

LEGISLATIVE ACTION

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Senate

House

Senator Bradley moved the following:
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) DEFINITIONSAs used in this section, the term:
(a) "Applicant" means an organization 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
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 organization
17	licensed approved by the department to cultivate, process, and
18	dispense low-THC cannabis pursuant to this section.
19	(d) "Harvest" means a specifically identified and numbered
20	quantity of low-THC cannabis cultivated using the same
21	herbicides, pesticides, and fungicides and harvested at the same
22	time from a single facility.
23	(e) "Independent testing laboratory" means a laboratory,
24	and the managers, employees, or contractors of the laboratory
25	which have no direct or indirect interest in a dispensing
26	organization.
27	<u>(f)</u> "Low-THC cannabis" means a plant of the genus
28	Cannabis, the dried flowers of which contain 15 0.8 percent or
29	less of tetrahydrocannabinol and more than 10 percent of
30	cannabidiol weight for weight; the seeds thereof; the resin
31	extracted from any part of such plant; or any compound,
32	manufacture, salt, derivative, mixture, or preparation of such
33	plant or its seeds or resin that is dispensed only from a
34	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. All low-
42	THC cannabis products must maintain concentrations, weight for
43	weight, of 15 percent or less of tetrahydrocannabinol and 10
44	percent cannabidiol.
45	(h) (c) "Medical use" means administration of the
46	recommended ordered amount of low-THC cannabis. The term does
47	not include <u>:</u>
48	<u>1.</u> The possession, use, or administration by smoking.
49	2. The term also does not include The transfer of low-THC
50	cannabis to a person other than the qualified patient for whom
51	it was <u>recommended</u> ordered or the qualified patient's legal
52	representative who is registered in the compassionate use
53	registry on behalf of the qualified patient.
54	3. The use or administration of low-THC cannabis or low-THC
55	cannabis products:
56	a. On any form of public transportation.
57	b. In any public place.
58	c. In a registered qualified patient's place of work, if
59	restricted by his or her employer.
60	d. In a correctional facility.
61	e. On the grounds of any preschool, primary school, or
62	secondary school.
63	<u>f. On a school bus.</u>
64	<u>(i)</u> "Qualified patient" means a resident of this state
65	who has been added to the compassionate use registry by a
66	physician licensed under chapter 458 or chapter 459 to receive
67	low-THC cannabis from a dispensing organization.
68	<u>(j)</u> "Smoking" means burning or igniting a substance and
69	inhaling the smoke. Smoking does not include the use of a

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(2) PHYSICIAN RECOMMENDING ORDERING.-

72 (a) Effective January 1, 2015, A physician licensed under 73 chapter 458 or chapter 459 who has examined and is treating a patient suffering from cancer, human immunodeficiency virus, 74 75 acquired immune deficiency syndrome, epilepsy, amyotrophic 76 lateral sclerosis, autism, multiple sclerosis, Crohn's disease, 77 Parkinson's disease, paraplegia, quadriplegia, or terminal illness a physical medical condition that chronically produces 78 79 symptoms of seizures or severe and persistent muscle spasms may 80 recommend order for the patient's medical use low-THC cannabis 81 to treat such disease, disorder, or condition; or to alleviate 82 symptoms of such disease, disorder, or condition; or to 83 alleviate symptoms caused by a treatment for such disease, 84 disorder, or condition, if no other satisfactory alternative 85 treatment options exist for that patient and all of the 86 following conditions apply:

<u>1.(a)</u> The patient is a permanent resident of this state.
<u>2.(b)</u> The physician determines that the risks of
<u>recommending</u> 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.

<u>3.(c)</u> The physician registers the patient, the patient's legal representative if requested by the patient, and himself or <u>herself</u> as the <u>recommender</u> orderer of low-THC cannabis for the named patient on the compassionate use registry maintained by the department and updates the registry to reflect the contents

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of the recommendation order. If the patient is a minor, the 100 physician must register a legal representative on the 101 compassionate use registry. The physician shall deactivate the 102 patient's registration when treatment is discontinued.

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

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

6.(f) 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 conditions or symptoms condition with low-THC cannabis, the medically acceptable alternatives, and the potential risks and side effects.

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

(3) PENALTIES.-

123 (a) A physician commits a misdemeanor of the first degree, 124 punishable as provided in s. 775.082 or s. 775.083, if the 125 physician recommends orders low-THC cannabis for a patient 126 without a reasonable belief that the patient is suffering from 127 at least one of the conditions listed in subsection (2).+

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128 1. Cancer or a physical medical condition that chronically 129 produces symptoms of seizures or severe and persistent muscle 130 spasms that can be treated with low-THC cannabis; or

2. Symptoms of cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms that can be alleviated with low-THC 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 <u>recommended</u> 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.

