1 A bill to be entitled 2 An act relating to the regulation of medical 3 marijuana; amending s. 381.986, F.S.; providing a definition; prohibiting qualified physicians from 4 5 engaging in certain advertising for their practices 6 relating to marijuana for medical use; providing 7 exceptions; prohibiting medical marijuana treatment 8 centers and certain other individuals and entities 9 from employing qualified physicians or having direct 10 or indirect economic interests in qualified physician 11 practices and medical marijuana testing laboratories; 12 revising a provision relating to the potency of tetrahydrocannabinol in edibles dispensed by a medical 13 14 marijuana treatment center; authorizing the Department of Health to select samples of marijuana available in 15 certain facilities for testing for specified purposes; 16 17 authorizing the department to sample marijuana delivery devices from a dispensing facility to 18 19 determine safety; requiring that a medical marijuana 20 treatment center recall all marijuana, rather than 21 only edibles, under certain circumstances; revising 22 advertising requirements for medical marijuana 23 treatment centers to prohibit radio and television 24 advertising; authorizing the department and certain 25 employees to acquire, possess, test, transport, and

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26 dispose of marijuana; prohibiting a qualified 27 physician from issuing a physician certification to a 28 minor patient for marijuana, except for low-THC 29 cannabis; providing an exception; revising the supply 30 limits of marijuana for which a physician certification may be issued; limiting the potency of 31 32 tetrahydrocannabinol in such supply; prohibiting a qualified physician from certifying a certain potency 33 of tetrahydrocannabinol in marijuana; providing an 34 35 exception; prohibiting a medical marijuana treatment center from dispensing a certain daily supply within a 36 37 specified period to conform to changes made by the act; prohibiting a medical marijuana treatment center 38 39 from dispensing marijuana that exceeds a certain potency of tetrahydrocannabinol; providing an 40 exception; amending s. 381.988, F.S.; prohibiting a 41 certified medical marijuana testing laboratory from 42 43 having an economic interest in or financial relationship with a medical marijuana treatment 44 center; providing construction; authorizing the 45 department and certain employees to acquire, possess, 46 47 test, transport, and dispose of marijuana; providing effective dates. 48 49 50 Be It Enacted by the Legislature of the State of Florida:

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51	
52	Section 1. Paragraphs (1) through (o) of subsection (1) of
53	section 381.986, Florida Statutes, are redesignated as
54	paragraphs (m) through (p), respectively, paragraph (a) of
55	subsection (3) and paragraphs (e) and (h) of subsection (8) are
56	amended, and a new paragraph (1) is added to subsection (1),
57	paragraph (d) is added to subsection (3), and paragraph (i) is
58	added to subsection (14) of that section, to read:
59	381.986 Medical use of marijuana.—
60	(1) DEFINITIONSAs used in this section, the term:
61	(1) "Potency" means the relative strength of cannabinoids,
62	and the total amount, in milligrams, of tetrahydrocannabinol as
63	the sum of delta-9-tetrahydrocannabinol plus (0.877 multiplied
64	by tetrahydrocannabinolic acid plus delta-8-
65	tetrahydrocannabinol) and cannabidiol as the sum of cannabidiol
66	plus (0.877 multiplied by cannabidiolic acid) in the final
67	product dispensed to a patient or caregiver.
68	(3) QUALIFIED PHYSICIANS AND MEDICAL DIRECTORS
69	(a) Before being approved as a qualified physician , as
70	$rac{defined in paragraph (1)(m),}{r}$ and before each license renewal, a
71	physician must successfully complete a 2-hour course and
72	subsequent examination offered by the Florida Medical
73	Association or the Florida Osteopathic Medical Association which
74	encompass the requirements of this section and any rules adopted
75	hereunder. The course and examination shall be administered at
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least annually and may be offered in a distance learning format, 76 77 including an electronic, online format that is available upon 78 request. The price of the course may not exceed \$500. A 79 physician who has met the physician education requirements of 80 former s. 381.986(4), Florida Statutes 2016, before June 23, 81 2017, shall be deemed to be in compliance with this paragraph 82 from June 23, 2017, until 90 days after the course and 83 examination required by this paragraph become available. With respect to his or her practice relating to 84 (d) 85 marijuana for medical use under this section, a qualified physician may not engage in radio or television advertising or 86 87 advertising that is visible to members of the public from any street, sidewalk, park, or other public place, except: 88 89 1. The qualified physician's practice may have a sign that 90 is affixed to the outside or hanging in the window of the 91 premises which identifies the qualified physician, a department-92 approved practice name, or a department-approved logo. A 93 qualified physician's practice name and logo may not contain 94 wording or images commonly associated with marketing targeted 95 toward children or which promote the recreational use of 96 marijuana. 2. A qualified physician may engage in Internet 97 98 advertising and marketing for his or her practice under the following conditions: 99 All advertisements must be approved by the department. 100 a.

