1	A bill to be entitled
2	An act relating to the medical use of marijuana;
3	amending s. 381.986, F.S.; revising a definition;
4	requiring a qualified patient's informed consent to
5	include the negative health risks associated with
6	smoking; requiring a qualified physician to submit
7	specified documentation to the Board of Medicine and
8	the Board of Osteopathic Medicine upon determination
9	that smoking is an appropriate route of administration
10	for a qualified patient, other than a terminally ill
11	patient; prohibiting a physician from authorizing
12	marijuana in a form for smoking for qualified patients
13	under 18 years of age; requiring the Board of Medicine
14	and the Board of Osteopathic Medicine to adopt by rule
15	practice standards for certifying smoking as a route
16	of administration; requiring certain medical marijuana
17	treatment centers to comply with certain standards in
18	the production and packaging of marijuana in a form
19	for smoking; providing applicability; amending s.
20	381.987, F.S.; conforming provisions to changes made
21	by the act; amending s. 1004.4351, F.S.; renaming the
22	Coalition for Medical Marijuana Research and Education
23	as the Consortium for Medical Marijuana Clinical
24	Outcomes Research; establishing the consortium within
25	a state university designated by the Board of
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26 Governors; renaming the Medical Marijuana Research and 27 Education Board as the Medical Marijuana Research 28 Board; requiring the board to direct the operations of 29 the consortium; requiring the board to annually adopt 30 a plan for medical marijuana research; providing duties of the consortium director; providing research 31 32 requirements for the plan; requiring the board to 33 issue an annual report to the Governor and Legislature by a specified date; requiring the Department of 34 35 Health to submit reports to the board containing 36 specified data; deleting responsibilities of the H. 37 Lee Moffitt Cancer Center and Research Institute, Inc.; providing appropriations; providing an effective 38 39 date. 40 41 Be It Enacted by the Legislature of the State of Florida: 42 43 Section 1. Paragraph (j) of subsection (1), subsection 44 (4), paragraphs (b) and (e) of subsection (8), and subsection (15) of section 381.986, Florida Statutes, are amended to read: 45 381.986 Medical use of marijuana.-46 DEFINITIONS.-As used in this section, the term: 47 (1)

(j) "Medical use" means the acquisition, possession, use, delivery, transfer, or administration of marijuana authorized by a physician certification. The term does not include:

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51 1. Possession, use, or administration of marijuana that 52 was not purchased or acquired from a medical marijuana treatment 53 center.

2. Possession, use, or administration of marijuana in a form for smoking <u>other than prerolled marijuana cigarettes</u>, in the form of commercially produced food items other than edibles, or of marijuana seeds or flower, except for flower in a sealed, tamper-proof receptacle for vaping <u>or flower in prerolled</u> marijuana cigarettes.

3. Use or administration of any form or amount of
marijuana in a manner that is inconsistent with the qualified
physician's directions or physician certification.

4. Transfer of marijuana to a person other than the
qualified patient for whom it was authorized or the qualified
patient's caregiver on behalf of the qualified patient.

5. Use or administration of marijuana in the followinglocations:

a. On any form of public transportation, except for low-THC cannabis not in a form for smoking.

D. In any public place, except for low-THC cannabis <u>not in</u>
a form for smoking.

72 c. In a qualified patient's place of employment, except73 when permitted by his or her employer.

74 d. In a state correctional institution, as defined in s.
75 944.02, or a correctional institution, as defined in s. 944.241.

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76 On the grounds of a preschool, primary school, or е. 77 secondary school, except as provided in s. 1006.062. 78 f. In a school bus, a vehicle, an aircraft, or a 79 motorboat, except for low-THC cannabis not in a form for 80 smoking. 81 6. The smoking of marijuana in an enclosed indoor 82 workplace as defined in s. 386.203(5). 83 (4) PHYSICIAN CERTIFICATION.-A qualified physician may issue a physician 84 (a) certification only if the qualified physician: 85 1. Conducted a physical examination while physically 86 87 present in the same room as the patient and a full assessment of the medical history of the patient. 88 2. 89 Diagnosed the patient with at least one qualifying 90 medical condition. Determined that the medical use of marijuana would 91 3. 92 likely outweigh the potential health risks for the patient, and 93 such determination must be documented in the patient's medical 94 record. If a patient is younger than 18 years of age, a second 95 physician must concur with this determination, and such 96 concurrence must be documented in the patient's medical record. Determined whether the patient is pregnant and 97 4. documented such determination in the patient's medical record. A 98 physician may not issue a physician certification, except for 99 100 low-THC cannabis, to a patient who is pregnant. Page 4 of 33

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101 5. Reviewed the patient's controlled drug prescription
102 history in the prescription drug monitoring program database
103 established pursuant to s. 893.055.

