House



LEGISLATIVE ACTION .

Senate

Floor: NC/2R 03/04/2016 10:09 AM

Senator Clemens moved the following:

Senate Amendment (with title amendment)

Delete lines 311 - 698

and insert:

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

7 (a) The department shall create a secure, electronic, and online compassionate use registry for the registration of 9 physicians and patients as provided under this section. The 10 registry must be accessible to law enforcement agencies and to a dispensing organization in order to verify patient authorization 11

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12 for low-THC cannabis and record the low-THC cannabis dispensed.
13 The registry must prevent an active registration of a patient by
14 multiple physicians.

15 (b)1. Beginning July 8, 2016, the department shall accept 16 applications for licensure as dispensing organizations. A 17 dispensing organization may be licensed to cultivate or process 18 low-THC cannabis or low-THC cannabis products or dispense low-19 THC cannabis or low-THC cannabis products through a dispensing 20 facility. A dispensing organization may be licensed to conduct 21 one or more of these activities. The department shall review 22 each application to determine whether the applicant meets the 23 criteria in subsection (6) and qualifies for licensure.

24 2. Within 10 days after receiving an application for 25 licensure, the department shall examine the application, notify 26 the applicant of any apparent errors or omissions, and request 27 any additional information the department is allowed by law to 28 require. An application for licensure must be filed with the department no later than 5 p.m. on August 1, 2016, and all 29 30 applications must be complete no later than 5 p.m. on August 30, 31 2016.

<u>3. Once licensed, applicants may operate in any region in</u> <u>the state, but a dispensing organization licensed to cultivate</u> <u>or process low-THC cannabis may not have cultivation or</u> <u>processing facilities outside the region in which it is</u> licensed.

4. The department shall license a selected applicant unless the applicant fails to pay the licensure fee within 10 days after selection.
5. This section is exempt from s. 120.60(1) Authorize the

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41	establishment of five dispensing organizations to ensure
42	reasonable statewide accessibility and availability as necessary
43	for patients registered in the compassionate use registry and
44	who are ordered low-THC cannabis under this section, one in each
45	of the following regions: northwest Florida, northeast Florida,
46	central Florida, southeast Florida, and southwest Florida.
47	<u>(c)</u> The department shall <u>use</u> develop an application form
48	that requires the applicant to state, as applicable:
49	1. Whether the application is for initial licensure or
50	renewal licensure;
51	2. Whether the application is for licensure as a
52	cultivator, processor, or dispenser of low-THC cannabis;
53	3. The name, the physical address, and the mailing address
54	of the applicant;
55	4. For a cultivating or processing license, the address
56	listed on the Department of Agriculture and Consumer Services
57	certificate of registration required in paragraph (6)(b);
58	5. The name, address, license number, and contact
59	information for the applicant's medical director; and
60	6. All information required to be included by subsection
61	<u>(6).</u>
62	(d) The department shall and impose an initial application
63	fee of \$10,000, an initial licensure fee of \$25,000, and a
64	biennial renewal fee of \$25,000 that is sufficient to cover the
65	costs of administering this section. An applicant for approval
66	as a dispensing organization must be able to demonstrate:
67	1. The technical and technological ability to cultivate and
68	produce low-THC cannabis. The applicant must possess a valid
69	certificate of registration issued by the Department of

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70	Agriculture and Consumer Services pursuant to s. 581.131 that is
71	issued for the cultivation of more than 400,000 plants, be
72	operated by a nurseryman as defined in s. 581.011, and have been
73	operated as a registered nursery in this state for at least 30
74	continuous years.
75	2. The ability to secure the premises, resources, and
76	personnel necessary to operate as a dispensing organization.
77	3. The ability to maintain accountability of all raw
78	materials, finished products, and any byproducts to prevent
79	diversion or unlawful access to or possession of these
80	substances.
81	4. An infrastructure reasonably located to dispense low-THC
82	cannabis to registered patients statewide or regionally as
83	determined by the department.
84	5. The financial ability to maintain operations for the
85	duration of the 2-year approval cycle, including the provision
86	of certified financials to the department. Upon approval, the
87	applicant must post a \$5 million performance bond.
88	6. That all owners and managers have been fingerprinted and
89	have successfully passed a level 2 background screening pursuant
90	to s. 435.04.
91	7. The employment of a medical director who is a physician
92	licensed under chapter 458 or chapter 459 to supervise the
93	activities of the dispensing organization.
94	(e) The department shall inspect each dispensing
95	organization's properties, cultivation facilities, processing
96	facilities, or dispensing facilities according to its licensure
97	before they begin operations and at least once every 2 years
98	thereafter. The department may conduct additional announced or

