

1 A bill to be entitled
2 An act relating to the use of psilocybin for mental
3 health treatment; providing a short title; creating s.
4 381.99, F.S.; providing definitions; providing
5 purposes for the act; providing authority and duties
6 of the Department of Health relating to the use of
7 psilocybin for mental health treatment; prohibiting
8 the department from issuing licenses relating to
9 psilocybin products during a specified period;
10 requiring the department to publish certain
11 information on its Internet website by a specified
12 date and periodically thereafter; requiring the
13 department to prescribe forms and adopt rules by a
14 specified date; establishing the Psilocybin Advisory
15 Board within the department; providing a purpose for
16 the board; providing for membership, meetings, and
17 duties of the board; requiring the Governor to appoint
18 certain persons to the board by a specified date;
19 requiring that the board hold its first meeting by a
20 specified date; requiring that the board submit its
21 findings and recommendations to certain persons by a
22 specified date; requiring the department to determine
23 whether to develop a certain tracking system for
24 psilocybin products or enter into an agreement with
25 the Office of Medical Marijuana Use; providing

26 requirements for such tracking system; requiring the
27 department to preapprove labels and packaging of
28 psilocybin products; providing requirements and
29 prohibitions relating to the sale of psilocybin
30 products; providing penalties; prohibiting the
31 imposition of an additional tax on the sale of
32 psilocybin products; requiring the department to
33 regularly review the tax rate for psilocybin products
34 and make recommendations to the Legislature regarding
35 adjustments to such rate; authorizing a psilocybin
36 product manufacturing facility to deliver psilocybin
37 products under certain circumstances; prohibiting
38 persons younger than 21 years of age from entering or
39 attempting to enter any portion of a psilocybin
40 product manufacturing facility or psilocybin service
41 center; providing penalties and exceptions; requiring
42 that the Department of Law Enforcement make the
43 investigation and arrest of certain persons for
44 specified offenses relating to psilocybin products a
45 low priority; requiring a law enforcement officer to
46 immediately notify the department of violations
47 relating to psilocybin products; requiring certain
48 governmental entities and authorities to immediately
49 notify the department of a conviction of a licensee or
50 licensee representative; providing sovereign immunity

51 for officers and employees of the department in the
52 performance of their duties relating to psilocybin
53 products; preempting the regulation of psilocybin
54 products and services to the state; creating s.
55 381.991, F.S.; providing duties of the department
56 relating to the licensing of psilocybin product
57 manufacturing facilities, service centers,
58 facilitators, and testing laboratories and the
59 permitting of licensee representatives; requiring that
60 the department receive applications for such licensure
61 or permitting by a specified date; providing
62 requirements for the application process for such
63 licensure or permitting; authorizing the department to
64 revoke, suspend, or refuse to issue or renew a license
65 or permit; authorizing an applicant to appeal
66 department determinations relating to such licensure
67 or permitting; providing certain requirements for an
68 application for licensure or permitting; providing
69 fingerprinting and background screening requirements;
70 providing requirements and prohibitions relating to
71 the licensure and operation of psilocybin product
72 manufacturing facilities, service centers,
73 facilitators, and testing laboratories and the
74 permitting of licensee representatives; providing
75 grounds for the revocation, suspension, or restriction

76 of a license or permit and refusal to issue a license
77 or permit; requiring the department to adopt rules
78 establishing standards relating to the operation of
79 psilocybin product manufacturing facilities, service
80 centers, facilitators, and testing laboratories and
81 the permitting of licensee representatives;
82 authorizing the department to inspect the records and
83 premises of licensees; providing certain prohibitions;
84 authorizing the department to require licensees to
85 maintain general liability insurance coverage;
86 authorizing the department to investigate and take
87 disciplinary action against licensees and licensee
88 representatives for certain violations; providing for
89 the enforceability of contracts; providing certain
90 protections for licensee representatives; providing
91 for the rights of deceased, insolvent, or bankrupt
92 persons or licensees and their property interests;
93 providing construction and severability; providing an
94 effective date.

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96 WHEREAS, the state has one of the highest prevalence rates
97 of mental illness among adults in the nation, and

98 WHEREAS, an estimated one in every five adults in the state
99 is coping with a mental health condition, and

100 WHEREAS, in 2020, the Governor announced a plan to use \$5

101 million from a grant provided through the United States
 102 Department of Labor for the Support to Communities: Fostering
 103 Opioid Recovery Through Workforce Development pilot program to
 104 combat addiction in the state, and

105 WHEREAS, the Governor's budget for the 2020-2021 fiscal
 106 year proposes spending more than \$770 million on mental and
 107 behavioral health programs, and

108 WHEREAS, studies conducted by nationally and
 109 internationally recognized medical institutions indicate that
 110 psilocybin has shown efficacy, tolerability, and safety in the
 111 treatment of a variety of mental health conditions, including,
 112 but not limited to, addiction, depression, anxiety disorders,
 113 and end-of-life psychological distress, and

114 WHEREAS, the United States Food and Drug Administration has
 115 determined that preliminary clinical evidence indicates that
 116 psilocybin may demonstrate substantial improvement over
 117 available therapies for treatment-resistant depression, has
 118 granted a Breakthrough Therapy designation for a treatment that
 119 uses psilocybin as a therapy for such depression, and has
 120 determined that microdose amounts of psilocybin products may
 121 improve mental health, reduce neuroticism, and alter attentional
 122 capacities by reducing mind wandering and increasing absorption,

123 NOW, THEREFORE,

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125 Be It Enacted by the Legislature of the State of Florida:

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Section 1. This act may be cited as the "Florida Psilocybin Mental Health Care Act."