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(4) PHYSICIAN EDUCATION.-

143 (a) Before recommending ordering low-THC cannabis for use 144 by a patient in this state, the appropriate board shall require 145 the recommending ordering physician licensed under chapter 458 or chapter 459 to successfully complete an 8-hour course and 146 147 subsequent examination offered by the Florida Medical 148 Association or the Florida Osteopathic Medical Association that 149 encompasses the clinical indications for the appropriate use of 150 low-THC cannabis, the appropriate delivery mechanisms, the 151 contraindications for such use, as well as the relevant state 152 and federal laws governing the recommending ordering, 153 dispensing, and possessing of this substance. The first course 154 and examination shall be presented by October 1, 2014, and shall 155 be administered at least four times annually thereafter. 156 Successful completion of the course may be used by a physician

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157 to satisfy 8 hours of the continuing medical education 158 requirements required by his or her respective board for 159 licensure renewal. This course may be offered in a distance 160 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 low-THC cannabis.

(c) Successful completion of the course and examination specified in paragraph (a) is required for every physician who <u>recommends</u> 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 <u>recommends</u> orders low-THC cannabis may be subject to disciplinary action under the applicable practice act and under s. 456.072(1)(k).

179 (5) DUTIES <u>AND POWERS</u> OF THE DEPARTMENT. By January 1, 180 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
registry must be accessible to law enforcement agencies and to a
dispensing organization in order to verify patient authorization

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186 for low-THC cannabis and record the low-THC cannabis dispensed. 187 The registry must prevent an active registration of a patient by 188 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. 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 45th day after the effective date of this act, and all applications must be complete no later than 5 p.m. on the 75th day after the effective date of this act.

3. The applications shall be reviewed and scored by a selection committee composed of:

a. The Director of the Office of Compassionate Use within the department.

b. A member of the Florida Medical Association appointed by the president of the association.

<u>c. A member of the Drug Policy Institute at the University</u> of Florida appointed by the president of the University of <u>Florida.</u>

4. Before the 90th day after the effective date of this
act, the department shall select, based on the scoring of meritbased applications, the two highest-scoring applicants in each

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215	of the state's five water management districts which meet the
216	criteria for licensure specified in subsection (6).
217	a. The scorecards of the selection committee members shall
218	be combined to generate an aggregate score for each application.
219	If a tie aggregate score occurs, the winner shall be the
220	applicant that has the highest number of points on the
221	aggregated scorecard attributable to the operating nurseryman's
222	cultivation experience. If a tie remains after consideration of
223	such points, the winner shall be the applicant that has the
224	highest number of points on the aggregated scorecard
225	attributable to the applicant's experience in processing
226	cannabis.
227	b. Each qualified nursery may submit one application in the
228	region listed as its primary location on its certificate of
229	registration with the Department of Agriculture and Consumer
230	Services as of the date this act takes effect.
231	5. After the department has selected 10 dispensing
232	organizations pursuant to subparagraph 4., the department shall
233	select, based on the scoring of the merit-based applications,
234	the next 5 highest-scoring applicants statewide which meet the
235	criteria for licensure specified in subsection (6). A tie shall
236	be resolved as specified in sub-subparagraph 4.a. An applicant
237	selected under this subparagraph after being licensed by the
238	department may operate as a dispensing organization in any
239	region of the state, but may not have cultivation or processing
240	facilities outside the region in which it is licensed.
241	6. The department shall license an applicant selected
242	pursuant to subparagraph 4. or subparagraph 5. unless the
243	applicant fails to pay the licensure fee within 20 days of

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244	selection.
245	7.a. An unsuccessful applicant may contest the final
246	selection of applicants by filing a written petition with the
247	State Surgeon General within 5 days after the final selection
248	occurs. Within 10 days after receipt of the petition, the State
249	Surgeon General shall review and issue a final determination
50	regarding the contested selection.
51	b. An unsuccessful applicant may appeal the State Surgeon
52	General's final determination to the circuit court within 10
53	days after issuance of the final determination by filing a
54	complaint, together with the fees prescribed in chapter 28, with
55	the clerk of the circuit court. The complaint must set forth the
56	grounds on which the petitioner requests that the final
57	selection of applicants be set aside.
58	c. Grounds for contesting the selection process are:
59	(I) Misconduct, fraud, or corruption by any member of the
60	selection committee.
61	(II) The ineligibility of a successful applicant.
62	(III) Proof that a member of the selection committee
63	accepted or intended to accept a bribe or reward in money,
64	property, or any other thing of value for the purpose of
65	influencing the selection of applicants.
66	d. A petitioner under sub-subparagraph b. is entitled to an
67	immediate hearing. However, the court in its discretion may
68	limit the time for taking testimony.
69	e. The issuance of a license may not be stayed by the
270	department or the Division of Administrative Hearings during the
271	pendency of any judicial review proceedings under this
272	subparagraph.