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

107 7. Registers as the issuer of the physician certification 108 for the named qualified patient on the medical marijuana use 109 registry in an electronic manner determined by the department, 110 and:

111 a. Enters into the registry the contents of the physician 112 certification, including the patient's qualifying condition and 113 the dosage not to exceed the daily dose amount determined by the 114 department, the amount and forms of marijuana authorized for the 115 patient, and any types of marijuana delivery devices needed by 116 the patient for the medical use of marijuana.

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

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

123 8. Obtains the voluntary and informed written consent of 124 the patient for medical use of marijuana each time the qualified 125 physician issues a physician certification for the patient,

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126 which shall be maintained in the patient's medical record. The 127 patient, or the patient's parent or legal guardian if the 128 patient is a minor, must sign the informed consent acknowledging 129 that the qualified physician has sufficiently explained its 130 content. The qualified physician must use a standardized 131 informed consent form adopted in rule by the Board of Medicine 132 and the Board of Osteopathic Medicine, which must include, at a 133 minimum, information related to:

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

b. The approval and oversight status of marijuana by theFood and Drug Administration.

138 c. The current state of research on the efficacy of 139 marijuana to treat the qualifying conditions set forth in this 140 section.

141

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.

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

g. The risks, benefits, and drug interactions ofmarijuana.

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151 That the patient's de-identified health information h. contained in the physician certification and medical marijuana 152 153 use registry may be used for research purposes. 154 If a qualified physician issues a physician (b) 155 certification for a qualified patient diagnosed with a 156 qualifying medical condition pursuant to paragraph (2)(k), the 157 physician must submit the following to the applicable board 158 within 14 days after issuing the physician certification: Documentation supporting the qualified physician's 159 1. opinion that the medical condition is of the same kind or class 160 as the conditions in paragraphs (2)(a)-(j). 161 162 2. Documentation that establishes the efficacy of marijuana as treatment for the condition. 163 164 3. Documentation supporting the qualified physician's 165 opinion that the benefits of medical use of marijuana would 166 likely outweigh the potential health risks for the patient. 167 4. Any other documentation as required by board rule. 168 169 The department must submit such documentation to the Consortium 170 Coalition for Medical Marijuana Clinical Outcomes Research and 171 Education established pursuant to s. 1004.4351. 172 (c) If a qualified physician determines smoking is an appropriate route of administration for a qualified patient, 173 174 other than a terminally ill patient, the qualified physician 175 must submit the following documentation to the applicable board:

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200

176 1. A list of other routes of administration, if any, 177 certified by a qualified physician that the patient has tried, 178 the length of time the patient used such routes of 179 administration, and an assessment of the effectiveness of those 180 routes of administration in treating the qualified patient's 181 qualifying condition. 182 2. Research documenting the effectiveness of smoking as a 183 route of administration to treat similarly situated patients 184 with the same qualifying condition as the qualified patient. 185 3. A statement signed by the qualified physician documenting the qualified physician's opinion that the benefits 186 187 of smoking as a route of administration outweigh the risks for 188 the qualified patient. 189 (d) A physician may not authorize marijuana in a form for 190 smoking for a patient under 18 years of age. 191 (e) The Board of Medicine and the Board of Osteopathic 192 Medicine shall review the documentation submitted pursuant to 193 paragraph (c) and shall each, by July 1, 2021, adopt by rule 194 practice standards for the certification of smoking as a route 195 of administration. 196 (f) (c) A qualified physician may not issue a physician 197 certification for more than three 70-day supply limits of marijuana. The department shall quantify by rule a daily dose 198 amount with equivalent dose amounts for each allowable form of 199

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marijuana dispensed by a medical marijuana treatment center. The

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201 department shall use the daily dose amount to calculate a 70-day
202 supply.

1. A qualified physician may request an exception to the daily dose amount limit. The request shall be made electronically on a form adopted by the department in rule and must include, at a minimum:

207

a. The qualified patient's qualifying medical condition.

208b. The dosage and route of administration that was209insufficient to provide relief to the qualified patient.

210 c. A description of how the patient will benefit from an 211 increased amount.

d. The minimum daily dose amount of marijuana that would
be sufficient for the treatment of the qualified patient's
qualifying medical condition.

215 2. A qualified physician must provide the qualified216 patient's records upon the request of the department.

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

221 (g)(d) A qualified physician must evaluate an existing 222 qualified patient at least once every 30 weeks before issuing a 223 new physician certification. A physician must:

Determine if the patient still meets the requirements
 to be issued a physician certification under paragraph (a).