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99	unannounced inspections, including followup inspections, at
100	reasonable hours in order to ensure that such properties or
101	facilities maintain compliance with all applicable requirements
102	in subsections (6) and (7) and to ensure that the dispensing
103	organization has not committed any act that would endanger the
104	health, safety, or security of a qualified patient, a dispensing
105	organization staff member, or the community in which the
106	dispensing organization is located. Licensure under this section
107	constitutes permission for the department to enter and inspect
108	the premises or facilities of any dispensing organization. A
109	dispensing organization must make all facility premises,
110	equipment, documents, low-THC cannabis, and low-THC cannabis
111	products available, as applicable, to the department upon
112	inspection. The department may test any low-THC cannabis or low-
113	THC cannabis product in order to ensure that it is safe for
114	human consumption and that it meets the requirements in this
115	section.
116	(f) The department may suspend or revoke a license, deny or
117	refuse to renew a license, or impose an administrative penalty
118	not to exceed \$10,000 for the following acts or omissions:
119	1. Violating this section, s. 499.0295, or department rule.
120	2. Failing to maintain qualifications for licensure.
121	3. Endangering the health, safety, or security of a
122	qualified patient.
123	4. Improperly disclosing personal and confidential
124	information of a qualified patient.
125	5. Attempting to procure a license by bribery or fraudulent
126	misrepresentation.
127	6. Being convicted or found guilty of, or entering a plea

128	of nolo contendere to, regardless of adjudication, a crime in
129	any jurisdiction which directly relates to the business of a
130	dispensing organization.
131	7. Making or filing a report or record that the licensee
132	knows to be false.
133	8. Willfully failing to maintain a record required by this
134	section or department rule.
135	9. Willfully impeding or obstructing an employee or agent
136	of the department in the furtherance of his or her official
137	duties.
138	10. Engaging in fraud or deceit, negligence, incompetence,
139	or misconduct in the business practices of a licensee.
140	11. Making misleading, deceptive, or fraudulent
141	representations in or related to the business practices of a
142	licensee.
143	12. Having a license or the authority to engage in any
144	regulated profession, occupation, or business that is related to
145	the business practices of a dispensing organization revoked,
146	suspended, or otherwise acted against, including the denial of
147	licensure, by the licensing authority of any jurisdiction,
148	including its agencies or subdivisions, for a violation that
149	would constitute a violation under state law. A licensing
150	authority's acceptance of a relinquishment of licensure or a
151	stipulation, consent order, or other settlement, offered in
152	response to or in anticipation of the filing of charges against
153	the license, shall be construed as an action against the
154	license.
155	13. Violating a lawful order of the department or an agency
156	of the state, or failing to comply with a lawfully issued
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157 subpoena of the department or an agency of the state. 158 (q) The department shall create a permitting process for 159 all dispensing organization vehicles used for the transportation 160 of low-THC cannabis or low-THC cannabis products. 161 (h) (c) The department shall monitor physician registration 162 and ordering of low-THC cannabis for ordering practices that 163 could facilitate unlawful diversion or misuse of low-THC 164 cannabis and take disciplinary action as indicated. (i) (d) The department shall adopt rules as necessary to 165 166 implement this section. 167 (6) DISPENSING ORGANIZATION.-168 (a) An applicant seeking licensure as a dispensing 169 organization, or the renewal of its license, must submit an 170 application to the department. An applicant may seek licensure 171 as a dispensing organization to cultivate, process, or dispense 172 low-THC cannabis. Each function of the dispensing organization 173 requires separate licensure; however, an applicant may seek 174 licensure for more than one function. The department must review 175 all applications for completeness, including an appropriate 176 inspection of the applicant's property or facilities, as 177 applicable, to verify the authenticity of the information 178 provided in, or in connection with, the application. An 179 applicant authorizes the department to inspect his or her 180 property or facilities for licensure by applying under this 181 subsection. 182 (b) In order to receive, maintain, or renew licensure as a 183 dispensing organization, an applicant must provide proof that: 184 1. For a cultivating or processing license, the applicant, 185 or a separate entity that is owned solely by the same persons or