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101 b. An advertisement may not have any content that 102 specifically targets individuals under the age of 18, including 103 cartoon characters or similar images. 104 c. An advertisement may not be an unsolicited pop-up 105 advertisement. 106 d. Opt-in marketing must include an easy and permanent 107 opt-out feature. 108 (8) MEDICAL MARIJUANA TREATMENT CENTERS.-109 A licensed medical marijuana treatment center shall (e) 110 cultivate, process, transport, and dispense marijuana for medical use. A licensed medical marijuana treatment center may 111 112 not contract for services directly related to the cultivation, processing, and dispensing of marijuana or marijuana delivery 113 114 devices, except that a medical marijuana treatment center 115 licensed pursuant to subparagraph (a)1. may contract with a single entity for the cultivation, processing, transporting, and 116 117 dispensing of marijuana and marijuana delivery devices. A 118 licensed medical marijuana treatment center must, at all times, 119 maintain compliance with the criteria demonstrated and 120 representations made in the initial application and the criteria 121 established in this subsection. Upon request, the department may 122 grant a medical marijuana treatment center a variance from the representations made in the initial application. Consideration 123 124 of such a request shall be based upon the individual facts and 125 circumstances surrounding the request. A variance may not be

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126 granted unless the requesting medical marijuana treatment center 127 can demonstrate to the department that it has a proposed 128 alternative to the specific representation made in its 129 application which fulfills the same or a similar purpose as the 130 specific representation in a way that the department can 131 reasonably determine will not be a lower standard than the 132 specific representation in the application. A variance may not 133 be granted from the requirements in subparagraph 2. and 134 subparagraphs (b)1. and 2.

135 1. A licensed medical marijuana treatment center may 136 transfer ownership to an individual or entity who meets the 137 requirements of this section. A publicly traded corporation or 138 publicly traded company that meets the requirements of this 139 section is not precluded from ownership of a medical marijuana 140 treatment center. To accommodate a change in ownership:

a. The licensed medical marijuana treatment center shall
notify the department in writing at least 60 days before the
anticipated date of the change of ownership.

b. The individual or entity applying for initial licensure due to a change of ownership must submit an application that must be received by the department at least 60 days before the date of change of ownership.

148 c. Upon receipt of an application for a license, the 149 department shall examine the application and, within 30 days 150 after receipt, notify the applicant in writing of any apparent

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151 errors or omissions and request any additional information 152 required.

153 d. Requested information omitted from an application for 154 licensure must be filed with the department within 21 days after 155 the department's request for omitted information or the 156 application shall be deemed incomplete and shall be withdrawn 157 from further consideration and the fees shall be forfeited.

159 Within 30 days after the receipt of a complete application, the 160 department shall approve or deny the application.

2. A medical marijuana treatment center, and any 161 162 individual or entity who directly or indirectly owns, controls, or holds with power to vote 5 percent or more of the voting 163 164 shares of a medical marijuana treatment center, may not acquire 165 direct or indirect ownership or control of any voting shares or 166 other form of ownership of any other medical marijuana treatment 167 center.

168 3. A medical marijuana treatment center and any individual 169 or entity that directly or indirectly owns, controls, or holds 170 with power to vote 5 percent or more of the voting shares of a medical marijuana treatment center may not employ a qualified 171 172 physician or have any direct or indirect economic interest in a 173 qualified physician's practice or a marijuana testing 174 laboratory. 4.3. A medical marijuana treatment center may not enter

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176 into any form of profit-sharing arrangement with the property 177 owner or lessor of any of its facilities where cultivation, 178 processing, storing, or dispensing of marijuana and marijuana 179 delivery devices occurs.

180 <u>5.4.</u> All employees of a medical marijuana treatment center 181 must be 21 years of age or older and have passed a background 182 screening pursuant to subsection (9).

183 <u>6.5.</u> Each medical marijuana treatment center must adopt 184 and enforce policies and procedures to ensure employees and 185 volunteers receive training on the legal requirements to 186 dispense marijuana to qualified patients.

187 <u>7.6.</u> When growing marijuana, a medical marijuana treatment 188 center:

a. May use pesticides determined by the department, after
consultation with the Department of Agriculture and Consumer
Services, to be safely applied to plants intended for human
consumption, but may not use pesticides designated as
restricted-use pesticides pursuant to s. 487.042.

b. Must grow marijuana within an enclosed structure and ina room separate from any other plant.

c. Must inspect seeds and growing plants for plant pests that endanger or threaten the horticultural and agricultural interests of the state in accordance with chapter 581 and any rules adopted thereunder.

200

d. Must perform fumigation or treatment of plants, or

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201 remove and destroy infested or infected plants, in accordance 202 with chapter 581 and any rules adopted thereunder.

203 <u>8.7.</u> Each medical marijuana treatment center must produce 204 and make available for purchase at least one low-THC cannabis 205 product.

206 9.8. A medical marijuana treatment center that produces 207 edibles must hold a permit to operate as a food establishment 208 pursuant to chapter 500, the Florida Food Safety Act, and must comply with all the requirements for food establishments 209 pursuant to chapter 500 and any rules adopted thereunder. 210 Edibles may not contain more than 200 milligrams of 211 212 tetrahydrocannabinol, and a single serving portion of an edible may not exceed 10 milligrams of tetrahydrocannabinol. Edibles 213 214 may have a potency variance of no greater than 15 percent of the 215 10 milligrams of tetrahydrocannabinol per single serving limit or 15 percent of the 200 milligrams of tetrahydrocannabinol per 216 217 product limit. Edibles may not be attractive to children; be 218 manufactured in the shape of humans, cartoons, or animals; be 219 manufactured in a form that bears any reasonable resemblance to 220 products available for consumption as commercially available 221 candy; or contain any color additives. To discourage consumption 222 of edibles by children, the department shall determine by rule any shapes, forms, and ingredients allowed and prohibited for 223 224 edibles. Medical marijuana treatment centers may not begin processing or dispensing edibles until after the effective date 225

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of the rule. The department shall also adopt sanitation rules providing the standards and requirements for the storage, display, or dispensing of edibles.

229 10.9. Within 12 months after licensure, a medical 230 marijuana treatment center must demonstrate to the department 231 that all of its processing facilities have passed a Food Safety 232 Good Manufacturing Practices, such as Global Food Safety 233 Initiative or equivalent, inspection by a nationally accredited 234 certifying body. A medical marijuana treatment center must 235 immediately stop processing at any facility which fails to pass 236 this inspection until it demonstrates to the department that 237 such facility has met this requirement.