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226 2. Identify and document in the qualified patient's 227 medical records whether the qualified patient experienced either 228 of the following related to the medical use of marijuana:

a. An adverse drug interaction with any prescription ornonprescription medication; or

b. A reduction in the use of, or dependence on, othertypes of controlled substances as defined in s. 893.02.

3. Submit a report with the findings required pursuant to subparagraph 2. to the department. The department shall submit such reports to the <u>Consortium</u> Coalition for Medical Marijuana <u>Clinical Outcomes</u> Research and Education established pursuant to s. 1004.4351.

238 (h) (e) An active order for low-THC cannabis or medical 239 cannabis issued pursuant to former s. 381.986, Florida Statutes 240 2016, and registered with the compassionate use registry before 241 June 23, 2017, is deemed a physician certification, and all 242 patients possessing such orders are deemed qualified patients 243 until the department begins issuing medical marijuana use 244 registry identification cards.

245 <u>(i) (f)</u> The department shall monitor physician registration 246 in the medical marijuana use registry and the issuance of 247 physician certifications for practices that could facilitate 248 unlawful diversion or misuse of marijuana or a marijuana 249 delivery device and shall take disciplinary action as 250 appropriate.

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251 (j) (g) The Board of Medicine and the Board of Osteopathic 252 Medicine shall jointly create a physician certification pattern 253 review panel that shall review all physician certifications 254 submitted to the medical marijuana use registry. The panel shall 255 track and report the number of physician certifications and the 256 qualifying medical conditions, dosage, supply amount, and form 257 of marijuana certified. The panel shall report the data both by 258 individual qualified physician and in the aggregate, by county, and statewide. The physician certification pattern review panel 259 shall, beginning January 1, 2018, submit an annual report of its 260 261 findings and recommendations to the Governor, the President of 262 the Senate, and the Speaker of the House of Representatives.

263 <u>(k) (h)</u> The department, the Board of Medicine, and the 264 Board of Osteopathic Medicine may adopt rules pursuant to ss. 265 120.536(1) and 120.54 to implement this subsection.

266

(8) MEDICAL MARIJUANA TREATMENT CENTERS.-

267 (b) An applicant for licensure as a medical marijuana 268 treatment center shall apply to the department on a form 269 prescribed by the department and adopted in rule. The department 270 shall adopt rules pursuant to ss. 120.536(1) and 120.54 271 establishing a procedure for the issuance and biennial renewal 272 of licenses, including initial application and biennial renewal fees sufficient to cover the costs of implementing and 273 administering this section, and establishing supplemental 274 licensure fees for payment beginning May 1, 2018, sufficient to 275

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276 cover the costs of administering s. 381.989 ss. 381.989 and 277 1004.4351. The department shall identify applicants with strong 278 diversity plans reflecting this state's commitment to diversity 279 and implement training programs and other educational programs 280 to enable minority persons and minority business enterprises, as 281 defined in s. 288.703, and veteran business enterprises, as 282 defined in s. 295.187, to compete for medical marijuana 283 treatment center licensure and contracts. Subject to the 284 requirements in subparagraphs (a)2.-4., the department shall 285 issue a license to an applicant if the applicant meets the requirements of this section and pays the initial application 286 287 fee. The department shall renew the licensure of a medical marijuana treatment center biennially if the licensee meets the 288 289 requirements of this section and pays the biennial renewal fee. 290 An individual may not be an applicant, owner, officer, board 291 member, or manager on more than one application for licensure as 292 a medical marijuana treatment center. An individual or entity 293 may not be awarded more than one license as a medical marijuana 294 treatment center. An applicant for licensure as a medical 295 marijuana treatment center must demonstrate:

296 1. That, for the 5 consecutive years before submitting the 297 application, the applicant has been registered to do business in 298 the state.

2. Possession of a valid certificate of registration
 300 issued by the Department of Agriculture and Consumer Services

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301 pursuant to s. 581.131.

302 3. The technical and technological ability to cultivate 303 and produce marijuana, including, but not limited to, low-THC 304 cannabis.

305 4. The ability to secure the premises, resources, and 306 personnel necessary to operate as a medical marijuana treatment 307 center.

308 5. The ability to maintain accountability of all raw 309 materials, finished products, and any byproducts to prevent 310 diversion or unlawful access to or possession of these 311 substances.

312 6. An infrastructure reasonably located to dispense
313 marijuana to registered qualified patients statewide or
314 regionally as determined by the department.

315 7. The financial ability to maintain operations for the 316 duration of the 2-year approval cycle, including the provision 317 of certified financial statements to the department.

a. Upon approval, the applicant must post a \$5 million
performance bond issued by an authorized surety insurance
company rated in one of the three highest rating categories by a
nationally recognized rating service. However, a medical
marijuana treatment center serving at least 1,000 qualified
patients is only required to maintain a \$2 million performance
bond.