Section 2. Section 381.99, Florida Statutes, is created to read:

381.99 Use of psilocybin for mental health treatment; advisory board; tracking, sale, and delivery of psilocybin products; prohibitions; penalties.—

(1) DEFINITIONS.—As used in this section and s. 381.991, the term:

(a) "Administration session" means a session held at a psilocybin service center at which a client purchases, consumes, and experiences the effects of a psilocybin product under the supervision of a psilocybin service facilitator.

(b) "Client" means a person who is provided psilocybin services.

(c) "Department" means the Department of Health.

(d) "Entheogenic plants and fungi" means any plant or fungus of any species in which ibogaine, dimethyltryptamine, mescaline, peyote, psilocybin, or psilocin occurs naturally in any form that would cause such plant or fungus to be named or described as a controlled substance in s. 893.03(1)(c).

(e) "Integration session" means a meeting between a client and a psilocybin service facilitator that may occur after the client completes an administration session.

151 (f) "Licensee" means a person who holds a license issued
152 under s. 381.991.

153 (g) "Licensee representative" means an owner, director,
154 officer, manager, employee, agent, or other representative of a
155 licensee, to the extent that such person is serving in a
156 representative capacity.

157 (h) "Manufacture" or "manufacturing" means the
158 manufacture, planting, cultivation, growing, harvesting,
159 production, preparation, propagation, compounding, conversion,
160 or processing of a psilocybin product, either directly or
161 indirectly by extraction from substances of natural origin, or
162 independently by means of chemical synthesis, or by a
163 combination of extraction and chemical synthesis. The term
164 includes any packaging or repackaging of the psilocybin product
165 or labeling or relabeling of the psilocybin product package.

166 (i) "One-year program development period" means the period
167 beginning on January 1, 2022, and ending no later than December
168 31, 2023.

169 (j) "Premises" includes all of the following areas of a
170 location licensed under s. 381.991:

171 1. All public and private enclosed areas that are used in
172 the business operated at the location, including offices,
173 kitchens, restrooms, and storerooms.

174 2. All areas outside a building that the department has
175 specifically licensed for the manufacturing of psilocybin

176 products or the operation of a psilocybin service center.

177 3. For a location that the department has specifically
178 licensed for the operation of a psilocybin service center
179 outside a building, that portion of the location used to operate
180 the center and provide psilocybin services to clients.

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182 The term does not include a primary residence.

183 (k) "Preparation session" means a meeting between a client
184 and a psilocybin service facilitator that must occur before the
185 client participates in an administration session.

186 (l) "Psilocybin" means a hallucinogenic compound obtained
187 from *P. cubensis* mushrooms.

188 (m) "Psilocybin product manufacturing facility" means a
189 facility that manufactures psilocybin products in this state.

190 (n) "Psilocybin products" means psilocybin-producing fungi
191 and mixtures or substances containing a detectable amount of
192 psilocybin. The term does not include psilocybin services.

193 (o) "Psilocybin service center" means a center where
194 administration sessions are held and other psilocybin services
195 may be provided.

196 (p) "Psilocybin service facilitator" means a person who
197 facilitates the provision of psilocybin services to a client.

198 (q) "Psilocybin services" means services provided to a
199 client before, during, or after the client's consumption of a
200 psilocybin product, including a preparation session, an

201 administration session, and an integration session.

202 (r) "Psilocybin testing laboratory" means a laboratory
203 that conducts tests on psilocybin products in accordance with s.
204 381.991.

205 (2) PURPOSES.—The purposes of this section are to:

206 (a) Educate the public about the safe and effective use of
207 psilocybin in treating mental health conditions.

208 (b) Reduce the prevalence of mental illness among adults
209 in the state and improve the physical, mental, and social well-
210 being of all people in the state.

211 (c) Develop a long-term strategic plan for ensuring that
212 psilocybin services will become and remain a safe, accessible,
213 and affordable therapeutic option for all persons 21 years of
214 age or older for whom psilocybin may be appropriate.

215 (d) Protect the public health, safety, and welfare by
216 prioritizing the state's limited law enforcement resources in
217 the most effective, consistent, and rational way.

218 (e) After a 1-year program development period:

219 1. Allow persons licensed, permitted, or regulated under
220 s. 391.991 to legally manufacture psilocybin products and
221 provide psilocybin services to persons 21 years of age or older
222 in accordance with this section and s. 391.991.

223 2. Establish a comprehensive regulatory framework
224 regarding psilocybin products and psilocybin services.

225 (f) Prevent the distribution of psilocybin products to

226 persons who are not allowed to possess psilocybin products under
227 this section, s. 381.991, and any rules adopted by the
228 department, including persons who are younger than 21 years of
229 age.

230 (g) Prevent the diversion of psilocybin products from this
231 state to other states.

232 (3) DEPARTMENT AUTHORITY AND DUTIES DURING 1-YEAR PROGRAM
233 DEVELOPMENT PERIOD.—

234 (a) During the 1-year program development period, the
235 department shall:

236 1. Examine, publish, and distribute to the public
237 available medical, psychological, and scientific studies,
238 research, and other information relating to the safety and
239 efficacy of psilocybin in treating mental health conditions.

