized procedures to test low-THC cannabis.
422	(c) The department may adopt standards for the approval of
423	laboratories contracting with dispensing organizations,
424	including standardized procedures, required equipment, and
425	conflict-of-interest provisions.
426	(d) The department may enter into interagency agreements
427	with the Department of Agriculture and Consumer Services, the
428	Department of Business and Professional Regulation, the
429	Department of Transportation, the Department of Highway Safety
430	and Motor Vehicles, and the Agency for Health Care
431	Administration, and such agencies are authorized to enter into
432	an interagency agreement with the department, to conduct
433	inspections or perform other responsibilities assigned to the
434	department under this section.
435	(e) The department must make a list of all approved
436	dispensing organizations and qualified ordering physicians and
437	medical directors publicly available on its website.
438	(f) The department may establish a system for issuing and
439	renewing patient and caregiver registration cards, establish the
440	circumstances under which the cards may be revoked by or must be
441	returned to the department, and establish fees to implement such
442	system. The department must require, at a minimum, the
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registration cards to:
1. Provide the name, address, and date of birth of the
patient or caregiver.
2. Have a full-face, passport-type, color photograph of
the patient or caregiver taken within the 90 days immediately
preceding registration.
3. Identify whether the cardholder is a patient or
caregiver.
4. List a unique numeric identifier for the patient or
caregiver that is matched to the identifier used for such pers
in the department's compassionate use registry.
5. Provide the expiration date, which shall be 1 year
after the date of the physician's initial order of low-THC
cannabis.
6. For the caregiver, provide the name and unique numeri
identifier of the patient that the caregiver is assisting.
7. Be resistant to counterfeiting or tampering.
(g) The department must create a schedule of violations
rule to impose reasonable fines not to exceed \$10,000 on a
dispensing organization. In determining the amount of the fine
to be levied for a violation, the department shall consider:
1. The severity of the violation.
2. Any actions taken by the dispensing organization to
correct the violation or to remedy the complaint.
3. Any previous violations.
(h) The department may suspend, revoke, or refuse to rer
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469	a dispensing organization's approval if the organization has had
470	a license or authority to practice any regulated profession or
471	the authority to conduct any business in any other state or
472	country revoked, suspended, or otherwise acted against,
473	including the denial of licensure by the licensing authority,
474	for a violation that would constitute a violation under Florida
475	law.
476	(i) The department may adopt rules necessary to implement
477	this section.
478	(8) (7) EXCEPTIONS TO OTHER LAWS
479	(a) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or
480	any other provision of law, but subject to the requirements of
481	this section, a qualified patient and the qualified patient's
482	caregiver legal representative may purchase and possess for the
483	patient's medical use up to the amount of low-THC cannabis
484	ordered for the patient, but not more than a 30-day supply of
485	low-THC cannabis.
486	(b) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or
487	any other provision of law, but subject to the requirements of
488	this section, an approved dispensing organization and its
489	owners, managers, and employees may manufacture, possess, sell,
490	deliver, distribute, dispense, and lawfully dispose of
491	reasonable quantities, as established by department rule, of
492	low-THC cannabis. For purposes of this subsection, the terms
493	"manufacture," "possession," "deliver," "distribute," and
494	"dispense" have the same meanings as provided in s. 893.02.
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495 Notwithstanding s. 893.13, s. 893.135, s. 893.147, or (C) 496 any other provision of law, but subject to the requirements of 497 this section, an approved laboratory and its employees may 498 possess, test, transport, and lawfully dispose of low-THC 499 cannabis or paraphernalia as provided by department rule. 500 An approved dispensing organization and its owners, (d) 501 managers, and employees are not subject to licensure or 502 regulation under chapter 465 or chapter 499 for manufacturing, 503 possessing, selling, delivering, distributing, dispensing, or 504 lawfully disposing of reasonable quantities, as established by 505 department rule, of low-THC cannabis.

506

Section 2. This act shall take effect July 1, 2016.

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