325

b. In lieu of the performance bond required under sub-

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subparagraph a., the applicant may provide an irrevocable letter 326 327 of credit payable to the department or provide cash to the 328 department. If provided with cash under this sub-subparagraph, 329 the department shall deposit the cash in the Grants and 330 Donations Trust Fund within the Department of Health, subject to 331 the same conditions as the bond regarding requirements for the 332 applicant to forfeit ownership of the funds. If the funds 333 deposited under this sub-subparagraph generate interest, the amount of that interest shall be used by the department for the 334 administration of this section. 335

336 8. That all owners, officers, board members, and managers337 have passed a background screening pursuant to subsection (9).

338 9. The employment of a medical director to supervise the339 activities of the medical marijuana treatment center.

340 10. A diversity plan that promotes and ensures the 341 involvement of minority persons and minority business 342 enterprises, as defined in s. 288.703, or veteran business 343 enterprises, as defined in s. 295.187, in ownership, management, 344 and employment. An applicant for licensure renewal must show the 345 effectiveness of the diversity plan by including the following 346 with his or her application for renewal:

347 a. Representation of minority persons and veterans in the348 medical marijuana treatment center's workforce;

349 b. Efforts to recruit minority persons and veterans for 350 employment; and

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351 A record of contracts for services with minority с. 352 business enterprises and veteran business enterprises. 353 A licensed medical marijuana treatment center shall (e) 354 cultivate, process, transport, and dispense marijuana for 355 medical use. A licensed medical marijuana treatment center may 356 not contract for services directly related to the cultivation, 357 processing, and dispensing of marijuana or marijuana delivery 358 devices, except that a medical marijuana treatment center 359 licensed pursuant to subparagraph (a)1. may contract with a single entity for the cultivation, processing, transporting, and 360 361 dispensing of marijuana and marijuana delivery devices. A 362 licensed medical marijuana treatment center must, at all times, 363 maintain compliance with the criteria demonstrated and 364 representations made in the initial application and the criteria 365 established in this subsection. Upon request, the department may 366 grant a medical marijuana treatment center a variance from the 367 representations made in the initial application. Consideration 368 of such a request shall be based upon the individual facts and 369 circumstances surrounding the request. A variance may not be 370 granted unless the requesting medical marijuana treatment center 371 can demonstrate to the department that it has a proposed 372 alternative to the specific representation made in its application which fulfills the same or a similar purpose as the 373 374 specific representation in a way that the department can 375 reasonably determine will not be a lower standard than the

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376 specific representation in the application. A variance may not 377 be granted from the requirements in subparagraph 2. and 378 subparagraphs (b)1. and 2.

379 1. A licensed medical marijuana treatment center may 380 transfer ownership to an individual or entity who meets the 381 requirements of this section. A publicly traded corporation or 382 publicly traded company that meets the requirements of this 383 section is not precluded from ownership of a medical marijuana 384 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.

392 c. Upon receipt of an application for a license, the 393 department shall examine the application and, within 30 days 394 after receipt, notify the applicant in writing of any apparent 395 errors or omissions and request any additional information 396 required.

397 d. Requested information omitted from an application for
398 licensure must be filed with the department within 21 days after
399 the department's request for omitted information or the
400 application shall be deemed incomplete and shall be withdrawn

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from further consideration and the fees shall be forfeited. 401 402 403 Within 30 days after the receipt of a complete application, the 404 department shall approve or deny the application. 405 2. A medical marijuana treatment center, and any 406 individual or entity who directly or indirectly owns, controls, 407 or holds with power to vote 5 percent or more of the voting 408 shares of a medical marijuana treatment center, may not acquire direct or indirect ownership or control of any voting shares or 409 410 other form of ownership of any other medical marijuana treatment 411 center. 412 3. A medical marijuana treatment center may not enter into 413 any form of profit-sharing arrangement with the property owner 414 or lessor of any of its facilities where cultivation, 415 processing, storing, or dispensing of marijuana and marijuana 416 delivery devices occurs. 417 4. All employees of a medical marijuana treatment center 418 must be 21 years of age or older and have passed a background 419 screening pursuant to subsection (9). 420 5. Each medical marijuana treatment center must adopt and 421 enforce policies and procedures to ensure employees and 422 volunteers receive training on the legal requirements to dispense marijuana to qualified patients. 423 424 When growing marijuana, a medical marijuana treatment 6. 425 center: Page 17 of 33