240 2. Adopt rules and regulations for the implementation of a
241 comprehensive regulatory framework authorizing persons 21 years
242 of age or older to be provided psilocybin services in this
243 state.

244 3. Establish an advisory board for the purpose of advising
245 and making recommendations to the department regarding the use
246 of psilocybin for mental health treatment.

247 (b) The jurisdiction, supervision, authority, and duties
248 of the department shall extend to any person who produces,
249 processes, transports, delivers, sells, or purchases a
250 psilocybin product in this state, or who provides a psilocybin

251 service in this state. The department may sue and be sued.

252 (c) After the 1-year program development period, the
253 duties of the department shall include all of the following:

254 1. Regulating the possession, manufacturing,
255 transportation, delivery, sale, and purchase of psilocybin
256 products and the provision of psilocybin services in this state
257 in accordance with this section and s. 381.991.

258 2. Issuing, renewing, suspending, revoking, or refusing to
259 issue or renew licenses for the manufacturing or sale of
260 psilocybin products or the provision of psilocybin services or
261 other licenses related to the consumption of psilocybin
262 products, and allowing the transfer of a license between
263 persons.

264 3. Issuing, renewing, suspending, revoking, or refusing to
265 issue or renew permits for licensee representatives.

266 4. Regulating the use of psilocybin products and
267 psilocybin services for other purposes as deemed necessary or
268 appropriate by the department.

269 5. Adopting, amending, or repealing rules as necessary to
270 implement this section and s. 381.991, including rules that the
271 department considers necessary to protect the public health,
272 safety, and welfare.

273 6. Exercising its authority to administer and implement
274 this section, s. 381.991, or any other law that authorizes the
275 department to regulate psilocybin products and psilocybin

276 services, which includes all of the following:

277 a. Issuing subpoenas.

278 b. Compelling the attendance of witnesses.

279 c. Administering oaths.

280 d. Certifying official acts.

281 e. Taking depositions.

282 f. Compelling the production of books, payrolls, accounts,

283 papers, records, documents, and testimony.

284 7. Adopting rules regulating the advertisement of

285 psilocybin products to the public.

286 8. Adopting rules prohibiting the advertisement of

287 psilocybin services in a manner that:

288 a. Is appealing to minors;

289 b. Promotes excessive use;

290 c. Promotes illegal activity;

291 d. Violates the code of professional conduct for

292 psilocybin service facilitators; or

293 e. Otherwise poses a significant risk to the public

294 health, safety, and welfare.

295 (d) The department may not require that a psilocybin

296 product be manufactured by means of chemical synthesis.

297 (e) The department may not require a client to be

298 diagnosed with or have any particular medical condition before

299 being provided psilocybin services.

300 (f) Subject to chapter 120, the department may purchase,

301 possess, seize, transfer to a licensee, or dispose of psilocybin
302 products as necessary for the department to ensure compliance
303 with and enforce this section, s. 381.991, and any department
304 rules.

305 (g) Unless otherwise provided by law, the department may
306 not issue any licenses or permits during the 1-year program
307 development period.

308 (h) By November 30, 2022, and periodically thereafter, the
309 department shall publish on its Internet website information
310 received from the Psilocybin Advisory Board established in
311 subsection (4) and available medical, psychological, and
312 scientific studies, research, and any other information relating
313 to the safety and efficacy of psilocybin in treating mental
314 health conditions, including, but not limited to, addiction,
315 depression, anxiety disorders, and end-of-life psychological
316 distress.

317 (i) On or before January 1, 2023, the department shall
318 prescribe forms and adopt rules necessary for the implementation
319 of this section and s. 381.991.

320 (4) PSILOCYBIN ADVISORY BOARD; MEMBERSHIP; DUTIES.—

321 (a) The Psilocybin Advisory Board is established within
322 the department for the purpose of advising and making
323 recommendations regarding the use of psilocybin for mental
324 health treatment to the department. The board shall consist of
325 at least 14 but not more than 16 members as follows:

326 1.a. The State Surgeon General or his or her designee.

327 b. The Commissioner of Agriculture or his or her designee.

328 c. The Attorney General or his or her designee.

329 d. The executive director of the Department of Law
330 Enforcement or his or her designee.

331 e. The Secretary of Children and Families or his or her
332 designee.

333 2. The following members shall be appointed by the
334 Governor:

335 a. A state employee employed by the Office of Medical
336 Marijuana Use established by the department pursuant to s.
337 385.212 who has experience working with the computer software
338 tracking system developed and maintained by the department under
339 s. 381.986.

340 b. An attorney who has experience with laws and
341 regulations relating to controlled substances.

342 c. A state employee who has technical and policy expertise
343 in the field of public health.

344 d. A person who is a member of, or who represents, a
345 federally recognized Indian tribe in this state.

346 e. A person who represents providers who deliver health
347 care services directly to the public.

348 f. A psychologist licensed under chapter 490 who has
349 professional experience diagnosing or treating a mental,
350 emotional, or behavioral health condition.

351 g. A physician licensed under chapter 458.

352 h. A naturopathic physician licensed under chapter 462.

353 i. A person who is an expert in the field of public health
354 and is employed by a postsecondary institution in the state.

355 j. A person who has professional experience conducting
356 scientific research regarding the use of psychedelic compounds
357 in clinical therapy.

358 k. A person who has experience in the field of mycology.

359 l. A person who has experience in the field of
360 ethnobotany.

361 m. A person who has experience in the field of
362 psychopharmacology.