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186	entities in the same ratio as the applicant, possesses a valid
187	certificate of registration issued by the Department of
188	Agriculture and Consumer Services pursuant to s. 581.131 for the
189	cultivation of more than 400,000 plants.
190	2. For a cultivating or processing license, the personnel
191	on staff or under contract for the applicant have experience
192	cultivating and introducing multiple varieties of plants in this
193	state, including plants that are not native to Florida;
194	experience with propagating plants; and experience with genetic
195	modification or breeding of plants.
196	3. For a cultivating or processing license, the personnel
197	on staff or under contract for the applicant include at least
198	one person who:
199	a. Has at least 5 years' experience with the United States
200	Department of Agriculture Good Agricultural Practices and Good
201	Handling Practices;
202	b. Has at least 5 years' experience with the United States
203	Food and Drug Administration Current Good Manufacturing
204	Practices for food production;
205	<u>c. Has a doctorate degree in organic chemistry or</u>
206	microbiology;
207	d. Has at least 5 years' of experience with laboratory
208	procedures which includes analytical laboratory quality control
209	measures, chain of custody procedures, and analytical laboratory
210	methods;
211	e. Has experience with cannabis cultivation and processing,
212	including cannabis extraction techniques and producing cannabis
213	products;
214	f. Has experience and qualifications in chain of custody or

215	other tracking mechanisms;
216	g. Works solely on inventory control; and
217	h. Works solely for security purposes.
218	4. The persons who have a direct or indirect interest in
219	any dispensing organization and the applicant's managers,
220	employees, and contractors who directly interact with low-THC
221	cannabis or low-THC cannabis products have been fingerprinted
222	and have successfully passed a level 2 background screening
223	pursuant to s. 435.04.
224	5. For a cultivating or processing license, the applicant
225	owns, or has at least a 2-year lease of, all properties,
226	facilities, and equipment necessary for the cultivation and
227	processing of low-THC cannabis. The applicant must provide a
228	detailed description of each facility and its equipment, a
229	cultivation and processing plan, and a detailed floor plan. The
230	description must include proof that:
231	a. The applicant is capable of cultivating and processing
232	sufficient low-THC cannabis or low-THC cannabis product to serve
233	at least 15,000 patients with an assumed daily use of 1,000 mg
234	per patient per day of low-THC cannabis or low-THC cannabis
235	product;
236	b. The applicant has arranged for access to all utilities
237	and resources necessary to cultivate or process low-THC cannabis
238	at each listed facility; and
239	c. Each facility is secured and has theft-prevention
240	systems, including an alarm system, cameras, and 24-hour
241	security personnel.
242	6. The applicant has diversion and tracking prevention
243	procedures, as applicable, including:

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244	a. A system for tracking low-THC material through
245	cultivation, processing, or dispensing, including the use of
246	batch and harvest numbers;
247	b. An inventory control system for low-THC cannabis and
248	low-THC cannabis products;
249	c. A vehicle tracking and security system; and
250	<u>d. A cannabis waste disposal plan.</u>
251	7. The applicant has recordkeeping policies and procedures
252	in place.
253	8. The applicant has a facility emergency management plan.
254	9. For a dispensing license, the applicant has a plan for
255	dispensing low-THC cannabis throughout the state. This plan must
256	include planned dispensing facilities and a delivery plan for
257	providing low-THC cannabis and low-THC cannabis products to
258	qualified patients who cannot travel to a dispensing facility.
259	10. The applicant has financial documentation, as
260	applicable, including:
261	a. Documentation that demonstrates the applicant's
262	financial ability to operate. If the applicant's assets, credit,
263	and projected revenues meet or exceed projected liabilities and
264	expenses and the applicant provides independent evidence that
265	the funds necessary for startup costs, working capital, and
266	contingency financing exist and are available as needed, the
267	applicant has demonstrated the financial ability to operate.
268	Financial ability to operate must be documented by:
269	I. The applicant's audited financial statements. If the
270	applicant is a newly formed entity and does not have a financial
271	history of business upon which audited financial statements may
272	be submitted, the applicant must provide audited financial
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273	statements for the separate entity that is owned solely by the
274	same persons or entities in the same ratio as the applicant;
275	II. The applicant's projected financial statements,
276	including a balance sheet, an income and expense statement, and
277	a statement of cash flow for the first 2 years of operation,
278	which provide evidence that the applicant has sufficient assets,
279	credit, and projected revenues to cover liabilities and
280	expenses; and
281	III. A statement of the applicant's estimated startup costs
282	and sources of funds, including a break-even projection and
283	documentation demonstrating that the applicant has the ability
284	to fund all startup costs, working capital costs, and
285	contingency financing requirements.
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287	All documents required under this sub-subparagraph shall be
288	prepared in accordance with generally accepted accounting
289	principles and signed by a certified public accountant. The
290	statements required by sub-sub-subparagraphs II. and III. may be
291	presented as a compilation;
292	b. A list of all subsidiaries of the applicant;
293	c. A list of all lawsuits pending and completed within the
294	past 7 years of which the applicant was a party; and
295	d. Proof of a \$1 million performance and compliance bond,
296	or other equivalent means of security deemed equivalent by the
297	department, such as an irrevocable letter of credit or a deposit
298	in a trust account or financial institution, payable to the
299	department, which must be posted once the applicant is approved
300	as a dispensing organization. The purpose of the bond is to
301	secure payment of any administrative penalties imposed by the
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302	department and any fees and costs incurred by the department
303	regarding the dispensing organization license, such as the
304	dispensing organization failing to pay 30 days after the fine or
305	costs become final. The department may make a claim against such
306	bond or security until 1 year after the dispensing
307	organization's license ceases to be valid or until 60 days after
308	any administrative or legal proceeding authorized in this
309	section involving the dispensing organization concludes,
310	including any appeal, whichever occurs later.
311	11. The employment of a medical director who is a physician
312	licensed under chapter 458 or chapter 459 to supervise the
313	activities of the dispensing organization.
314	(c) An approved dispensing organization shall maintain
315	compliance with the criteria in paragraphs (b), (d), and (e) and
316	subsection (7) demonstrated for selection and approval as a
317	dispensing organization under subsection (5) at all times.
318	Before dispensing low-THC cannabis or low-THC cannabis products
319	to a qualified patient or to the qualified patient's legal
320	representative, the dispensing organization shall verify the
321	identity of the qualified patient or the qualified patient's
322	legal representative by requiring the qualified patient or the
323	qualified patient's legal representative to produce a
324	government-issued identification card and shall verify that the
325	qualified patient and the qualified patient's legal
326	representative have has an active registration in the
327	compassionate use registry, that the order presented matches the
328	order contents as recorded in the registry, and that the order
329	has not already been filled. Upon dispensing the low-THC
330	cannabis or low-THC cannabis products, the dispensing