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426 May use pesticides determined by the department, after a. 427 consultation with the Department of Agriculture and Consumer 428 Services, to be safely applied to plants intended for human 429 consumption, but may not use pesticides designated as 430 restricted-use pesticides pursuant to s. 487.042. 431 Must grow marijuana within an enclosed structure and in b. 432 a room separate from any other plant. 433 Must inspect seeds and growing plants for plant pests с. 434 that endanger or threaten the horticultural and agricultural 435 interests of the state in accordance with chapter 581 and any 436 rules adopted thereunder. 437 d. Must perform fumigation or treatment of plants, or remove and destroy infested or infected plants, in accordance 438 439 with chapter 581 and any rules adopted thereunder. 440 Each medical marijuana treatment center must produce 7. and make available for purchase at least one low-THC cannabis 441 442 product. 443 8. A medical marijuana treatment center that produces 444 edibles must hold a permit to operate as a food establishment 445 pursuant to chapter 500, the Florida Food Safety Act, and must 446 comply with all the requirements for food establishments 447 pursuant to chapter 500 and any rules adopted thereunder. Edibles may not contain more than 200 milligrams of 448 tetrahydrocannabinol, and a single serving portion of an edible 449 450 may not exceed 10 milligrams of tetrahydrocannabinol. Edibles Page 18 of 33

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451 may have a potency variance of no greater than 15 percent. 452 Edibles may not be attractive to children; be manufactured in 453 the shape of humans, cartoons, or animals; be manufactured in a 454 form that bears any reasonable resemblance to products available 455 for consumption as commercially available candy; or contain any 456 color additives. To discourage consumption of edibles by 457 children, the department shall determine by rule any shapes, 458 forms, and ingredients allowed and prohibited for edibles. 459 Medical marijuana treatment centers may not begin processing or dispensing edibles until after the effective date of the rule. 460 461 The department shall also adopt sanitation rules providing the 462 standards and requirements for the storage, display, or 463 dispensing of edibles.

464 9. Within 12 months after licensure, a medical marijuana 465 treatment center must demonstrate to the department that all of 466 its processing facilities have passed a Food Safety Good 467 Manufacturing Practices, such as Global Food Safety Initiative 468 or equivalent, inspection by a nationally accredited certifying 469 body. A medical marijuana treatment center must immediately stop 470 processing at any facility which fails to pass this inspection 471 until it demonstrates to the department that such facility has 472 met this requirement.

473 <u>10. A medical marijuana treatment center that produces</u>
474 <u>prerolled marijuana cigarettes may not use wrapping paper made</u>
475 <u>with tobacco or hemp.</u>

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476 <u>11.10.</u> When processing marijuana, a medical marijuana 477 treatment center must:

478 a. Process the marijuana within an enclosed structure and479 in 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.

486 c. Comply with federal and state laws and regulations and 487 department rules for solid and liquid wastes. The department 488 shall determine by rule procedures for the storage, handling, 489 transportation, management, and disposal of solid and liquid 490 waste generated during marijuana production and processing. The 491 Department of Environmental Protection shall assist the 492 department in developing such rules.

Test the processed marijuana using a medical marijuana 493 d. 494 testing laboratory before it is dispensed. Results must be 495 verified and signed by two medical marijuana treatment center 496 employees. Before dispensing, the medical marijuana treatment 497 center must determine that the test results indicate that low-THC cannabis meets the definition of low-THC cannabis, the 498 concentration of tetrahydrocannabinol meets the potency 499 requirements of this section, the labeling of the concentration 500

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501 of tetrahydrocannabinol and cannabidiol is accurate, and all 502 marijuana is safe for human consumption and free from 503 contaminants that are unsafe for human consumption. The 504 department shall determine by rule which contaminants must be 505 tested for and the maximum levels of each contaminant which are 506 safe for human consumption. The Department of Agriculture and 507 Consumer Services shall assist the department in developing the 508 testing requirements for contaminants that are unsafe for human 509 consumption in edibles. The department shall also determine by 510 rule the procedures for the treatment of marijuana that fails to meet the testing requirements of this section, s. 381.988, or 511 512 department rule. The department may select a random sample from 513 edibles available for purchase in a dispensing facility which 514 shall be tested by the department to determine that the edible 515 meets the potency requirements of this section, is safe for 516 human consumption, and the labeling of the tetrahydrocannabinol 517 and cannabidiol concentration is accurate. A medical marijuana 518 treatment center may not require payment from the department for 519 the sample. A medical marijuana treatment center must recall 520 edibles, including all edibles made from the same batch of 521 marijuana, which fail to meet the potency requirements of this 522 section, which are unsafe for human consumption, or for which the labeling of the tetrahydrocannabinol and cannabidiol 523 524 concentration is inaccurate. The medical marijuana treatment 525 center must retain records of all testing and samples of each