363 n. A person who has experience in the field of psilocybin
364 harm reduction.

365 o. One or two at-large members.

366 (b)1. A board member shall serve for a 4-year term at the
367 pleasure of the Governor. Before the expiration of his or her
368 term, the Governor shall appoint a successor whose term begins
369 on January 1 of the following year. A member is eligible for
370 reappointment. If there is a vacancy for any cause, the Governor
371 shall make an appointment to become immediately effective for
372 the unexpired term.

373 2. A majority of voting members of the board constitutes a
374 quorum for the transaction of business. Official action by the
375 board requires the approval of a majority of voting members of

376 the board.

377 3. The board shall elect one of its members to serve as
378 chairperson.

379 4. During the 1-year program development period, the board
380 shall meet at least bimonthly at a time and place determined by
381 the chairperson or a majority of the voting members of the
382 board. After the 1-year program development period, the board
383 shall meet at least quarterly at a time and place determined by
384 the chairperson or a majority of the voting members of the
385 board. The board may also meet at other times and places at the
386 call of the chairperson or a majority of the voting members of
387 the board.

388 5. The board may adopt bylaws and rules and establish
389 committees and subcommittees necessary for its operation.

390 6. The Governor must appoint the persons specified in
391 subparagraph (a)2. to the board no later than April 30, 2022.

392 (c) The board shall:

393 1. Advise the department regarding the implementation of
394 this section and s. 381.991.

395 2. Make recommendations to the department on available
396 medical, psychological, and scientific studies, research, and
397 other information relating to the safety and efficacy of
398 psilocybin in treating mental health conditions, including, but
399 not limited to, addiction, depression, anxiety disorders, and
400 end-of-life psychological distress.

401 3. Make recommendations to the department on the
402 requirements, specifications, and guidelines for providing
403 psilocybin services to a client, including:

404 a. The requirements, specifications, and guidelines for
405 holding and verifying the completion of a preparation session,
406 an administration session, and an integration session.

407 b. The contents of the client information form that a
408 client must complete and sign before the client participates in
409 a preparation session, including:

410 (I) Information that must be solicited from the client to
411 determine whether it is appropriate for the client to
412 participate in the preparation session which may identify risk
413 factors and contraindications.

414 (II) Information that must be solicited from the client to
415 assist the psilocybin service center and the psilocybin service
416 facilitator in meeting any public health and safety standards
417 and industry best practices during the administration session.

418 (III) Health and safety warnings and other disclosures
419 that must be made to the client before the client participates
420 in the administration session.

421 4. Make recommendations to the department on public health
422 and safety standards and industry best practices for each type
423 of licensee and licensee representative under this section.

424 5. Make recommendations to the department on the
425 formulation of a code of professional conduct for psilocybin

426 service facilitators, including a code of ethics.

427 6. Make recommendations to the department on the education
428 and training that psilocybin service facilitators must complete,
429 including:

430 a. Facilitation skills that are affirming, nonjudgmental,
431 and nondirective.

432 b. Skills to support clients during an administration
433 session, including specialized skills for client safety and
434 clients who may have a mental health condition.

435 c. The optimal environment in which psilocybin services
436 must occur.

437 d. Social and cultural considerations.

438 e. Whether such education and training should be made
439 available through online resources.

440 7. Make recommendations to the department on the
441 examinations that psilocybin service facilitators and licensee
442 representatives must pass.

443 8. Make recommendations to the department on public health
444 and safety standards and industry best practices for holding and
445 completing an administration session, including:

446 a. Whether group administration sessions will be made
447 available.

448 b. Whether clients will be able to access common or
449 outside areas on the premises of the psilocybin service center
450 at which the administration session is held.

451 9. Make recommendations to the department as to whether
452 and how psilocybin service centers and psilocybin service
453 facilitators may safely and effectively provide administration
454 sessions using telehealth as defined in s. 456.47(1).

455 10. Make recommendations to the department regarding the
456 circumstances under which an administration session is
457 considered complete.

458 11. Make recommendations to the department regarding the
459 transportation needs of the client after the completion of an
460 administration session.

461 12. Develop a long-term strategic plan for ensuring that
462 psilocybin services are and will remain a safe, accessible, and
463 affordable therapeutic option for all persons 21 years of age or
464 older for whom psilocybin may be appropriate.

465 13. Make recommendations to the department about
466 technologies that can be used and implemented by the department
467 to track:

468 a. Product information.

469 b. Client data.

470 c. Outcomes of clients during and after receiving
471 psilocybin services.

472 14. Monitor and study federal laws, regulations, and
473 policies relating to psilocybin.

474 (d) By June 30, 2022, the board shall hold its first
475 meeting at a time and place specified by the Governor.

476 (e) By August 31, 2022, and periodically thereafter, the
477 board shall also submit its findings and recommendations to the
478 State Surgeon General, the President of the Senate, the Speaker
479 of the House of Representatives, and the Governor regarding the
480 implementation of this section, s. 381.991, and any department
481 rules.

482 (5) TRACKING SYSTEM FOR PSILOCYBIN PRODUCTS.—

483 (a) The department shall determine whether to:

484 1. Develop and maintain a computer software tracking
485 system to track the transfer of psilocybin products between
486 premises; or

487 2. Enter into an agreement with the Office of Medical
488 Marijuana Use within the department which allows the department
489 to use the computer software tracking system developed and
490 maintained under s. 381.986 to track the transfer of psilocybin
491 products between premises.