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SENATOR AMENDMENT

Florida Senate - 2016 Bill No. CS for SB 460

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331 organization shall record in the registry the date, time, 332 quantity, and form of low-THC cannabis dispensed. (d)1. A dispensing organization may have cultivation 333 334 facilities, processing facilities, or dispensing facilities. 335 2. A municipality must determine by ordinance the criteria 336 for the number and location of, and other permitting 337 requirements for, all dispensing facilities located within its 338 municipal boundaries. A dispensing facility may be established in a municipality only after such an ordinance has been created. 339 340 A county must determine by ordinance the criteria for the 341 number, location, and other permitting requirements for all 342 dispensing facilities located within the unincorporated areas of 343 that county. A dispensing facility may be established in the 344 unincorporated areas of a county only after such an ordinance 345 has been created. Dispensing facilities must have all utilities 346 and resources necessary to store and dispense low-THC cannabis 347 and low-THC cannabis products. Dispensing facilities must be 348 secured and have theft-prevention systems, including an alarm system, cameras, and 24-hour security personnel. Dispensing 349 350 facilities may not sell, or contract for the sale of, anything other than low-THC cannabis or low-THC cannabis products on the 351 352 property of the dispensing facilities. Before a dispensing 353 facility may dispense low-THC cannabis or a low-THC cannabis 354 product, the dispensing organization must have a computer 355 network compliant with the federal Health Insurance Portability 356 and Accountability Act of 1996 which can access and upload data 357 to the compassionate use registry and which shall be used by all 358 dispensing facilities. 359 (e) Within 15 days after such information becoming

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360	available, a dispensing organization must provide the department
361	with updated information, as applicable, including:
362	1. The location and a detailed description of any new or
363	proposed facility.
364	2. The updated contact information, including electronic
365	and voice communication, for all dispensing organization
366	facilities.
367	3. The registration information for any vehicle used for
368	the transportation of low-THC cannabis and low-THC cannabis
369	products, including confirmation that all such vehicles have
370	tracking and security systems.
371	4. A plan for the recall of any or all low-THC cannabis or
372	low-THC cannabis products.
373	(f)1. A dispensing organization may transport low-THC
374	cannabis or low-THC cannabis products in a vehicle departing
375	from its place of business only in a vehicle that is owned or
376	leased by the licensee or by a person designated by the
377	dispensing organization, and for which a valid vehicle permit
378	has been issued for such vehicle by the department.
379	2. A vehicle owned or leased by the dispensing
380	organization, or by a person designated by the dispensing
381	organization and approved by the department, must be operated by
382	a person designated by the dispensing organization and approved
383	by the department when transporting low-THC cannabis or low-THC
384	products from the licensee's place of business.
385	3. A vehicle permit may be obtained by a dispensing
386	organization upon application and payment of a fee of \$5 per
387	vehicle to the department. The signature of the person
388	designated by the dispensing organization to drive the vehicle

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389 must be included on the vehicle permit application. Such permit 390 remains valid and does not expire unless the licensee or any 391 person designated by the dispensing organization disposes of his 392 or her vehicle, or the licensee's license is transferred, 393 canceled, not renewed, or is revoked by the department, 394 whichever occurs first. The department shall cancel a vehicle 395 permit upon request of the licensee or owner of the vehicle. 396 4. By acceptance of a license issued under this section, 397 the licensee agrees that the permitted vehicle is, at all times 398 it is being used to transport low-THC cannabis or low-THC cannabis products, subject to inspection and search without a 399 400 search warrant by authorized employees of the department, 401 sheriffs, deputy sheriffs, police officers, or other law 402 enforcement officers to determine that the licensee is 403 transporting such products in compliance with this section. 404 (7) TESTING AND LABELING OF LOW-THC CANNABIS.-(a) All low-THC cannabis and low-THC cannabis products must 405 406 be tested by an independent testing laboratory before the 407 dispensing organization may dispense them. The independent 408 testing laboratory shall provide the dispensing organization 409 with lab results. Before dispensing, the dispensing organization 410 must determine that the lab results indicate that the low-THC 411 cannabis or low-THC cannabis product meets the definition of 412 low-THC cannabis or low-THC cannabis product, is safe for human 413 consumption, and is free from harmful contaminants. 414 (b) All low-THC cannabis and low-THC cannabis products must 415 be labeled before dispensing. The label must include, at a 416 minimum: 417 1. A statement that the low-THC cannabis or low-THC