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526 homogenous batch of marijuana for at least 9 months. The medical 527 marijuana treatment center must contract with a marijuana 528 testing laboratory to perform audits on the medical marijuana 529 treatment center's standard operating procedures, testing 530 records, and samples and provide the results to the department 531 to confirm that the marijuana or low-THC cannabis meets the 532 requirements of this section and that the marijuana or low-THC 533 cannabis is safe for human consumption. A medical marijuana 534 treatment center shall reserve two processed samples from each 535 batch and retain such samples for at least 9 months for the 536 purpose of such audits. A medical marijuana treatment center may 537 use a laboratory that has not been certified by the department under s. 381.988 until such time as at least one laboratory 538 539 holds the required certification, but in no event later than 540 July 1, 2018.

541 e. Package the marijuana in compliance with the United
542 States Poison Prevention Packaging Act of 1970, 15 U.S.C. ss.
543 1471 et seq.

544 f. Package the marijuana in a receptacle that has a firmly 545 affixed and legible label stating the following information:

546 (I) The marijuana or low-THC cannabis meets the547 requirements of sub-subparagraph d.

548 (II) The name of the medical marijuana treatment center 549 from which the marijuana originates.

550 (III) The batch number and harvest number from which the

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551 marijuana originates and the date dispensed.

(IV) The name of the physician who issued the physician certification.

554

(V) The name of the patient.

(VI) The product name, if applicable, and dosage form, including concentration of tetrahydrocannabinol and cannabidiol. The product name may not contain wording commonly associated with products marketed by or to children.

559

(VII) The recommended dose.

560 (VIII) A warning that it is illegal to transfer medical 561 marijuana to another person.

562 (IX) A marijuana universal symbol developed by the 563 department.

564 <u>12.11.</u> The medical marijuana treatment center shall 565 include in each package a patient package insert with 566 information on the specific product dispensed related to: 567 a. Clinical pharmacology.

- 568 b. Indications and use.
- 569 c. Dosage and administration.
- d. Dosage forms and strengths.
- 571 e. Contraindications.
- 572 f. Warnings and precautions.

573 g. Adverse reactions.

574 <u>13.</u> In addition to the packaging and labeling requirements 575 in subparagraphs 11. and 12., marijuana in a form for smoking

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576 must be packaged in a sealed receptacle with a legible and 577 prominent warning to keep away from children and a warning that 578 states marijuana smoke contains carcinogens and may negatively 579 affect health. Receptacles for marijuana in a form for smoking 580 must be plain, opaque, and white without depictions of the 581 product or images other than the medical marijuana treatment 582 center's department-approved logo and the marijuana universal 583 symbol.

14.12. Each edible shall be individually sealed in plain, 584 585 opaque wrapping marked only with the marijuana universal symbol. Where practical, each edible shall be marked with the marijuana 586 587 universal symbol. In addition to the packaging and labeling 588 requirements in subparagraphs 11. 10. and 12. 11., edible 589 receptacles must be plain, opaque, and white without depictions 590 of the product or images other than the medical marijuana 591 treatment center's department-approved logo and the marijuana 592 universal symbol. The receptacle must also include a list all of 593 the edible's ingredients, storage instructions, an expiration 594 date, a legible and prominent warning to keep away from children 595 and pets, and a warning that the edible has not been produced or 596 inspected pursuant to federal food safety laws.

597 <u>15.13.</u> When dispensing marijuana or a marijuana delivery 598 device, a medical marijuana treatment center:

599a. May dispense any active, valid order for low-THC600cannabis, medical cannabis and cannabis delivery devices issued

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601 pursuant to former s. 381.986, Florida Statutes 2016, which was 602 entered into the medical marijuana use registry before July 1, 603 2017.

b. May not dispense more than a 70-day supply of marijuanato a qualified patient or caregiver.

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
name or unique employee identifier.

Must verify that the qualified patient and the 610 d. caregiver, if applicable, each have an active registration in 611 612 the medical marijuana use registry and an active and valid 613 medical marijuana use registry identification card, the amount 614 and type of marijuana dispensed matches the physician 615 certification in the medical marijuana use registry for that 616 qualified patient, and the physician certification has not 617 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,
bongs, or wrapping papers, other than a marijuana delivery
device required for the medical use of marijuana and which is

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626 specified in a physician certification.

g. Must, upon dispensing the marijuana or marijuana
delivery device, record in the registry the date, time,
quantity, and form of marijuana dispensed; the type of marijuana
delivery device dispensed; and the name and medical marijuana
use registry identification number of the qualified patient or
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.