492 (b) The purposes of the computer software tracking system
493 designated by the department under paragraph (a) include all of
494 the following:

495 1. Preventing the diversion of psilocybin products to
496 other states.

497 2. Preventing persons from substituting or tampering with
498 psilocybin products.

499 3. Ensuring an accurate accounting of the production,
500 processing, and sale of psilocybin products.

501 4. Ensuring that testing results from a psilocybin testing
502 laboratory are accurately reported.

503 5. Ensuring compliance with this section, s.
504 381.991, department rules, and any other law of this state that
505 authorizes the department to regulate psilocybin.

506 (c) At a minimum, the tracking system must be capable of
507 tracking all of the following:

508 1. The manufacturing of psilocybin products.

509 2. The sale of psilocybin products by a psilocybin service
510 center to a client.

511 3. The sale and purchase of psilocybin products between
512 licensees.

513 4. The transfer of psilocybin products between premises.

514 5. Any other information that the department determines is
515 reasonably necessary to accomplish its duties under this section
516 and s. 381.991.

517 (6) PREAPPROVAL OF LABELS AND PACKAGING.—The department
518 may adopt rules requiring a licensee to submit:

519 (a) A label intended for use on a psilocybin product for
520 preapproval by the department before the licensee may sell or
521 transfer a psilocybin product bearing the label.

522 (b) Packaging intended for a psilocybin product for
523 preapproval by the department before the licensee may sell or
524 transfer a psilocybin product in the packaging.

525 (7) SALE OR DELIVERY OF PSILOCYBIN PRODUCTS; PENALTIES.—

526 (a) A licensee or licensee representative may not sell or
527 deliver a psilocybin product to a person younger than 21 years
528 of age.

529 (b) Before selling or delivering a psilocybin product to a
530 person, a licensee or licensee representative must require the
531 person to produce one of the following forms of identification:

532 1. A valid driver license issued by this state or another
533 state;

534 2. A valid United States passport;

535 3. A valid military identification card;

536 4. A valid identification card issued by a federally
537 recognized Indian tribe; or

538 5. Any other valid identification card issued by a state
539 or territory of the United States that bears a picture, name,
540 date of birth, and physical description of the person.

541 (c)1. A person may not produce a form of identification
542 that misrepresents his or her age. A person who violates this
543 subparagraph commits a misdemeanor of the first degree,
544 punishable as provided in s. 775.082 or s. 775.083.

545 2. If a form of identification is offered as evidence in
546 any administrative or criminal proceeding involving a licensee
547 or licensee representative for the sale or delivery of a
548 psilocybin product to a person younger than 21 years of age, the
549 licensee or licensee representative is not guilty of any offense
550 prohibiting the sale or delivery of a psilocybin product to a

551 person younger than 21 years of age, unless it is demonstrated
552 that a reasonable person would have determined that the form of
553 identification exhibited by the person younger than 21 years of
554 age was altered, or that the form of identification exhibited by
555 the person younger than 21 years of age did not accurately
556 describe the person to whom the psilocybin product was sold or
557 delivered.

558 (d) A psilocybin product may not be given as a prize,
559 premium, or consideration for a lottery, contest, game of
560 chance, game of skill, or competition of any kind. A person who
561 violates this paragraph commits a misdemeanor of the first
562 degree, punishable as provided in s. 775.082 or s. 775.083.

563 (e) A person may not sell, deliver, or otherwise make
564 available a psilocybin product to a person who is visibly
565 intoxicated. A person who violates this paragraph commits a
566 misdemeanor of the first degree, punishable as provided in s.
567 775.082 or s. 775.083.

568 (8) TAX ON THE SALE OF PSILOCYBIN PRODUCTS.—

569 (a) An additional tax may not be imposed upon the sale of
570 psilocybin products which exceeds the tax rate effective on July
571 1, 2021. The tax shall be collected by a psilocybin product
572 manufacturing facility at the point of sale of a psilocybin
573 product or by a psilocybin service center when a psilocybin
574 product is sold.

575 (b) A psilocybin service center may not discount a

576 psilocybin product or offer a psilocybin product for free if the
577 sale of the psilocybin product is made in conjunction with the
578 sale of any other item or service.

579 (c) The department shall regularly review the tax rate and
580 make recommendations to the Legislature regarding the
581 appropriate adjustments to the rate that will provide funding
582 sufficient to implement this section and s. 381.991.

583 (9) DELIVERY OF PSILOCYBIN PRODUCTS.—

584 (a) A psilocybin product manufacturing facility that is
585 licensed under s. 381.991 may deliver psilocybin products only
586 to or on a premises.

587 (b) A psilocybin service center and a psilocybin service
588 facilitator that is licensed under s. 381.991 may:

589 1. Deliver psilocybin products only to or on a premises.
590 2. Receive psilocybin products only from a psilocybin
591 product manufacturing facility or a psilocybin service center.

592 (c) The sale of psilocybin products to a client by a
593 psilocybin service center or a psilocybin service facilitator
594 must be restricted to the premises.

595 (d) Notwithstanding subparagraph (b)1., the department may
596 adopt rules to allow for delivery of psilocybin products to a
597 client's residence.

598 (10) PERSONS YOUNGER THAN 21 YEARS OF AGE ON PREMISES.—

599 (a) Except as authorized by the department by rule, or as
600 necessary in the case of an emergency, a person younger than 21

601 years of age may not enter or attempt to enter any portion of
602 the premises of a psilocybin product manufacturing facility or
603 psilocybin service center. A person who violates this paragraph
604 commits a misdemeanor of the second degree, punishable as
605 provided in s. 775.082 or s. 775.083.