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273 f. A court may grant a stay or an injunction in an action 274 relating to the denial of a license only if a bond is posted by 275 the petitioner seeking a stay or injunction and the court finds 276 that: 277 (I) The petitioner has a substantial likelihood of success 278 on the merits; 279 (II) The threatened harm or injury to the petitioner 280 clearly outweighs any possible injury to a qualified patient 281 occasioned by granting the stay or injunction; and 282 (III) It is in the public interest to grant the stay or 283 injunction. 284 g. A proceeding pursuant to this subparagraph is the 285 exclusive means to contest or appeal the final selection of 286 applicants. Chapter 120 does not apply to this subparagraph 287 Authorize the establishment of five dispensing organizations to 288 ensure reasonable statewide accessibility and availability as 289 necessary for patients registered in the compassionate use 290 registry and who are ordered low-THC cannabis under this 291 section, one in each of the following regions: northwest 292 Florida, northeast Florida, central Florida, southeast Florida, 293 and southwest Florida. 294 8. The timeframes specified in s. 120.60(1) does not apply 295 to this paragraph. 296 (c) The department shall use develop an application form that requires the applicant to state: 297 298 1. Whether the application is for initial licensure or 299 renewal licensure; 300 2. The name, the physical address, the mailing address, the 301 address listed on the Department of Agriculture and Consumer

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302	Services certificate required in paragraph (6)(b), and the
303	contact information for the applicant and for the nursery that
304	holds the Department of Agriculture and Consumer Services
305	certificate, if different from the applicant;
306	3. The name, address, and contact information for the
307	operating nurseryman of the organization that holds the
308	Department of Agriculture and Consumer Services certificate;
309	4. The name, address, license number, and contact
310	information for the applicant's medical director; and
311	5. All information required to be included by subsection
312	(6).
313	(d) The department shall and impose an initial application
314	fee of \$50,000, an initial licensure fee of \$125,000, and <u>a</u>
315	biennial renewal fee of \$125,000 that is sufficient to cover the
316	costs of administering this section. An applicant for approval
317	as a dispensing organization must be able to demonstrate:
318	1. The technical and technological ability to cultivate and
319	produce low-THC cannabis. The applicant must possess a valid
320	certificate of registration issued by the Department of
321	Agriculture and Consumer Services pursuant to s. 581.131 that is
322	issued for the cultivation of more than 400,000 plants, be
323	operated by a nurseryman as defined in s. 581.011, and have been
324	operated as a registered nursery in this state for at least 30
325	continuous years.
326	2. The ability to secure the premises, resources, and
327	personnel necessary to operate as a dispensing organization.
328	3. The ability to maintain accountability of all raw
329	materials, finished products, and any byproducts to prevent
330	diversion or unlawful access to or possession of these

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331	substances.
332	4. An infrastructure reasonably located to dispense low-THC
333	cannabis to registered patients statewide or regionally as
334	determined by the department.
335	5. The financial ability to maintain operations for the
336	duration of the 2-year approval cycle, including the provision
337	of certified financials to the department. Upon approval, the
338	applicant must post a \$5 million performance bond.
339	6. That all owners and managers have been fingerprinted and
340	have successfully passed a level 2 background screening pursuant
341	to s. 435.04.
342	7. The employment of a medical director who is a physician
343	licensed under chapter 458 or chapter 459 to supervise the
344	activities of the dispensing organization.
345	(e) The department may inspect each dispensing
346	organization's properties, cultivation facilities, processing
347	facilities, and retail facilities before and after the
348	organization begins operations. The department may conduct
349	announced or unannounced inspections, including followup
350	inspections, at reasonable hours in order to ensure that such
351	property and facilities maintain compliance with all applicable
352	requirements in subsections (6) and (7) and to ensure that the
353	dispensing organization has not committed any other act that
354	would endanger the health, safety, or security of a qualified
355	patient, dispensing organization staff, or the community in
356	which the dispensing organization is located. Licensure under
357	this section constitutes permission for the department to enter
358	and inspect the premises and facilities of any dispensing
359	organization. The department may inspect any licensed dispensing

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360	organization, and a dispensing organization must make all
361	facility premises, equipment, documents, low-THC cannabis, and
362	low-THC cannabis products available to the department upon
363	inspection. The department may test any low-THC cannabis or low-
364	THC cannabis product in order to ensure that it is safe for
365	human consumption and that it meets the requirements in this
366	section.
367	(f)1. Subject to subparagraph 2., the department may impose
368	an administrative penalty not to exceed \$10,000 for each of the
369	following violations:
370	a. Violating this section or department rule.
371	b. Failing to maintain qualifications for licensure.
372	c. Endangering the health, safety, or security of a
373	qualified patient.
374	d. Improperly disclosing personal and confidential
375	information of the qualified patient.
376	e. Attempting to procure a license by bribery or fraudulent
377	misrepresentation.
378	f. Being convicted or found guilty of, or entering a plea
379	of nolo contendere to, regardless of adjudication, a crime in
380	any jurisdiction which directly relates to the business of a
381	dispensing organization.
382	g. Making or filing a report or record that the licensee
383	knows to be false.
384	h. Willfully failing to maintain a record required by this
385	section or rule of the department.
386	i. Willfully impeding or obstructing an employee or agent
387	of the department in the furtherance of his or her official
388	duties.