636

(15) APPLICABILITY.-

(a) This section does not limit the ability of an employer
to establish, continue, or enforce a drug-free workplace program
or policy.

(b) This section does not require an employer to
accommodate the medical use of marijuana in any workplace or any
employee working while under the influence of marijuana.

643 (c) This section does not create a cause of action against 644 an employer for wrongful discharge or discrimination.

(d) This section does not impair the ability of any party
 (d) This section does not impair the ability of any party
 (e) This section does not prohibit the medical use of
 (e) This section does not prohibit the medical use of
 (f) marijuana or a caregiver assisting with the medical use of
 (f) marijuana in a nursing home facility licensed under part II of
 (f) chapter 400, a hospice facility licensed under part IV of

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C F 1	alantan 400 yang seriatan birring fasilita birring dan sert
651	chapter 400, or an assisted living facility licensed under part
652	I of chapter 429, if the medical use of marijuana is not
653	prohibited in the facility's policies.
654	(f) Marijuana, as defined in this section, is not
655	reimbursable under chapter 440.
656	Section 2. Paragraph (h) of subsection (2) and paragraph
657	(b) of subsection (3) of section 381.987, Florida Statutes, are
658	amended to read:
659	381.987 Public records exemption for personal identifying
660	information relating to medical marijuana held by the
661	department
662	(2) The department shall allow access to the confidential
663	and exempt information in the medical marijuana use registry to:
664	(h) The <u>Consortium</u> Coalition for Medical Marijuana
665	<u>Clinical Outcomes</u> Research and Education established in s.
666	1004.4351(4).
667	(3) The department shall allow access to the confidential
668	and exempt information pertaining to the physician certification
669	for marijuana and the dispensing thereof, whether in the
670	registry or otherwise held by the department, to:
671	(b) The <u>Consortium</u> Coalition for Medical Marijuana
672	<u>Clinical Outcomes</u> Research and Education pursuant to s. 381.986
673	for the purpose of conducting research regarding the medical use
674	of marijuana.
675	Section 3. Section 1004.4351, Florida Statutes, is amended
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(2)

676 to read:

680

677 1004.4351 Medical marijuana research and education.678 (1) SHORT TITLE.-This section shall be known and may be
679 cited as the "Medical Marijuana Research and Education Act."

LEGISLATIVE FINDINGS.-The Legislature finds that:

(a) The present state of knowledge concerning the use of
marijuana to alleviate pain and treat illnesses is limited
because permission to perform clinical studies on marijuana is
difficult to obtain, with access to research-grade marijuana so
restricted that little or no unbiased studies have been
performed.

(b) Under the State Constitution, marijuana is availablefor the treatment of certain debilitating medical conditions.

(c) Additional clinical studies are needed to ensure that
the residents of this state obtain the correct dosing,
formulation, route, modality, frequency, quantity, and quality
of marijuana for specific illnesses.

(d) An effective medical marijuana research and education
program would mobilize the scientific, educational, and medical
resources that presently exist in this state to determine the
appropriate and best use of marijuana to treat illness.

(3) DEFINITIONS.—As used in this section, the term:

(a) "Board" means the Medical Marijuana Research and
 Education Board.

700

(b) "Consortium" "Coalition" means the Consortium

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701 Coalition for Medical Marijuana <u>Clinical Outcomes</u> Research and 702 Education. 703 (c) "Marijuana" has the same meaning as provided in s. 29, 704 Art. X of the State Constitution. 705 (4) <u>CONSORTIUM</u> COALITION FOR MEDICAL MARIJUANA <u>CLINICAL</u> 706 OUTCOMES RESEARCH AND EDUCATION.-

707 (a) There is established within a state university 708 designated by the Board of Governors the H. Lee Moffitt Cancer Center and Research Institute, Inc., the Consortium Coalition 709 710 for Medical Marijuana Clinical Outcomes Research which shall 711 consist of public and private universities and Education. The 712 purpose of the consortium coalition is to conduct rigorous 713 scientific research and, provide education, disseminate such 714 research, and guide policy for the adoption of a statewide 715 policy on ordering and dosing practices for the medical use of 716 marijuana. The coalition shall be physically located at the H. 717 Lee Moffitt Cancer Center and Research Institute, Inc.