238 <u>11.10.</u> A medical marijuana treatment center that produces 239 prerolled marijuana cigarettes may not use wrapping paper made 240 with tobacco or hemp.

241 <u>12.11.</u> When processing marijuana, a medical marijuana 242 treatment center must:

a. Process the marijuana within an enclosed structure andin a room separate from other plants or products.

b. Comply with department rules when processing marijuana with hydrocarbon solvents or other solvents or gases exhibiting potential toxicity to humans. The department shall determine by rule the requirements for medical marijuana treatment centers to use such solvents or gases exhibiting potential toxicity to humans.

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c. Comply with federal and state laws and regulations and department rules for solid and liquid wastes. The department shall determine by rule procedures for the storage, handling, transportation, management, and disposal of solid and liquid waste generated during marijuana production and processing. The Department of Environmental Protection shall assist the department in developing such rules.

258 13.d. A medical marijuana treatment center must test the 259 processed marijuana using a medical marijuana testing laboratory 260 before it is dispensed. Results must be verified and signed by 261 two medical marijuana treatment center employees. Before 262 dispensing, the medical marijuana treatment center must 263 determine that the test results indicate that low-THC cannabis meets the definition of low-THC cannabis, the concentration of 264 265 tetrahydrocannabinol meets the potency requirements of this 266 section, the labeling of the concentration of 267 tetrahydrocannabinol and cannabidiol is accurate, and all marijuana is safe for human consumption and free from 268 269 contaminants that are unsafe for human consumption. The 270 department shall determine by rule which contaminants must be 271 tested for and the maximum levels of each contaminant which are 272 safe for human consumption. The Department of Agriculture and Consumer Services shall assist the department in developing the 273 274 testing requirements for contaminants that are unsafe for human 275 consumption in edibles. The department shall also determine by

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276 rule the procedures for the treatment of marijuana that fails to 277 meet the testing requirements of this section, s. 381.988, or 278 department rule. The department may select samples of marijuana 279 a random sample from edibles available in a cultivation 280 facility, processing facility, or for purchase in a dispensing 281 facility which shall be tested by the department to determine 282 that the marijuana edible meets the potency requirements of this 283 section, is safe for human consumption, and the labeling of the tetrahydrocannabinol and cannabidiol concentration is accurate 284 285 or to verify medical marijuana testing laboratory results. The 286 department may also sample marijuana delivery devices from a 287 dispensing facility to determine that the marijuana delivery device is safe for use by qualified patients. A medical 288 289 marijuana treatment center may not require payment from the 290 department for the sample. A medical marijuana treatment center 291 must recall all marijuana which fails edibles, including all 292 edibles made from the same batch of marijuana, which fail to 293 meet the potency requirements of this section, which is are 294 unsafe for human consumption, or for which the labeling of the 295 tetrahydrocannabinol and cannabidiol concentration is 296 inaccurate. The medical marijuana treatment center must retain 297 records of all testing and samples of each homogenous batch of marijuana for at least 9 months. The medical marijuana treatment 298 center must contract with a marijuana testing laboratory to 299 300 perform audits on the medical marijuana treatment center's

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301	standard operating procedures, testing records, and samples and
302	provide the results to the department to confirm that the
303	marijuana or low-THC cannabis meets the requirements of this
304	section and that the marijuana or low-THC cannabis is safe for
305	human consumption. A medical marijuana treatment center shall
306	reserve two processed samples from each batch and retain such
307	samples for at least 9 months for the purpose of such audits. A
308	medical marijuana treatment center may use a laboratory that has
309	not been certified by the department under s. 381.988 until such
310	time as at least one laboratory holds the required
311	certification, but in no event later than July 1, 2018.
312	14. When packaging marijuana, a medical marijuana
313	treatment center must:
314	a.e. Package the marijuana in compliance with the United
315	States Poison Prevention Packaging Act of 1970, 15 U.S.C. ss.
316	1471 et seq.
317	<u>b.f.</u> Package the marijuana in a receptacle that has a
318	firmly affixed and legible label stating the following
319	information:
320	(I) The marijuana or low-THC cannabis meets the
321	requirements of <u>subparagraph 13</u> sub-subparagraph d .
322	(II) The name of the medical marijuana treatment center
323	from which the marijuana originates.
324	(III) The batch number and harvest number from which the
325	marijuana originates and the date dispensed.
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326 The name of the physician who issued the physician (IV) 327 certification. 328 (V) The name of the patient. 329 The product name, if applicable, and dosage form, (VI) 330 including concentration of tetrahydrocannabinol and cannabidiol. 331 The product name may not contain wording commonly associated 332 with products marketed by or to children. 333 (VII) The recommended dose. 334 (VIII) A warning that it is illegal to transfer medical marijuana to another person. 335 336 A marijuana universal symbol developed by the (IX) 337 department. 338 15.12. The medical marijuana treatment center shall 339 include in each package a patient package insert with 340 information on the specific product dispensed related to: Clinical pharmacology. 341 a. 342 b. Indications and use. 343 Dosage and administration. с. 344 d. Dosage forms and strengths. 345 e. Contraindications. 346 f. Warnings and precautions. q. Adverse reactions. 347 16.13. In addition to the packaging and labeling 348 requirements specified in subparagraphs 14. and 15., 11. and 349 12., marijuana in a form for smoking must be packaged in a 350

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351 sealed receptacle with a legible and prominent warning to keep 352 away from children and a warning that states marijuana smoke 353 contains carcinogens and may negatively affect health. Such 354 receptacles for marijuana in a form for smoking must be plain, 355 opaque, and white without depictions of the product or images 356 other than the medical marijuana treatment center's department-357 approved logo and the marijuana universal symbol.