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389	j. Engaging in fraud or deceit, negligence, incompetence,
390	or misconduct in the business practices of a dispensing
391	organization.
392	k. Making misleading, deceptive, or fraudulent
393	representations in or related to the business practices of a
394	dispensing organization.
395	1. Having a license or the authority to engage in any
396	regulated profession, occupation, or business that is related to
397	the business practices of a dispensing organization revoked,
398	suspended, or otherwise acted against, including the denial of
399	licensure, by the licensing authority of any jurisdiction,
400	including its agencies or subdivisions, for a violation that
401	would constitute a violation under state law. A licensing
402	authority's acceptance of a relinquishment of licensure or a
403	stipulation, consent order, or other settlement, offered in
404	response to or in anticipation of the filing of charges against
405	the license, shall be construed as an action against the
406	license.
407	m. Violating a lawful order of the department or an agency
408	of the state, or failing to comply with a lawfully issued
409	subpoena of the department or an agency of the state.
410	2. Prior to imposing an administrative penalty under this
411	paragraph, the department shall provide to the dispensing
412	organization notice of the alleged violation and allow 20
413	business days for the dispensing organization to take corrective
414	action to cure the alleged violation and, if applicable, to
415	implement corrective action to prevent a future violation. If
416	the dispensing organization takes appropriate corrective action
417	to cure the alleged violation and, if applicable, takes

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418	appropriate corrective action to prevent a future violation, the
419	violation shall be deemed cured and an administrative penalty
420	may not be imposed. If the violation is not cured, the
421	department may impose an administrative penalty on the
422	dispensing organization and may suspend, revoke, deny, or refuse
423	to renew the license of the dispensing organization.
424	(g) The department shall create a permitting process for
425	all dispensing organization vehicles used for the transportation
426	of low-THC cannabis or low-THC cannabis products.
427	(h) (c) The department shall monitor physician registration
428	and <u>recommendation</u> ordering of low-THC cannabis for
429	recommendation ordering practices that could facilitate unlawful
430	diversion or misuse of low-THC cannabis and take disciplinary
431	action as indicated.
432	(i) (d) The department shall adopt rules as necessary to
433	implement this section; however, the application process
434	specified under paragraph (b) to award licenses shall not be
435	contingent upon rules being first adopted.
436	(6) DISPENSING ORGANIZATION
437	(a) An applicant seeking licensure as a dispensing
438	organization, or the renewal of its license, must submit an
439	application to the department. The department must review all
440	applications for completeness, including any department-
441	requested inspection of the applicant's property and facilities
442	to verify the authenticity of the information provided in, or in
443	connection with, the application. An applicant authorizes the
444	department to inspect its property and facilities for licensure
445	by applying under this subsection.
446	(b) In order to receive or maintain licensure as a

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447	dispensing organization, an applicant must provide proof that
448	the applicant, or a separate entity that is owned solely by the
449	same persons or entities in the same ratio as the applicant:
450	1. Possesses a valid certificate of registration issued by
451	the Department of Agriculture and Consumer Services pursuant to
452	s. 581.131 for the cultivation of more than 400,000 plants, is
453	operated by a nurseryman as defined in s. 581.011, and has
454	operated as a registered nursery in this state as the same
455	corporate entity, or the legal successor of such entity by
456	merger or acquisition, for at least 30 continuous years as
457	verified by registrations from both the Division of Corporations
458	of the Department of State and the Department of Agriculture and
459	Consumer Services; or
460	2. Is a recognized class member of Pigford v. Glickman, 182
461	F.R.D. 82 (D.D.C. 1999) or In re Black Farmers Litig., 856 F.
462	Supp. 2d 1 (D.D.C. 2011), possesses a valid certificate of
463	registration issued by the Department of Agriculture and
464	Consumer Services pursuant to s. 581.131 for the cultivation of
465	more than 100,000 plants, and has operated as a registered
466	nursery in this state as the same corporate entity, or the legal
467	successor of such entity by merger or acquisition, for at least
468	10 continuous years as verified by registrations from both the
469	Division of Corporations of the Department of State and the
470	Department of Agriculture and Consumer Services.
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472	An applicant or a separate entity under this paragraph must be
473	capable of obtaining a zoning permit that authorizes the
474	cultivation of low-THC cannabis in the municipality or county
475	listed on the applicant's or entity's certificate of
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476	registration with the Department of Agriculture and Consumer
477	Services where the cultivation activities are proposed to occur.
478	(c) Each applicant for a license must provide proof that:
479	1. The applicant's nurseryman as defined in s. 581.011 has
480	experience cultivating and propagating multiple varieties of
481	mature, finished, nonnative plants in this state and mature,
482	finished, potted herbs as evidenced by crop insurance reports or
483	invoices or bills of sale.
484	2. The applicant's personnel on staff or under contract
485	include at least one person who:
486	a. Has experience with laboratory procedures which includes
487	analytical laboratory quality control measures, chain of custody
488	procedures, and analytical laboratory methods;
489	b. Has experience with cannabis cultivation and processing,
490	in a state or nationally regulated market, including cannabis
491	extraction techniques and producing cannabis products;
492	c. Has experience and qualifications in chain of custody or
493	other tracking mechanisms; and
494	d. Works solely for security purposes.
495	3. Each owner who has a 10 percent or greater interest in
496	the dispensing organization and the applicant's managers,
497	employees, and contractors who directly interact with low-THC
498	cannabis or low-THC cannabis products have been fingerprinted
499	and have successfully passed a level 2 background screening
500	pursuant to s. 435.04.
501	4. The applicant owns, has at least a 2-year lease of, or
502	has an option to lease or own, all proposed properties,
503	facilities, and equipment necessary for the cultivation and
504	processing of low-THC cannabis. The applicant must provide a