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418	cannabis product meets the requirements in paragraph (a);
419	2. The name of the independent testing laboratory that
420	tested the low-THC cannabis or low-THC cannabis product;
421	3. The name of the cultivation and processing facility
422	where the low-THC cannabis or low-THC cannabis product
423	originates; and
424	4. The batch number and harvest number from which the low-
425	THC cannabis or low-THC cannabis product originates.
426	(8) SAFETY AND EFFICACY RESEARCH FOR LOW-THC CANNABISThe
427	University of Florida College of Pharmacy shall establish and
428	maintain a safety and efficacy research program for the use of
429	low-THC cannabis or low-THC cannabis products to treat
430	qualifying conditions and symptoms. The program must include a
431	fully integrated electronic information system for the broad
432	monitoring of health outcomes and safety signal detection. The
433	electronic information system must include information from the
434	compassionate use registry; provider reports, including
435	treatment plans, adverse event reports, and treatment
436	discontinuation reports; patient reports of adverse impacts;
437	event-triggered interviews and medical chart reviews performed
438	by the University of Florida clinical research staff;
439	information from external databases, including Medicaid billing
440	reports and information in the prescription drug monitoring
441	database for registered patients; and all other medical reports
442	required by the University of Florida to conduct the research
443	required by this subsection. The department must provide access
444	to information from the compassionate use registry and the
445	prescription drug monitoring database, established in s.
446	893.055, as needed by the University of Florida to conduct

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447	research under this subsection. The Agency for Health Care
448	Administration must provide access to registered patient
449	Medicaid records, to the extent allowed under federal law, as
450	needed by the University of Florida to conduct research under
451	this subsection.
452	(9) PERSONS WITH INTEREST IN THE DISPENSING ORGANIZATION
453	The persons who have direct or indirect interest in the
454	dispensing organization and the dispensing organization's
455	managers, employees, and contractors who directly interact with
456	low-THC cannabis or low-THC cannabis products may not make
457	recommendations, offer prescriptions, or provide medical advice
458	to qualified patients.
459	(10) DEPARTMENT AUTHORITY AND RESPONSIBILITIES
460	(a) The department may conduct announced or unannounced
461	inspections of dispensing organizations to determine compliance
462	with this section or rules adopted pursuant to this section.
463	(b) The department shall inspect a dispensing organization
464	upon complaint or notice provided to the department that the
465	dispensing organization has dispensed low-THC cannabis or low-
466	THC cannabis products containing any mold, bacteria, or other
467	contaminant that may cause or has caused an adverse effect to
468	human health or the environment.
469	(c) The department shall conduct at least a biennial
470	inspection of each dispensing organization to evaluate the
471	dispensing organization's records, personnel, equipment,
472	processes, security measures, sanitation practices, and quality
473	assurance practices.
474	(d) The department may enter into interagency agreements
475	with the Department of Agriculture and Consumer Services, the

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476	Department of Business and Professional Regulation, the
477	Department of Transportation, the Department of Highway Safety
478	and Motor Vehicles, and the Agency for Health Care
479	Administration, and such agencies are authorized to enter into
480	an interagency agreement with the department, to conduct
481	inspections or perform other responsibilities assigned to the
482	department under this section.
483	(e) The department must make a list of all approved
484	dispensing organizations and qualified ordering physicians and
485	medical directors publicly available on its website.
486	(f) The department may establish a system for issuing and
487	renewing registration cards for qualified patients and their
488	legal representatives, establish the circumstances under which
489	the cards may be revoked by or must be returned to the
490	department, and establish fees to implement such system. The
491	department must require, at a minimum, the registration cards
492	to:
493	1. Provide the name, address, and date of birth of the
494	qualified patient or legal representative.
495	2. Have a full-face, passport-type, color photograph of the
496	qualified patient or legal representative taken within the 90
497	days immediately preceding registration.
498	3. Identify whether the cardholder is a qualified patient
499	or legal representative.
500	4. List a unique numeric identifier for the qualified
501	patient or legal representative which is matched to the
502	identifier used for such person in the department's
503	compassionate use registry.
504	5. Provide the expiration date, which shall be 1 year after