606 (b) Paragraph (a) does not apply to a person younger than
607 21 years of age who is:

608 1. Temporarily at the premises to make a service,
609 maintenance, or repair call or for other purposes independent of
610 the operations of the premises.

611 2. Acting under the direction of the department or state
612 or local law enforcement agencies for the purpose of
613 investigating possible violations of laws prohibiting sales of
614 psilocybin products to persons younger than 21 years of age.

615 3. Acting under the direction of a licensee for the
616 purpose of investigating possible violations of laws prohibiting
617 sales of psilocybin products to persons younger than 21 years of
618 age by licensee representatives.

619 (c)1. A person younger than 21 years of age is not in
620 violation of, and is immune from prosecution under, this section
621 if:

622 a. The person contacted emergency medical services or a
623 law enforcement agency in order to obtain medical assistance for
624 another person who was in need of medical assistance because
625 that person consumed a psilocybin product; or

626 b. The person was in need of medical assistance because he
627 or she consumed a psilocybin product and the evidence of the
628 violation was obtained as a result of the person seeking or
629 obtaining such medical assistance.

630 2. Subparagraph 1. does not exclude the use of evidence
631 obtained as a result of a person seeking or obtaining medical
632 assistance in proceedings for crimes or offenses other than a
633 violation of this subsection.

634 (11) INVESTIGATIONS, ARRESTS, PROSECUTIONS, AND
635 CONVICTIONS FOR OFFENSES INVOLVING PSILOCYBIN; DUTY TO NOTIFY.-

636 (a) The Department of Law Enforcement shall make the
637 investigation and arrest of persons 18 years of age or older
638 engaged in noncommercial planting, cultivating, purchasing,
639 transporting, distributing, engaging in practices with, or
640 possessing entheogenic plants and fungi one of its lowest
641 enforcement priorities. This paragraph does not affect the
642 priority of enforcing any provision of chapter 316 or s.
643 893.13(1)(c).

644 (b) The Attorney General and a United States Attorney from
645 a federal judicial circuit within this state shall cease
646 prosecution of residents of the state for noncommercial
647 planting, cultivating, purchasing, transporting, distributing,
648 engaging in practices with, or possessing entheogenic plants and
649 fungi.

650 (c) A law enforcement officer may enforce this section and

651 assist the department in detecting violations of this section
652 and apprehending offenders. A law enforcement officer who has
653 notice, knowledge, or reasonable ground of suspicion of a
654 violation of this section shall immediately notify the
655 department.

656 (d) The county courts, district attorneys, and municipal
657 authorities shall, immediately upon the conviction of a licensee
658 or licensee representative for a violation of this section or
659 any other law, notify the department of such conviction.

660 (12) SOVEREIGN IMMUNITY.—An officer or employee of the
661 department shall incur no civil liability and is entitled to
662 immunity as provided in s. 768.28 for performing any duty in
663 accordance with this section or s. 381.991 or any other law
664 requiring the department to perform any duty related to
665 psilocybin products.

666 (13) PREEMPTION.—This section and s. 381.991 are intended
667 to operate uniformly throughout the state, expressly preempt the
668 regulation of psilocybin products and services to the state, and
669 supersede any municipal or county ordinance on the subject.

670 Section 3. Section 381.991, Florida Statutes, is created
671 to read:

672 381.991 Licensing of psilocybin product manufacturing
673 facilities, service centers, service facilitators, and testing
674 laboratories; permitting of licensee representatives;
675 inspections; prohibitions; general liability insurance;

676 investigations and enforcement; protections and rights of
677 licensees and licensee representatives.—

678 (1) APPLICATIONS FOR LICENSURE.—The department shall
679 approve or deny an application for licensure under this section
680 without unreasonable delay.

681 (a) The department may not issue a license for premises as
682 defined in s. 381.99 that do not have defined boundaries. The
683 premises do not need to be enclosed by a wall, fence, or other
684 structure. However, the department may require the premises to
685 be enclosed as a condition of issuing or renewing a license. The
686 department may not issue a license to a mobile premises.

687 (b) A license issued under this section serves the purpose
688 of exempting the licensee from the criminal laws of this state
689 for the possession, transportation, delivery, manufacturing, or
690 sale of psilocybin products to the extent that the person
691 complies with all state laws and rules applicable to licensees.

692 (c) By February 1, 2023, the department shall begin
693 receiving applications for the licensing of all of the
694 following:

- 695 1. Psilocybin product manufacturing facilities.
- 696 2. Psilocybin service centers.
- 697 3. Psilocybin service facilitators.
- 698 4. Psilocybin testing laboratories.

699 (d) An applicant for a license or renewal of a license
700 shall apply to the department in a form prescribed by department

701 rule. The application must show the name and address of the
702 applicant, location of the premises that will be operated under
703 the license, and any other pertinent information required by the
704 department. The department may not issue or renew a license
705 until the applicant has complied with this section and s. 381.99
706 and rules adopted by the department.

707 (e) The department may reject any application that is not
708 submitted in the form prescribed by department rule. In
709 addition, the department may revoke, or refuse to issue or
710 renew, a license issued under this section.

711 (f) An applicant may appeal any action taken by the
712 department pursuant to this section in a proceeding under s.
713 120.569.