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505	detailed description of each proposed facility and its
506	equipment, a cultivation and processing plan, and a detailed
507	floor plan. The description must include proof that each
508	facility is secured and has theft-prevention systems including
509	an alarm system, cameras, and security personnel.
510	5. The applicant has diversion and tracking prevention
511	procedures, including:
512	a. A system for tracking low-THC material through
513	cultivation, processing, and dispensing, including the use of
514	batch and harvest numbers;
515	b. An inventory control system for low-THC cannabis and
516	low-THC cannabis products;
517	c. A vehicle tracking and security system; and
518	d. A cannabis waste-disposal plan.
519	6. The applicant has recordkeeping policies and procedures
520	in place.
521	7. The applicant has a facility emergency management plan.
522	8. The applicant has the financial ability to operate as
523	demonstrated by \$4 million in escrowed funds or the equivalent
524	of \$4 million in pledged assets, securities, or irrevocable
525	letters of credit.
526	9. The applicant has a \$1 million performance and
527	compliance bond, or other equivalent means of security, such as
528	an irrevocable letter of credit, pledged securities, or a
529	deposit in a trust account or financial institution, payable to
530	the department, which must be posted once the applicant is
531	approved as a dispensing organization. The purpose of the bond
532	is to secure payment of any administrative penalties imposed by
533	the department. The department may make a claim against such

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534	bond or security until 1 year after the dispensing
535	organization's license ceases to be valid or until 60 days after
536	any administrative or legal proceeding authorized in this
537	section involving the dispensing organization concludes,
538	including any appeal, whichever occurs later.
539	10. The applicant employs or contracts a medical director
540	who is a Florida resident and a physician licensed under chapter
541	458 or chapter 459 to supervise the activities of the dispensing
542	organization.
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544	Each applicant that submits a complete application shall be
545	reviewed and scored by the reviewers under paragraph (5)(b)
546	based on the degree to which the applicant meets and exceeds the
547	criteria specified in this paragraph.
548	(d) The license of a dispensing organization shall be
549	renewed by the department biennially if the dispensing
550	organization meets the requirements of paragraphs (b) and (c),
551	pays the biennial renewal fee, and, if applicable, has cured
552	each violation alleged under paragraph (5)(f).
553	(e) An approved dispensing organization shall maintain
554	compliance with the criteria in paragraphs (b), (c), and (f) and
555	subsection (7) demonstrated for selection and approval as a
556	dispensing organization under subsection (5) at all times.
557	Before dispensing low-THC cannabis or low-THC cannabis products
558	to a qualified patient or to the qualified patient's legal
559	representative, the dispensing organization shall verify the
560	identity of the qualified patient or the qualified patient's
561	legal representative by requiring the qualified patient or the
562	qualified patient's legal representative to produce a