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505	the date of the physician's initial order of low-THC cannabis.
506	6. For the legal representative, provide the name and
507	unique numeric identifier of the qualified patient that the
508	legal representative is assisting.
509	7. Be resistant to counterfeiting or tampering.
510	(g) The department may suspend, revoke, or refuse to renew
511	a dispensing organization's approval if a dispensing
512	organization commits any of the violations in paragraph (g).
513	(h) The department shall renew the approval of a dispensing
514	organization biennially if the dispensing organization meets the
515	requirements of this section and pays the biennial renewal fee.
516	(i) The department may adopt rules necessary to implement
517	this section.
518	(11) PREEMPTION
519	(a) All matters regarding the regulation of the cultivation
520	and processing of medical cannabis or low-THC cannabis by
521	dispensing organizations are preempted to the state.
522	(b) A municipality may determine by ordinance the criteria
523	for the number and location of, and other permitting
524	requirements that do not conflict with state law or department
525	rule for, dispensing facilities of dispensing organizations
526	located within its municipal boundaries. A county may determine
527	by ordinance the criteria for the number, location, and other
528	permitting requirements that do not conflict with state law or
529	department rule for all dispensing facilities of dispensing
530	organizations located within the unincorporated areas of that
531	county.
532	(12) (7) EXCEPTIONS TO OTHER LAWS
533	(a) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or

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534 any other provision of law, but subject to the requirements of 535 this section, a qualified patient and the qualified patient's 536 legal representative who is registered with the department on 537 the compassionate use registry may purchase and possess for the 538 patient's medical use up to the amount of low-THC cannabis or 539 medical cannabis ordered for the patient, but not more than a 45-day supply, and a cannabis delivery device ordered for the 540 541 patient. This section does not exempt any person from the 542 prohibition against driving under the influence provided in s. 543 316.193.

544 (b) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or 545 any other provision of law, but subject to the requirements of 546 this section, an approved dispensing organization and its 547 owners, managers, and employees, and the owners, managers, and 548 employees of contractors who have direct contact with low-THC cannabis or low-THC cannabis products may manufacture, possess, 549 sell, deliver, distribute, dispense, and lawfully dispose of 550 551 reasonable quantities, as established by department rule, of 552 low-THC cannabis or low-THC cannabis products in accordance with 553 their licensure. For purposes of this subsection, the terms "manufacture," "possession," "deliver," "distribute," and 554 555 "dispense" have the same meanings as provided in s. 893.02. 556 (c) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or

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

561 <u>(d) (c)</u> An approved dispensing organization and its owners, 562 managers, and employees are not subject to licensure or

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563 regulation under chapter 465 <u>or chapter 499</u> for manufacturing, 564 possessing, selling, delivering, distributing, dispensing, or 565 lawfully disposing of reasonable quantities, as established by 566 department rule, of low-THC cannabis.

(e) 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 or low-THC cannabis products for the sole purpose of testing the low-THC cannabis or low-THC cannabis products to ensure compliance with this section.

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

(g) This subsection does not preclude a person from being prosecuted for a criminal offense related to impairment or intoxication resulting from the medical use of low-THC cannabis or medical cannabis or relieve a person from any requirement under law to submit to a breath, blood, urine, or other test to detect the presence of a controlled substance.

(13) RULES.-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).

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592 Delete lines 21 - 81 593 and insert: 594 requiring the department to accept applications for 595 licensure as dispensing organizations according to a 596 specified application process; authorizing a 597 dispensing organization to be licensed to cultivate, 598 to process, or to dispense low-THC cannabis; requiring 599 the department to review all applications, notify 600 applicants of deficient applications, and request any 601 additional information within a specified period; 602 requiring an application for licensure to be filed and 603 complete by specified dates; authorizing licensed 604 applicants to operate in any region of the state; 605 prohibiting a dispensing organization licensed to 606 cultivate or process low-THC cannabis from having 607 cultivation or processing facilities outside the 608 region in which it is licensed; requiring licensure 609 fees to be paid within a specified timeframe; 610 providing an exemption for the application process; 611 requiring the department to use an application form 612 that requires specified information from the applicant; specifying application fees, licensure 613 614 fees, and renewal fees; requiring the department to 615 inspect each dispensing organization's properties, 616 cultivation facilities, processing facilities, or 617 dispensing facilities before those facilities may 618 operate; authorizing followup inspections at 619 reasonable hours; providing that licensure constitutes 620 permission for the department to enter and inspect the