358 <u>17.14.</u> The department shall adopt rules to regulate the 359 types, appearance, and labeling of marijuana delivery devices 360 dispensed from a medical marijuana treatment center. The rules 361 must require marijuana delivery devices to have an appearance 362 consistent with medical use.

18.15. Each edible shall be individually sealed in plain, 363 364 opaque wrapping marked only with the marijuana universal symbol. 365 Where practical, each edible shall be marked with the marijuana 366 universal symbol. In addition to the packaging and labeling 367 requirements in subparagraphs 14. and 15. 11. and 12., edible 368 receptacles must be plain, opaque, and white without depictions 369 of the product or images other than the medical marijuana 370 treatment center's department-approved logo and the marijuana 371 universal symbol. The receptacle must also include a list of all 372 the edible's ingredients, storage instructions, an expiration date, a legible and prominent warning to keep away from children 373 374 and pets, and a warning that the edible has not been produced or 375 inspected pursuant to federal food safety laws.

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376 <u>19.16.</u> When dispensing marijuana or a marijuana delivery 377 device, a medical marijuana treatment center:

a. May dispense any active, valid order for low-THC
cannabis, medical cannabis and cannabis delivery devices issued
pursuant to former s. 381.986, Florida Statutes 2016, which was
entered into the medical marijuana use registry before July 1,
2017.

b. May not dispense more than a 70-day supply of marijuana within any 70-day period to a qualified patient or caregiver. May not dispense more than one 35-day supply of marijuana in a form for smoking within any 35-day period to a qualified patient or caregiver. A 35-day supply of marijuana in a form for smoking may not exceed 2.5 ounces unless an exception to this amount is approved by the department pursuant to paragraph (4)(f).

390 c. Must have the medical marijuana treatment center's 391 employee who dispenses the marijuana or a marijuana delivery 392 device enter into the medical marijuana use registry his or her 393 name or unique employee identifier.

394 d. Must verify that the qualified patient and the 395 caregiver, if applicable, each have an active registration in 396 the medical marijuana use registry and an active and valid 397 medical marijuana use registry identification card, the amount 398 and type of marijuana dispensed matches the physician 399 certification in the medical marijuana use registry for that 400 qualified patient, and the physician certification has not

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401 already been filled.

e. May not dispense marijuana to a qualified patient who
is younger than 18 years of age. If the qualified patient is
younger than 18 years of age, marijuana may only be dispensed to
the qualified patient's caregiver.

f. May not dispense or sell any other type of cannabis, alcohol, or illicit drug-related product, including pipes or wrapping papers made with tobacco or hemp, other than a marijuana delivery device required for the medical use of marijuana and which is specified in a physician certification.

411 g. Must, upon dispensing the marijuana or marijuana 412 delivery device, record in the registry the date, time, 413 quantity, and form of marijuana dispensed; the type of marijuana 414 delivery device dispensed; and the name and medical marijuana 415 use registry identification number of the qualified patient or 416 caregiver to whom the marijuana delivery device was dispensed.

h. Must ensure that patient records are not visible to
anyone other than the qualified patient, his or her caregiver,
and authorized medical marijuana treatment center employees.

(h) A medical marijuana treatment center may not engage in
radio or television advertising or advertising that is visible
to members of the public from any street, sidewalk, park, or
other public place, except:

1. The dispensing location of a medical marijuanatreatment center may have a sign that is affixed to the outside

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426 or hanging in the window of the premises which identifies the 427 dispensary by the licensee's business name, a department-428 approved trade name, or a department-approved logo. A medical 429 marijuana treatment center's trade name and logo may not contain 430 wording or images commonly associated with marketing targeted 431 toward children or which promote recreational use of marijuana. 432 2. A medical marijuana treatment center may engage in 433 Internet advertising and marketing under the following 434 conditions: 435 a. All advertisements must be approved by the department. 436 An advertisement may not have any content that b. 437 specifically targets individuals under the age of 18, including 438 cartoon characters or similar images. 439 c. An advertisement may not be an unsolicited pop-up 440 advertisement. Opt-in marketing must include an easy and permanent 441 d. 442 opt-out feature. 443 (14) EXCEPTIONS TO OTHER LAWS.-444 (i) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or 445 any other provision of law, but subject to the requirements of 446 this section, the department, including an employee of the 447 department acting within the scope of his or her employment, may acquire, possess, test, transport, and lawfully dispose of 448 449 marijuana as provided in this section. 450 Section 2. Effective July 1, 2022, paragraphs (g) through

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451	(k) of subsection (4) of s. 381.986, Florida Statutes, are
452	redesignated as paragraphs (h) through (l), respectively,
453	paragraphs (a), (d), and (f) of that subsection, paragraph (e)
454	of subsection (8), and paragraph (a) of subsection (14) are
455	amended, and a new paragraph (g) is added to subsection (4) of
456	that section, to read:
457	381.986 Medical use of marijuana.—
458	(4) PHYSICIAN CERTIFICATION
459	(a) A qualified physician may issue a physician
460	certification only if the qualified physician:
461	1. Conducted a physical examination while physically
462	present in the same room as the patient and a full assessment of
463	the medical history of the patient.
464	2. Diagnosed the patient with at least one qualifying
465	medical condition.
466	3. Determined that the medical use of marijuana would
467	likely outweigh the potential health risks for the patient, and
468	such determination must be documented in the patient's medical
469	record. If a patient is younger than 18 years of age, a second
470	physician must concur with this determination, and such
471	concurrence must be documented in the patient's medical record.
472	4. Determined whether the patient is pregnant and
473	documented such determination in the patient's medical record. A
474	physician may not issue a physician certification, except for
475	low-THC cannabis, to a patient who is pregnant.
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476 5. Reviewed the patient's controlled drug prescription
477 history in the prescription drug monitoring program database
478 established pursuant to s. 893.055.