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563	government-issued identification card and shall verify that the
564	qualified patient and the qualified patient's legal
565	representative have has an active registration in the
566	compassionate use registry, that the recommendation order
567	presented matches the <u>recommended</u> order contents as recorded in
568	the registry, and <u>that</u> the <u>recommendation</u> order has not already
569	been filled. Upon dispensing the low-THC cannabis, the
570	dispensing organization shall record in the registry the date,
571	time, quantity, and form of low-THC cannabis dispensed.
572	(f) A dispensing organization may have cultivation
573	facilities, processing facilities, and retail facilities.
574	1. The cultivation facilities and processing facilities
575	must be closed to the public.
576	2. A municipality may determine by ordinance the criteria
577	for the number and location of, and other permitting
578	requirements for, all cultivation, processing, and retail
579	facilities located within its municipal boundaries. A county may
580	determine by ordinance the criteria for the number, location,
581	and other permitting requirements for all cultivation,
582	processing, and retail facilities located within the
583	unincorporated areas of that county. Retail facilities must have
584	all utilities and resources necessary to store and dispense low-
585	THC cannabis and low-THC cannabis products. Retail facilities
586	must be secured and have theft-prevention systems, including an
587	alarm system, cameras, and 24-hour security personnel. Before a
588	retail facility may dispense low-THC cannabis or a low-THC
589	cannabis product, the dispensing organization must have a
590	computer network compliant with the federal Health Insurance
591	Portability and Accountability Act of 1996 which is able to
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592	access and upload data to the compassionate use registry and
593	which shall be used by all retail facilities.
594	(g) Within 15 days after such information becoming
595	available, a dispensing organization must provide the department
596	with updated information, as applicable, including:
597	1. The location and a detailed description of any new or
598	proposed facilities.
599	2. The updated contact information, including electronic
600	and voice communication, for all dispensing organization
601	facilities.
602	3. The registration information for any vehicles used for
603	the transportation of low-THC cannabis and low-THC cannabis
604	products, including confirmation that all such vehicles have
605	tracking and security systems.
606	4. A plan for the recall of any or all low-THC cannabis or
607	low-THC cannabis products.
608	(h)1. A dispensing organization or a contractor of the
609	organization may transport low-THC cannabis or low-THC cannabis
610	products in vehicles departing from their places of business
611	only in vehicles that are owned or leased by the licensee or by
612	a person or contractor designated by the dispensing
613	organization, and for which a valid vehicle permit has been
614	issued for such vehicle by the department.
615	2. A vehicle owned or leased by the dispensing organization
616	or a person or contractor designated by the dispensing
617	organization and approved by the department must be operated by
618	such person when transporting low-THC cannabis or low-THC
619	products from the licensee's place of business.
620	3. A vehicle permit may be obtained by a dispensing

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621 organization upon application and payment of a fee of \$5 per 622 vehicle to the department. The signature of the person 623 designated by the dispensing organization to drive the vehicle 624 must be included on the vehicle permit application. Such permit 625 remains valid and does not expire unless the licensee or any 626 person designated by the dispensing organization disposes of his 627 or her vehicle, or the licensee's license is transferred, 628 canceled, not renewed, or is revoked by the department, 629 whichever occurs first. The department shall cancel a vehicle 630 permit upon request of the licensee or owner of the vehicle. 631 4. By acceptance of a license issued under this section, 632 the licensee agrees that the licensed vehicle is, at all times 633 it is being used to transport low-THC cannabis or low-THC 634 cannabis products, subject to inspection and search without a 635 search warrant by authorized employees of the department, sheriffs, deputy sheriffs, police officers, or other law 636 637 enforcement officers to determine that the licensee is 638 transporting such products in compliance with this section. 639 (i) A dispensing organization may wholesale low-THC 640 cannabis or a low-THC cannabis product to another licensed 641 dispensing organization. 642 (7) TESTING AND LABELING OF LOW-THC CANNABIS.-643 (a) All low-THC cannabis and low-THC cannabis products must 644 be tested by an independent testing laboratory before the 645 dispensing organization may dispense them. The independent 646 testing laboratory shall provide the dispensing organization 647 with lab results. Before dispensing, the dispensing organization 648 must determine that the lab results indicate that the low-THC 649 cannabis or low-THC cannabis product meets the definition of

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650	low-THC cannabis or low-THC cannabis product, is safe for human
651	consumption, and is free from contaminants that are unsafe for
652	human consumption.
653	(b) All low-THC cannabis and low-THC cannabis products must
654	be labeled before dispensing. The label must include, at a
655	minimum:
656	1. A statement that the low-THC cannabis or low-THC
657	cannabis product meets the requirements in paragraph (a);
658	2. The name of the independent testing laboratory that
659	tested the low-THC cannabis or low-THC cannabis product;
660	3. The name of the cultivation and processing facility
661	where the low-THC cannabis or low-THC cannabis product
662	originates; and
663	4. The batch number and harvest number from which the low-
664	THC cannabis or low-THC cannabis product originates.
665	(8) SAFETY AND EFFICACY RESEARCH FOR LOW-THC CANNABISThe
666	University of Florida College of Pharmacy shall establish and
667	maintain a safety and efficacy research program for the use of
668	low-THC cannabis or low-THC cannabis products to treat
669	qualifying conditions and symptoms. The program must include a
670	fully integrated electronic information system for the broad
671	monitoring of health outcomes and safety signal detection. The
672	electronic information system must include information from the
673	compassionate use registry; provider reports, including
674	treatment plans, adverse event reports, and treatment
675	discontinuation reports; patient reports of adverse impacts;
676	event-triggered interviews and medical chart reviews performed
677	by University of Florida clinical research staff; information
678	from external databases, including Medicaid billing reports and

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679 information in the prescription drug monitoring database for 680 registered patients; and all other medical reports required by 681 the University of Florida to conduct the research required by 682 this subsection. The department must provide access to 683 information from the compassionate use registry and the 684 prescription drug monitoring database, established in s. 685 893.055, as needed by the University of Florida to conduct 686 research under this subsection. The Agency for Health Care 687 Administration must provide access to registered patient 688 Medicaid records, to the extent allowed under federal law, as 689 needed by the University of Florida to conduct research under 690 this subsection. 691 (9) The persons who have direct or indirect interest in the 692 dispensing organization and the dispensing organization's 693 managers, employees, and contractors who directly interact with low-THC cannabis or low-THC cannabis products are prohibited 694 695

from making recommendations, offering prescriptions, or providing medical advice to qualified patients.