718 The Medical Marijuana Research and Education Board is (b) 719 established to direct the operations of the consortium 720 coalition. The board shall be composed of seven members 721 representing each participating university appointed by the 722 president of each participating university the chief executive 723 officer of the H. Lee Moffitt Cancer Center and Research 724 Institute, Inc. Board members must have experience in a variety 725 of scientific and medical fields, including, but not limited to,

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726 oncology, neurology, psychology, pediatrics, nutrition, and 727 addiction. Members shall be appointed to 4-year terms and may be 728 reappointed to serve additional terms. The chair shall be 729 elected by the board from among its members to serve a 2-year 730 term. The board shall meet at least semiannually at the call of 731 the chair or, in his or her absence or incapacity, the vice 732 chair. Four members constitute a quorum. A majority vote of the 733 members present is required for all actions of the board. The 734 board may prescribe, amend, and repeal a charter governing the 735 manner in which it conducts its business. A board member shall 736 serve without compensation but is entitled to be reimbursed for 737 travel expenses by the consortium coalition or the organization 738 he or she represents in accordance with s. 112.061.

(c) The <u>consortium</u> coalition shall be administered by a coalition director, who shall be appointed by and serve at the pleasure of the board. The <u>coalition</u> director shall, subject to the approval of the board:

743

1. Propose a budget for the consortium coalition.

744 2. Foster the collaboration of scientists, researchers,
745 and other appropriate personnel in accordance with the
746 <u>consortium's</u> coalition's charter.

747 <u>3. Engage individuals in public and private university</u>
 748 programs relevant to the consortium's work to participate in the
 749 <u>consortium.</u>

750

4.3. Identify and prioritize the research to be conducted

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751 by the consortium coalition.

752 <u>5.4.</u> Prepare <u>a plan for medical marijuana research the</u>
 753 <u>Medical Marijuana Research and Education Plan</u> for submission to
 754 the board.

755 <u>6.5.</u> Apply for grants to obtain funding for research
756 conducted by the consortium coalition.

757 <u>7.6.</u> Perform other duties as determined by the board.
(d) The board shall advise the Board of Governors, the
759 State Surgeon General, the Governor, and the Legislature with
760 respect to medical marijuana research and education in this
761 state. The board shall explore methods of implementing and
762 enforcing medical marijuana laws in relation to cancer control,
763 research, treatment, and education.

764 (d) (e) The board shall annually adopt a plan for medical 765 marijuana research. The plan shall organize a program of 766 research that contributes to the body of scientific knowledge on 767 the effects of the medical use of marijuana and informs both 768 policy and medical practice related to the treatment of 769 debilitating medical conditions with marijuana. Research shall 770 include tracking clinical outcomes, certification standards, 771 dosing standards, routes of administration, efficacy, and side 772 effects. Research must also include the study of the effects of 773 smoking marijuana to treat debilitating medical conditions. The 774 board must award funds to members of the consortium to perform research consistent with the plan, known as the "Medical 775

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776 Marijuana Research and Education Plan," which must be in 777 accordance with state law and coordinate with existing programs 778 in this state. The plan must include recommendations for the 779 coordination and integration of medical, pharmacological, 780 nursing, paramedical, community, and other resources connected 781 with the treatment of debilitating medical conditions; research 782 related to the treatment of such medical conditions; and 783 education.

784 <u>(e) (f)</u> By February 15 of each year, the board shall issue 785 a report to the Governor, the President of the Senate, and the 786 Speaker of the House of Representatives on research projects, 787 <u>research findings</u>, community outreach initiatives, and future 788 plans for the <u>consortium</u> coalition.

789 (f) (g) Beginning August 1, 2019 January 15, 2018, and 790 quarterly thereafter, the Department of Health shall submit to 791 the board a data set that includes, for each patient registered 792 in the medical marijuana use registry, the patient's qualifying 793 medical condition and the daily dose amount, routes of 794 administration, and forms of marijuana certified for the 795 patient. The department shall also provide the board with such 796 data for all patients registered in the medical marijuana use 797 registry before August 1, 2019.

798 (5) RESPONSIBILITIES OF THE H. LEE MOFFITT CANCER CENTER
 799 AND RESEARCH INSTITUTE, INC.—The H. Lee Moffitt Cancer Center
 800 and Research Institute, Inc., shall allocate staff and provide

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2019

801	information and assistance, as the coalition's budget permits,
802	to assist the board in fulfilling its responsibilities.
803	Section 4. (1) For the 2019-2020 fiscal year, the sum of
804	\$1.5 million in recurring funds is appropriated from the General
805	Revenue Fund to the Board of Governors for the purpose of
806	implementing the Consortium for Medical Marijuana Clinical
807	Outcomes Research established under s. 1004.4351, Florida
808	Statutes.
809	(2) For the 2019-2020 fiscal year, the sums of \$705,331 in
810	recurring funds and \$215,000 in nonrecurring funds are
811	appropriated from the Grants and Donations Trust Fund to the
812	Department of Health for the purpose of implementing the
813	requirements of this act.
814	Section 5. This act shall take effect upon becoming a law.

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