714 (g) A license issued under this section:

715 1. Is a personal privilege.

716 2. Is renewable except for a cause that would be grounds
717 for refusal to issue the license.

718 3. Is revocable or may be subject to suspension.

719 4. Except for a license issued to a psilocybin service
720 facilitator, is transferable from the premises for which the
721 license was originally issued to another premises.

722 5. If the license was issued to a person, expires upon the
723 death of the licensee, except as otherwise provided in this
724 section.

725 6. Does not constitute property.

726 7. Is not alienable.

727 8. Is not subject to attachment or execution.

728 9. Does not descend by the laws of testate or intestate
729 estates.

730 (h)1. The department may require an applicant for a
731 license or a licensee to submit to the department, in a form and
732 manner prescribed by the department, a sworn statement showing
733 both of the following:

734 a. The name and address of each person who has a financial
735 interest in the business operating or to be operated under the
736 license.

737 b. The nature and extent of the financial interest of each
738 person who has a financial interest in the business operating or
739 to be operated under the license.

740 2. The department may refuse to issue, or may suspend,
741 revoke, or refuse to renew, a license issued under this section
742 if the department determines that a person who has a financial
743 interest in the business operating or to be operated under the
744 license committed or failed to commit an act that would
745 constitute grounds for the department to refuse to issue, or to
746 suspend, revoke, or refuse to renew, the license if the person
747 were the licensee or applicant for the license.

748 (i) A person or a legal entity that directly or indirectly
749 owns, controls, or holds with power to vote 5 percent or more of
750 the voting shares of a psilocybin product manufacturing facility

751 or psilocybin service center may not acquire direct or indirect
752 ownership or control of any voting shares or other form of
753 ownership of any other psilocybin product manufacturing facility
754 or psilocybin service center. For purposes of this paragraph,
755 the term "legal entity" means a corporation, limited liability
756 company, limited partnership, or other entity that is registered
757 with the office of the Secretary of State or with a comparable
758 office in another jurisdiction.

759 (j)1. Before receiving a license for a psilocybin product
760 manufacturing facility or psilocybin service center, an
761 applicant shall request a land use compatibility statement from
762 the city or county in which the applicant will operate. The land
763 use compatibility statement must demonstrate that the requested
764 license is for a land use that is allowable as a permitted or
765 conditional use within the applicable zoning designation where
766 the land is located. The department may not issue a license if
767 the land use compatibility statement shows that the proposed
768 land use is prohibited in the applicable zone.

769 2. Except as otherwise provided in law, a city or county
770 that receives a request for a land use compatibility statement
771 must act on such request within 21 days after receipt of the
772 request, if the land use is allowable as an outright permitted
773 use, or 21 days after final local permit approval, if the land
774 use is allowable as a conditional use.

775 3. A city or county that receives a request for a land use

776 compatibility statement is not required to act on that request
777 during the period that the department suspends licensing for the
778 premises.

779 (k)1. The department may require the fingerprints of any
780 person listed on an application. However, the department shall
781 require the fingerprints of all of the following:

782 a. Each general partner of the limited partnership, if the
783 applicant is a limited partnership.

784 b. Each manager of the limited liability company, if the
785 applicant is a manager-managed limited liability company.

786 c. Each voting member of the limited liability company, if
787 the applicant is a member-managed limited liability company.

788 d. Each director and officer of the corporation, if the
789 applicant is a corporation.

790 e. Any person who holds a financial interest, whether
791 direct or indirect, in a psilocybin product manufacturing
792 facility or psilocybin service center.

793 f. Any licensee representative.

794 2. A person required to undergo a background screening
795 pursuant to this section must pass a level 2 background
796 screening as provided under chapter 435, which, in addition to
797 the disqualifying offenses provided in s. 435.04, shall exclude
798 a person who has an arrest awaiting final disposition for, has
799 been found guilty of, regardless of adjudication, or has entered
800 a plea of nolo contendere or guilty to an offense under chapter

801 837, chapter 895, or chapter 896 or any similar law of another
802 jurisdiction.

803 a. Such person must submit a full set of fingerprints to
804 the department or to a vendor, private entity, or public agency
805 under s. 943.053(13). The department, vendor, private entity, or
806 public agency shall forward the fingerprints to the Department
807 of Law Enforcement for state processing, and the Department of
808 Law Enforcement shall forward the fingerprints to the Federal
809 Bureau of Investigation for national processing.

810 b. Fingerprints submitted to the Department of Law
811 Enforcement shall be retained by the Department of Law
812 Enforcement as provided in s. 943.05(2)(g) and (h) and, when the
813 Department of Law Enforcement begins participation in the
814 program, enrolled in the Federal Bureau of Investigation's
815 national retained print arrest notification program. Any arrest
816 record identified shall be reported to the department.

817 (2) PSILOCYBIN PRODUCT MANUFACTURING FACILITY LICENSE.—

818 (a) The manufacture of psilocybin products is subject to
819 regulation by the department. Any psilocybin products used by a
820 psilocybin service center must be manufactured by a psilocybin
821 product manufacturing facility licensed under this section. A
822 psilocybin product manufacturing facility must have a psilocybin
823 product manufacturing facility license issued by the department
824 for the premises at which the psilocybin products will be
825 manufactured. To hold a psilocybin product manufacturing

826 facility license, a psilocybin product manufacturing facility
827 must complete all of the following:

828 1. Apply for a license in the manner described in
829 subsection (1).