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

698 (a) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or 699 any other provision of law, but subject to the requirements of 700 this section, a qualified patient and the qualified patient's 701 legal representative who is registered with the department on 702 the compassionate use registry may purchase and possess for the patient's medical use up to the amount of low-THC cannabis 703 704 recommended ordered for the patient. The patient or patient's 705 representative may purchase, consume, or possess only low-THC 706 cannabis that has been produced by a dispensing organization 707 licensed under this section. Nothing in this section exempts any

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708 person from the prohibition against driving under the influence 709 provided in s. 316.193.

(b) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or any other provision of law, but subject to the requirements of this section, an approved dispensing organization and its owners, managers, and employees and the owners, managers, and employees of contractors who have direct contact with low-THC cannabis or low-THC cannabis product may manufacture, possess, sell, deliver, distribute, dispense, and lawfully dispose of reasonable quantities, as established by department rule, of low-THC cannabis. For purposes of this subsection, the terms "manufacture," "possession," "deliver," "distribute," and "dispense" have the same meanings as provided in s. 893.02.

(c) An approved dispensing organization and its owners, managers, and employees, and contractors 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, an independent testing 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.

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

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

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

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737 including access to confidential and exempt information, to: 738 (g) Persons engaged in research at the University of Florida pursuant to s. 381.986(8). 739 740 Section 3. Paragraph (b) of subsection (7) of section 741 893.055, Florida Statutes, is amended to read: 742 893.055 Prescription drug monitoring program.-743 (7)744 (b) A pharmacy, prescriber, or dispenser shall have access 745 to information in the prescription drug monitoring program's 746 database which relates to a patient of that pharmacy, 747 prescriber, or dispenser in a manner established by the department as needed for the purpose of reviewing the patient's 748 749 controlled substance prescription history. Persons engaged in 750 research at the University of Florida pursuant to s. 381.986(8) 751 shall have access to information in the prescription drug 752 monitoring program's database which relates to qualified 753 patients as defined in s. 381.986(1) for the purpose of 754 conducting such research. Other access to the program's database 755 shall be limited to the program's manager and to the designated 756 program and support staff, who may act only at the direction of 757 the program manager or, in the absence of the program manager, 758 as authorized. Access by the program manager or such designated 759 staff is for prescription drug program management only or for 760 management of the program's database and its system in support 761 of the requirements of this section and in furtherance of the 762 prescription drug monitoring program. Confidential and exempt 763 information in the database shall be released only as provided 764 in paragraph (c) and s. 893.0551. The program manager, 765 designated program and support staff who act at the direction of

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766 or in the absence of the program manager, and any individual who 767 has similar access regarding the management of the database from 768 the prescription drug monitoring program shall submit 769 fingerprints to the department for background screening. The 770 department shall follow the procedure established by the 771 Department of Law Enforcement to request a statewide criminal 772 history record check and to request that the Department of Law 773 Enforcement forward the fingerprints to the Federal Bureau of 774 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. If an application for licensure as a dispensing organization was submitted to the Department of Health before the effective date of this act, the department shall within 7 days after the effective date of this act examine the application and notify the applicant if the application does not comply with s. 381.986, Florida Statutes. The department shall allow an applicant to correct and refile its application in compliance with the deadlines specified in s. 381.986(5), Florida Statutes.

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

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796	=========== T I T L E A M E N D M E N T =================================
797	And the title is amended as follows:
798	Delete everything before the enacting clause
799	and insert:
800	A bill to be entitled
801	An act relating to low-THC cannabis; amending s.
802	381.986, F.S.; defining and redefining terms; revising
803	the illnesses and symptoms for which a physician may
804	recommend for the patient's medical use low-THC
805	cannabis; revising requirements applicable to such
806	recommendations; providing that a physician who
807	improperly recommends low-THC cannabis is subject to
808	specified disciplinary action; providing that a
809	physician who recommends low-THC cannabis without a
810	specified reasonable belief is subject to certain
811	criminal penalties; providing that a patient who
812	fraudulently misrepresents a condition to obtain low-
813	THC cannabis is subject to certain criminal penalties;
814	requiring specified physician education to be offered
815	by the Florida Medical Association or Florida
816	Osteopathic Medical Association a certain number of
817	times annually; revising the duties of the Department
818	of Health; requiring the department to create a
819	secure, electronic, and online compassionate use
820	registry; requiring the department to begin accepting
821	applications for licensure as a dispensing
822	organization within a certain period according to a
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824 to be reviewed and scored by a selection committee; 825 specifying the composition of the committee; requiring 826 the department to select a specified number of 827 applicants based on certain criteria for licensure as 828 dispensing organizations in certain regions of the 829 state and statewide; authorizing certain applicants to 830 operate as a dispensing organization in any region of 831 the state, but prohibiting such organization from 8.32 having cultivation or processing facilities outside 833 the region in which it is licensed; requiring the 834 department to license selected applicants unless the 835 applicant fails to pay the licensure fee within a 836 specified period; providing a process for an 837 unsuccessful applicant to contest and appeal the 838 department's final selection of applicants; providing 839 that ch. 120, F.S., does not apply to such process; 840 providing that certain timeframes do not apply to the 841 application and licensure process; requiring the 842 department to use an application form requiring 843 specified information; requiring the department to 844 impose certain application, licensure, and renewal 845 fees; authorizing the department to inspect each 846 dispensing organization's properties, cultivation facilities, processing facilities, and retail 847 848 facilities before and after those facilities begin 849 operations; requiring dispensing organizations to make 850 all facility premises, equipment, documents, low-THC 851 cannabis, and low-THC cannabis products available to 852 the department upon inspection; authorizing the