479 6. Reviews the medical marijuana use registry and
480 confirmed that the patient does not have an active physician
481 certification from another qualified physician.

482 7. Registers as the issuer of the physician certification 483 for the named qualified patient on the medical marijuana use 484 registry in an electronic manner determined by the department, 485 and:

a. Enters into the registry the contents of the physician
certification, including the patient's qualifying condition and
the dosage not to exceed the daily dose amount determined by the
department, the amount and forms of marijuana authorized for the
patient, and any types of marijuana delivery devices needed by
the patient for the medical use of marijuana.

492 b. Updates the registry within 7 days after any change is
493 made to the original physician certification to reflect such
494 change.

c. Deactivates the registration of the qualified patient
and the patient's caregiver when the physician no longer
recommends the medical use of marijuana for the patient.

8. Obtains the voluntary and informed written consent of
the patient for medical use of marijuana each time the qualified
physician issues a physician certification for the patient,

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which shall be maintained in the patient's medical record. The 501 502 patient, or the patient's parent or legal guardian if the 503 patient is a minor, must sign the informed consent acknowledging 504 that the qualified physician has sufficiently explained its 505 content. The qualified physician must use a standardized 506 informed consent form adopted in rule by the Board of Medicine 507 and the Board of Osteopathic Medicine, which must include, at a 508 minimum, information related to:

a. The Federal Government's classification of marijuana asa Schedule I controlled substance.

511 b. The approval and oversight status of marijuana by the 512 Food and Drug Administration.

513 c. The current state of research on the efficacy of 514 marijuana to treat the qualifying conditions set forth in this 515 section.

516

d. The potential for addiction.

e. The potential effect that marijuana may have on a patient's coordination, motor skills, and cognition, including a warning against operating heavy machinery, operating a motor vehicle, or engaging in activities that require a person to be alert or respond quickly.

522 f. The potential side effects of marijuana use, including 523 the negative health risks associated with smoking marijuana.

524 g. The risks, benefits, and drug interactions of 525 marijuana.

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h. That the patient's de-identified health information
contained in the physician certification and medical marijuana
use registry may be used for research purposes.

529 A qualified physician may not issue a physician (d) 530 certification to a patient under 18 years of age for marijuana, 531 except for low-THC cannabis, unless the qualified physician 532 determines that marijuana other than low-THC cannabis is the 533 most effective treatment for the patient and a second physician 534 who is a board-certified pediatrician concurs with such 535 determination. A qualified physician may not issue a physician 536 certification for marijuana in a form for smoking to a patient 537 under 18 years of age unless the patient is diagnosed with a terminal condition, the qualified physician determines that 538 539 smoking is the most effective route of administration for the 540 patient, and a second physician who is a board-certified pediatrician concurs with such determination. Such 541 542 determinations determination and concurrences concurrence must 543 be documented in the patient's medical record and in the medical 544 marijuana use registry. The certifying physician must obtain the 545 written informed consent of such patient's parent or legal 546 guardian before issuing a physician certification to the patient 547 for marijuana or marijuana in a form for smoking. The qualified physician must use a standardized informed consent form adopted 548 in rule by the Board of Medicine and the Board of Osteopathic 549 550 Medicine which must include information concerning the negative

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551 health effects of <u>marijuana and</u> smoking marijuana on persons 552 under 18 years of age and an acknowledgment that the qualified 553 physician has sufficiently explained the contents of the form.

554 A qualified physician may not issue a physician (f) 555 certification for more than three 70-day supply limits of 556 marijuana or more than six 35-day supply limits of marijuana in 557 a form for smoking. The department may shall quantify by rule a 558 daily dose amount with equivalent dose amounts for each allowable form of marijuana dispensed by a medical marijuana 559 treatment center. A 35-day supply of marijuana may not exceed 560 561 15,000 milligrams of tetrahydrocannabinol The department shall 562 use the daily dose amount to calculate a 70-day supply.

1. A qualified physician may request an exception to the daily dose amount limit, the 35-day supply limit of marijuana in a form for smoking, and the 4-ounce possession limit of marijuana in a form for smoking established in paragraph (14) (a). The request shall be made electronically on a form adopted by the department in rule and must include, at a minimum:

a. The qualified patient's qualifying medical condition.

571 b. The dosage and route of administration that was 572 insufficient to provide relief to the qualified patient.

573 c. A description of how the patient will benefit from an 574 increased amount.

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d. The minimum daily dose amount of marijuana that would

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576 be sufficient for the treatment of the qualified patient's 577 qualifying medical condition.

578 2. A qualified physician must provide the qualified 579 patient's records upon the request of the department.

580 3. The department shall approve or disapprove the request 581 within 14 days after receipt of the complete documentation 582 required by this paragraph. The request shall be deemed approved 583 if the department fails to act within this time period.

584 (g) A qualified physician may not issue a physician 585 certification for marijuana that has a tetrahydrocannabinol 586 potency, by weight or volume, of greater than 10 percent for 587 marijuana in a form for smoking or greater than 60 percent in 588 the final product for all other forms of marijuana, excluding 589 edibles. A qualified physician may certify marijuana with any 590 potency of tetrahydrocannabinol, if the qualified patient is 591 diagnosed with a terminal condition and the qualified physician 592 indicates such diagnosis on the physician certification.