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621 premises or facilities of any dispensing organization; 622 requiring dispensing organizations to make all 623 facility premises, equipment, documents, low-THC 624 cannabis, and low-THC cannabis products, as 625 applicable, available to the department upon 626 inspection; authorizing the department to test low-THC 627 cannabis or low-THC cannabis products; authorizing the 628 department to suspend or revoke a license, deny or 62.9 refuse to renew a license, or impose an administrative 630 penalty for specified acts or omissions; requiring the 631 department to create a permitting process for vehicles 632 used for the transportation of low-THC cannabis or 633 low-THC cannabis products; providing procedures and 634 requirements for an applicant seeking licensure as a 635 dispensing organization or the renewal of its license; 636 requiring the dispensing organization to verify 637 specified information of specified persons in certain 638 circumstances; authorizing a dispensing organization 639 to have cultivation facilities, processing facilities, 640 or dispensing facilities; providing that all matters 641 regarding the location of cultivation facilities and 642 processing facilities are preempted to the state; 643 providing requirements for cultivation facilities and 644 processing facilities; requiring a municipality to 645 determine by ordinance specified criteria related to 646 dispensing facilities; authorizing a dispensing 647 facility to be established in a municipality only 648 after such an ordinance has been created; authorizing a dispensing facility to be established in the 649

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650 unincorporated areas of a county only after such an 651 ordinance has been created; requiring dispensing 652 facilities to have all utilities and resources 653 necessary to store and dispense low-THC and low-THC cannabis products; requiring dispensing facilities to 654 655 be secured with specified theft-prevention systems; 656 requiring a dispensing organization to provide the 657 department with specified updated information within a 658 specified period; authorizing a dispensing 659 organization to transport low-THC cannabis or low-THC 660 cannabis products in vehicles in certain 661 circumstances; requiring such vehicles to be operated 662 by specified persons in certain circumstances; 663 requiring a fee for a vehicle permit; requiring the 664 signature of the designated driver with a vehicle 665 permit application; providing for expiration of the 666 permit in certain circumstances; requiring the 667 department to cancel a vehicle permit upon the request 668 of specified persons; providing that the licensee 669 authorizes the inspection and search of his or her 670 vehicle without a search warrant by specified persons; 671 requiring all low-THC cannabis and low-THC cannabis 672 products to be tested by an independent testing 673 laboratory before the dispensing organization may 674 dispense them; requiring the independent testing 675 laboratory to provide the lab results to the 676 dispensing organization for a specified determination; 677 requiring all low-THC cannabis and low-THC cannabis 678 products to be labeled with specified information

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679 before dispensing; requiring the University of Florida College of Pharmacy to establish and maintain a 680 681 specified safety and efficacy research program; 682 providing program requirements; requiring the 683 department to provide access to information from the compassionate use registry and the prescription drug 684 685 monitoring program database to the University of 686 Florida as needed; requiring the Agency for Health 687 Care Administration to provide access to specified 688 patient records under certain circumstances; 689 prohibiting persons who have direct or indirect 690 interest in a dispensing organization and the 691 dispensing organization's managers, employees, and 692 contractors who directly interact with low-THC 693 cannabis and low-THC cannabis products from making 694 recommendations, offering prescriptions, or providing 695 medical advice to qualified patients; revising duties 696 and responsibilities of the department; providing that 697 certain matters are preempted to the state; 698 authorizing a municipality to determine by ordinance 699 certain criteria relating to dispensing organizations; 700 providing that the act does not provide an exception 701 to the prohibition against driving under the influence; authorizing specified individuals to 702 703 manufacture, possess, sell, deliver, distribute, 704 dispense, and lawfully dispose of reasonable 705 quantities of low-THC cannabis according to their 706 licensure; authorizing a licensed laboratory and its 707 employees to receive and possess low-THC cannabis in

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708 certain circumstances; providing applicability; 709 providing that specified rules adopted by the 710 department are exempt from the requirement to be 711 ratified by the Legislature; amending s. 499.0295, 712 F.S.;