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853 department to test low-THC cannabis or low-THC 854 cannabis products; authorizing the department to 855 impose an administrative penalty and take other 856 specified administrative action against the license of 857 a dispensing organization based on specified 858 violations if the dispensing organization fails to 859 cure a violation after being providing certain notice 860 and an opportunity to cure; requiring the department 861 to create a permitting process for vehicles used for 862 the transportation of low-THC cannabis or low-THC 863 cannabis products; requiring the department to adopt 864 rules as necessary for implementation of the section; 865 specifying that the award of certain licenses is not 866 contingent on such rules being first adopted; 867 providing procedures and requirements for an applicant 868 seeking licensure as a dispensing organization and for 869 the renewal and maintenance of such license; requiring 870 the dispensing organization to verify specified 871 information of specified persons in certain 872 circumstances; authorizing a dispensing organization 873 to have cultivation facilities, processing facilities, 874 and retail facilities; authorizing a municipality and 875 county to determine by ordinance the number and 876 location of, and other permitting requirements for, 877 all cultivation, processing, and retail facilities 878 located within its respective boundaries; specifying 879 requirements for retail facilities; requiring a 880 dispensing organization to provide the department with 881 certain updated information within a specified period;

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882 authorizing a dispensing organization or contractor to 883 transport low-THC cannabis or low-THC cannabis 884 products in vehicles in certain circumstances; 885 requiring such vehicles to be operated by specified 886 persons in certain circumstances; requiring a fee for 887 a vehicle permit; requiring the signature of the 888 designated driver with a vehicle permit application; 889 providing for expiration of the permit in certain 890 circumstances; requiring the department to cancel a 891 vehicle permit upon the request of specified persons; 892 providing that the licensee authorizes the inspection 893 and search of his or her vehicle without a search 894 warrant by specified persons; requiring all low-THC 895 cannabis and low-THC cannabis products to be tested by 896 an independent testing laboratory before the 897 dispensing organization may dispense it; requiring the 898 independent testing laboratory to provide the lab 899 results to the dispensing organization for a specified 900 determination; requiring all low-THC cannabis and low-901 THC cannabis products to be labeled with specified 902 information before dispensing; requiring the 903 University of Florida College of Pharmacy to establish 904 and maintain a specified safety and efficacy research 905 program; providing program requirements; requiring the 906 department to provide information from the 907 prescription drug monitoring program to the University 908 of Florida as needed; requiring the Agency for Health 909 Care Administration to provide access to specified 910 patient records under certain circumstances;

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911 prohibiting persons who have direct or indirect 912 interest in a dispensing organization and the 913 dispensing organization's managers, employees, and 914 contractors who directly interact with low-THC 915 cannabis and low-THC cannabis products from making 916 recommendations, offering prescriptions, or providing 917 medical advice to qualified patients; providing that 918 the act does not provide an exception to the 919 prohibition against driving under the influence; 920 authorizing specified individuals to manufacture, 921 possess, sell, deliver, distribute, dispense, and 922 lawfully dispose of reasonable quantities of low-THC 923 cannabis; authorizing a laboratory and its employees 924 to receive and possess low-THC cannabis in certain 925 circumstances; amending s. 381.987, F.S.; requiring 926 the department to allow specified persons engaged in 927 research to access the compassionate use registry; 928 amending s. 893.055, F.S.; providing that persons 929 engaged in research at the University of Florida shall 930 have access to specified information; amending s. 931 893.0551, F.S.; authorizing certain persons engaged in 932 research at the University of Florida to have access 933 to specified information in the prescription drug 934 monitoring program's database; requiring the 935 Department of Health to provide notice to certain 936 applicants for licensure as a dispensing organization 937 if their applications do not comply with specified 938 law; requiring the department to allow such applicant to correct and refile its application; providing an 939

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effective date.