593

(8) MEDICAL MARIJUANA TREATMENT CENTERS.-

(e) A licensed medical marijuana treatment center shall cultivate, process, transport, and dispense marijuana for medical use. A licensed medical marijuana treatment center may not contract for services directly related to the cultivation, processing, and dispensing of marijuana or marijuana delivery devices, except that a medical marijuana treatment center licensed pursuant to subparagraph (a)1. may contract with a

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601 single entity for the cultivation, processing, transporting, and 602 dispensing of marijuana and marijuana delivery devices. A 603 licensed medical marijuana treatment center must, at all times, 604 maintain compliance with the criteria demonstrated and 605 representations made in the initial application and the criteria 606 established in this subsection. Upon request, the department may 607 grant a medical marijuana treatment center a variance from the 608 representations made in the initial application. Consideration 609 of such a request shall be based upon the individual facts and 610 circumstances surrounding the request. A variance may not be granted unless the requesting medical marijuana treatment center 611 612 can demonstrate to the department that it has a proposed 613 alternative to the specific representation made in its 614 application which fulfills the same or a similar purpose as the 615 specific representation in a way that the department can reasonably determine will not be a lower standard than the 616 617 specific representation in the application. A variance may not 618 be granted from the requirements in subparagraph 2. and 619 subparagraphs (b)1. and 2.

620 1. A licensed medical marijuana treatment center may 621 transfer ownership to an individual or entity who meets the 622 requirements of this section. A publicly traded corporation or 623 publicly traded company that meets the requirements of this 624 section is not precluded from ownership of a medical marijuana 625 treatment center. To accommodate a change in ownership:

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a. The licensed medical marijuana treatment center shall
notify the department in writing at least 60 days before the
anticipated date of the change of ownership.

b. The individual or entity applying for initial licensure
due to a change of ownership must submit an application that
must be received by the department at least 60 days before the
date of change of ownership.

c. Upon receipt of an application for a license, the
department shall examine the application and, within 30 days
after receipt, notify the applicant in writing of any apparent
errors or omissions and request any additional information
required.

d. Requested information omitted from an application for
licensure must be filed with the department within 21 days after
the department's request for omitted information or the
application shall be deemed incomplete and shall be withdrawn
from further consideration and the fees shall be forfeited.

644 Within 30 days after the receipt of a complete application, the 645 department shall approve or deny the application.

646 2. A medical marijuana treatment center, and any 647 individual or entity who directly or indirectly owns, controls, 648 or holds with power to vote 5 percent or more of the voting 649 shares of a medical marijuana treatment center, may not acquire 650 direct or indirect ownership or control of any voting shares or

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651 other form of ownership of any other medical marijuana treatment 652 center.

3. A medical marijuana treatment center and any individual or entity that directly or indirectly owns, controls, or holds with power to vote 5 percent or more of the voting shares of a medical marijuana treatment center may not employ a qualified physician or have any direct or indirect economic interest in a qualified physician's practice or a marijuana testing laboratory.

4. A medical marijuana treatment center may not enter into
any form of profit-sharing arrangement with the property owner
or lessor of any of its facilities where cultivation,
processing, storing, or dispensing of marijuana and marijuana
delivery devices occurs.

665 5. All employees of a medical marijuana treatment center
666 must be 21 years of age or older and have passed a background
667 screening pursuant to subsection (9).

6. Each medical marijuana treatment center must adopt and
enforce policies and procedures to ensure employees and
volunteers receive training on the legal requirements to
dispense marijuana to qualified patients.

672 7. When growing marijuana, a medical marijuana treatment673 center:

a. May use pesticides determined by the department, afterconsultation with the Department of Agriculture and Consumer

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676 Services, to be safely applied to plants intended for human
677 consumption, but may not use pesticides designated as
678 restricted-use pesticides pursuant to s. 487.042.

b. Must grow marijuana within an enclosed structure and ina room separate from any other plant.

c. Must inspect seeds and growing plants for plant pests
that endanger or threaten the horticultural and agricultural
interests of the state in accordance with chapter 581 and any
rules adopted thereunder.

d. Must perform fumigation or treatment of plants, or
remove and destroy infested or infected plants, in accordance
with chapter 581 and any rules adopted thereunder.

8. Each medical marijuana treatment center must produce
and make available for purchase at least one low-THC cannabis
product.

691 9. A medical marijuana treatment center that produces 692 edibles must hold a permit to operate as a food establishment 693 pursuant to chapter 500, the Florida Food Safety Act, and must 694 comply with all the requirements for food establishments 695 pursuant to chapter 500 and any rules adopted thereunder. 696 Edibles may not contain more than 200 milligrams of 697 tetrahydrocannabinol, and a single serving portion of an edible may not exceed 10 milligrams of tetrahydrocannabinol. Edibles 698 may have a potency variance of no greater than 15 percent of the 699 10 milligrams of tetrahydrocannabinol per single serving limit 700

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or 15 percent of the 200 milligrams of tetrahydrocannabinol per 701 702 product limit. Edibles may not be attractive to children; be 703 manufactured in the shape of humans, cartoons, or animals; be 704 manufactured in a form that bears any reasonable resemblance to 705 products available for consumption as commercially available 706 candy; or contain any color additives. To discourage consumption 707 of edibles by children, the department shall determine by rule 708 any shapes, forms, and ingredients allowed and prohibited for 709 edibles. Medical marijuana treatment centers may not begin processing or dispensing edibles until after the effective date 710 of the rule. The department shall also adopt sanitation rules 711 712 providing the standards and requirements for the storage, 713 display, or dispensing of edibles.

714 10. Within 12 months after licensure, a medical marijuana 715 treatment center must demonstrate to the department that all of 716 its processing facilities have passed a Food Safety Good 717 Manufacturing Practices, such as Global Food Safety Initiative 718 or equivalent, inspection by a nationally accredited certifying 719 body. A medical marijuana treatment center must immediately stop 720 processing at any facility which fails to pass this inspection 721 until it demonstrates to the department that such facility has 722 met this requirement.

11. A medical marijuana treatment center that produces
prerolled marijuana cigarettes may not use wrapping paper made
with tobacco or hemp.

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726 12. When processing marijuana, a medical marijuana727 treatment center must:

a. Process the marijuana within an enclosed structure andin a room separate from other plants or products.

b. Comply with department rules when processing marijuana with hydrocarbon solvents or other solvents or gases exhibiting potential toxicity to humans. The department shall determine by rule the requirements for medical marijuana treatment centers to use such solvents or gases exhibiting potential toxicity to humans.

c. Comply with federal and state laws and regulations and
department rules for solid and liquid wastes. The department
shall determine by rule procedures for the storage, handling,
transportation, management, and disposal of solid and liquid
waste generated during marijuana production and processing. The
Department of Environmental Protection shall assist the
department in developing such rules.

743 A medical marijuana treatment center must test 13. 744 marijuana using a medical marijuana testing laboratory before it 745 is dispensed. Results must be verified and signed by two medical 746 marijuana treatment center employees. Before dispensing, the 747 medical marijuana treatment center must determine that the test results indicate that low-THC cannabis meets the definition of 748 749 low-THC cannabis, the concentration of tetrahydrocannabinol 750 meets the potency requirements of this section, the labeling of

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751 the concentration of tetrahydrocannabinol and cannabidiol is 752 accurate, and all marijuana is safe for human consumption and 753 free from contaminants that are unsafe for human consumption. 754 The department shall determine by rule which contaminants must 755 be tested for and the maximum levels of each contaminant which 756 are safe for human consumption. The Department of Agriculture 757 and Consumer Services shall assist the department in developing 758 the testing requirements for contaminants that are unsafe for 759 human consumption in edibles. The department shall also 760 determine by rule the procedures for the treatment of marijuana 761 that fails to meet the testing requirements of this section, s. 762 381.988, or department rule. The department may select samples 763 of marijuana available in a cultivation facility, processing 764 facility, or for purchase in a dispensing facility which shall 765 be tested by the department to determine that the marijuana 766 meets the potency requirements of this section, is safe for 767 human consumption, and the labeling of the tetrahydrocannabinol 768 and cannabidiol concentration is accurate or to verify medical 769 marijuana testing laboratory results. The department may also 770 sample marijuana delivery devices from a dispensing facility to 771 determine that the marijuana delivery device is safe for use by 772 qualified patients. A medical marijuana treatment center may not require payment from the department for the sample. A medical 773 774 marijuana treatment center must recall all marijuana which fails 775 to meet the potency requirements of this section, which is

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776 unsafe for human consumption, or for which the labeling of the 777 tetrahydrocannabinol and cannabidiol concentration is 778 inaccurate. The medical marijuana treatment center must retain 779 records of all testing and samples of each homogenous batch of 780 marijuana for at least 9 months. The medical marijuana treatment 781 center must contract with a marijuana testing laboratory to 782 perform audits on the medical marijuana treatment center's 783 standard operating procedures, testing records, and samples and 784 provide the results to the department to confirm that the 785 marijuana or low-THC cannabis meets the requirements of this section and that the marijuana or low-THC cannabis is safe for 786 787 human consumption. A medical marijuana treatment center shall 788 reserve two processed samples from each batch and retain such 789 samples for at least 9 months for the purpose of such audits. A 790 medical marijuana treatment center may use a laboratory that has 791 not been certified by the department under s. 381.988 until such 792 time as at least one laboratory holds the required 793 certification, but in no event later than July 1, 2018. 794 14. When packaging marijuana, a medical marijuana 795 treatment center must: 796 Package the marijuana in compliance with the United a.

797 States Poison Prevention Packaging Act of 1970, 15 U.S.C. ss.798 1471 et seq.

b. Package the marijuana in a receptacle that has a firmlyaffixed and legible label stating the following information:

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The marijuana or low-THC cannabis meets the 801 (I) 802 requirements of subparagraph 13. 803 (II) The name of the medical marijuana treatment center 804 from which the marijuana originates. 805 (III) The batch number and harvest number from which the 806 marijuana originates and the date dispensed. 807 (IV) The name of the physician who issued the physician certification. 808 809 The name of the patient. (V) The product name, if applicable, and dosage form, 810 (VI) including concentration of tetrahydrocannabinol and cannabidiol. 811 812 The product name may not contain wording commonly associated 813 with products marketed by or to children. 814 (VII) The recommended dose. 815 (VIII) A warning that it is illegal to transfer medical 816 marijuana to another person. 817 (IX) A marijuana universal symbol developed by the 818 department. 819 15. The medical marijuana treatment center shall include 820 in each package a patient package insert with information on the 821 specific product dispensed related to: 822 a. Clinical pharmacology. b. Indications and use. 823 824 c. Dosage and administration. 825 d. Dosage forms and strengths.

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e. Contraindications.

- f. Warnings and precautions.
- 828

q. Adverse reactions.

829 16. In addition to the packaging and labeling requirements 830 specified in subparagraphs 14. and 15., marijuana in a form for 831 smoking must be packaged in a sealed receptacle with a legible 832 and prominent warning to keep away from children and a warning 833 that states marijuana smoke contains carcinogens and may negatively affect health. Such receptacles for marijuana in a 834 835 form for smoking must be plain, opaque, and white without 836 depictions of the product or images other than the medical 837 marijuana treatment center's department-approved logo and the 838 marijuana universal symbol.

839 17. The department shall adopt rules to regulate the 840 types, appearance, and labeling of marijuana delivery devices 841 dispensed from a medical marijuana treatment center. The rules 842 must require marijuana delivery devices to have an appearance 843 consistent with medical use.

18. Each edible shall be individually sealed in plain, opaque wrapping marked only with the marijuana universal symbol. Where practical, each edible shall be marked with the marijuana universal symbol. In addition to the packaging and labeling requirements in subparagraphs 14. and 15., edible receptacles must be plain, opaque, and white without depictions of the product or images other than the medical marijuana treatment

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851 center's department-approved logo and the marijuana universal 852 symbol. The receptacle must also include a list of all the 853 edible's ingredients, storage instructions, an expiration date, 854 a legible and prominent warning to keep away from children and 855 pets, and a warning that the edible has not been produced or 856 inspected pursuant to federal food safety laws.

857 19. When dispensing marijuana or a marijuana delivery858 device, a medical marijuana treatment center:

a. May dispense any active, valid order for low-THC
cannabis, medical cannabis and cannabis delivery devices issued
pursuant to former s. 381.986, Florida Statutes 2016, which was
entered into the medical marijuana use registry before July 1,
2017.

864 b. May not dispense more than two 35-day supplies a 70-day 865 supply of marijuana within any 70-day period to a qualified 866 patient or caregiver. May not dispense more than one 35-day 867 supply of marijuana in a form for smoking within any 35-day 868 period to a qualified patient or caregiver. A 35-day supply of 869 marijuana in a form for smoking may not exceed 15,000 milligrams 870 of tetrahydrocannabinol 2.5 ounces unless an exception to this 871 amount is approved by the department pursuant to paragraph 872 (4)(f).

c. Must have the medical marijuana treatment center's
employee who dispenses the marijuana or a marijuana delivery
device enter into the medical marijuana use registry his or her

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876 name or unique employee identifier.

877 Must verify that the qualified patient and the d. 878 caregiver, if applicable, each have an active registration in 879 the medical marijuana use registry and an active and valid 880 medical marijuana use registry identification card, the amount 881 and type of marijuana dispensed matches the physician 882 certification in the medical marijuana use registry for that 883 qualified patient, and the physician certification has not 884 already been filled.

e. May not dispense marijuana to a qualified patient who is younger than 18 years of age. If the qualified patient is younger than 18 years of age, marijuana may only be dispensed to the qualified patient's caregiver.

889 f. May not dispense marijuana that has a 890 tetrahydrocannabinol potency, by weight or volume, of greater 891 than 10 percent for marijuana in a form for smoking or greater 892 than 60 percent in the final product for all other forms of 893 marijuana, excluding edibles, to a qualified patient or 894 caregiver, unless the qualified physician certification 895 indicates that the qualified patient has been diagnosed with a 896 terminal condition.

897 <u>g.f.</u> May not dispense or sell any other type of cannabis, 898 alcohol, or illicit drug-related product, including pipes or 899 wrapping papers made with tobacco or hemp, other than a 900 marijuana delivery device required for the medical use of

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901	marijuana and which is specified in a physician certification.
902	<u>h.g.</u> Must, upon dispensing the marijuana or marijuana
903	delivery device, record in the registry the date, time,
904	quantity, and form of marijuana dispensed; the type of marijuana
905	delivery device dispensed; and the name and medical marijuana
906	use registry identification number of the qualified patient or
907	caregiver to whom the marijuana delivery device was dispensed.
908	<u>i.</u> h. Must ensure that patient records are not visible to
909	anyone other than the qualified patient, his or her caregiver,
910	and authorized medical marijuana treatment center employees.
911	(14) EXCEPTIONS TO OTHER LAWS
912	(a) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or
913	any other provision of law, but subject to the requirements of
914	this section, a qualified patient and the qualified patient's
915	caregiver may purchase from a medical marijuana treatment center
916	for the patient's medical use a marijuana delivery device and up
917	to the amount of marijuana authorized in the physician
918	certification, but may not possess more than two 35-day supplies
919	a 70-day supply of marijuana, or the greater of 4 ounces of
920	marijuana in a form for smoking or an amount of marijuana in a
921	form for smoking approved by the department pursuant to
922	paragraph (4)(f), at any given time and all marijuana purchased
923	must remain in its original packaging.

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924	Section 3. Subsection (11) of section 381.988, Florida
925	Statutes, is renumbered as subsection (13), and new subsections
926	(11) and (12) are added to that section, to read:
927	381.988 Medical marijuana testing laboratories; marijuana
928	tests conducted by a certified laboratory
929	(11) A certified medical marijuana testing laboratory and
930	its officers, directors, and employees may not have a direct or
931	indirect economic interest in, or financial relationship with, a
932	medical marijuana treatment center. Nothing in this subsection
933	may be construed to prohibit a certified medical marijuana
934	testing laboratory from contracting with a medical marijuana
935	treatment center to provide testing services.
936	(12) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or
937	any other provision of law, but subject to the requirements of
938	this section, the department, including an employee of the
939	department acting within the scope of his or her employment, may
940	acquire, possess, test, transport, and lawfully dispose of
941	marijuana as provided in this section.
942	Section 4. Except as otherwise expressly provided in this
943	act, this act shall take effect July 1, 2021.

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