830 2. Provide proof that the applicant is owned and
831 controlled by a person or persons who are 21 years of age or
832 older.

833 3. Provide proof that the applicant's psilocybin product
834 manufacturing facility is located in an area zoned for
835 industrial or agricultural use.

836 (b)1. For purposes of this subsection, the department
837 shall adopt rules that designate different types of psilocybin
838 product manufacturing activities. A psilocybin product
839 manufacturing facility may only engage in a type of psilocybin
840 product manufacturing activity if the psilocybin product
841 manufacturing facility has received an endorsement from the
842 department for that type of psilocybin product manufacturing
843 activity.

844 a. An applicant must request an endorsement upon
845 submission of an initial application but the applicant or
846 licensee may request an endorsement at any time after licensure.

847 b. Only one application is required regardless of how many
848 endorsements an applicant or licensee requests or at what time
849 the request is made.

850 2. A psilocybin product manufacturing facility licensee

851 may hold multiple endorsements.

852 3. The department may deny a psilocybin product
853 manufacturing facility's request for an endorsement or revoke an
854 existing endorsement if the psilocybin product manufacturing
855 facility cannot or does not meet the requirements for the
856 endorsement.

857 (3) PSILOCYBIN SERVICE CENTER LICENSE.—

858 (a) The operation of a psilocybin service center is
859 subject to regulation by the department. A psilocybin service
860 center is not a health care facility subject to ss. 408.031-
861 408.08. A psilocybin service center must receive a psilocybin
862 service center license issued by the department for the premises
863 at which psilocybin services will be provided. To hold such a
864 license under this section, a psilocybin service center must
865 complete all of the following:

866 1. Apply for a license in the manner described in
867 subsection (1).

868 2. Provide proof that the applicant is owned and
869 controlled by a person or persons who are 21 years of age or
870 older.

871 3. Provide proof that the psilocybin service center is
872 located in an area that is not:

873 a. Zoned exclusively for residential use; or

874 b. Located within 500 feet of the real property that
875 comprises a public or private elementary school, middle school,

876 or high school. If a school that has not previously been
877 attended by children is established within 500 feet of a
878 premises for which a license has been issued, the psilocybin
879 service center located at that premises may remain at that
880 location, unless the department revokes the license of the
881 psilocybin service center.

882 (b) For purposes of this subsection, the department shall
883 adopt rules that require all of the following:

884 1. A psilocybin service center to annually renew a license
885 issued under this section.

886 2. Any psilocybin products sold or used by a psilocybin
887 service center to be tested in accordance with this section.

888 3. A psilocybin service center to meet any public health
889 and safety standards and industry best practices established by
890 department rule.

891 (4) PSILOCYBIN SERVICE FACILITATOR LICENSE.—

892 (a) The facilitation of psilocybin services is subject to
893 regulation by the department. A psilocybin service facilitator
894 must have a facilitator license issued by the department. To
895 hold a facilitator license issued under this section, a
896 psilocybin service facilitator must complete all of the
897 following:

898 1. Apply for a license in the manner described in
899 subsection (1).

900 2. Provide proof that the applicant is 21 years of age or

901 older.

902 3. Submit evidence of completion of the required education
903 and training as approved by the department.

904 4. Submit evidence of passing an examination approved,
905 administered, or recognized by the department.

906 (b) For purposes of this subsection, the department shall
907 adopt rules that require a psilocybin service facilitator to
908 complete both of the following:

909 1. Annually renew a license issued under this section.

910 2. Meet any public health and safety standards and
911 industry best practices established by department rule.

912 (c) A psilocybin service facilitator may only be an
913 employee, manager, director, officer, partner, member,
914 shareholder, or direct or indirect owner of one psilocybin
915 service center.

916 (d) A license issued to a psilocybin service facilitator
917 under this section is not limited to any one or more premises.

918 (e) The department shall:

919 1. Determine the qualifications, training, and education,
920 including conducting background screenings, of applicants for
921 licenses to facilitate psilocybin services, with an emphasis on
922 all of the following:

923 a. Facilitation skills that are affirming, nonjudgmental,
924 and nondirective.

925 b. Support skills for clients during an administration

926 session, including specialized skills for client safety and
927 clients who may have a mental health condition.

928 c. The environment in which psilocybin services should
929 occur.

930 d. Social and cultural considerations.

931 2. Formulate a code of professional conduct for psilocybin
932 service facilitators, including a code of ethics.

933 3. Establish standards of practice and professional
934 responsibility for persons licensed by the department to
935 facilitate psilocybin services.

936 4. Develop or select examinations for licensure as a
937 psilocybin service facilitator.

938 5. Provide for waivers of examinations as appropriate.

939 6. Appoint representatives to conduct or supervise
940 examinations of applicants.

941 (f) The department shall adopt by rule minimum standards
942 of education and training requirements applicable to psilocybin
943 service facilitators. The department shall approve courses that
944 psilocybin service facilitators must complete. To obtain
945 approval of a course, the provider of a course must submit a
946 curriculum outline to the department and the Department of
947 Education. The outline must include the approved courses, total
948 number of hours of instruction, total number of hours of
949 lectures in theory, and total number of hours of instruction in
950 the application of practical skills.

951 (g) The department shall offer an examination for
952 psilocybin service facilitator applicants at least twice
953 annually. An applicant who fails any section of the examination
954 may retake the failed section of the examination in accordance
955 with rules adopted by the department.

956 (5) PSILOCYBIN TESTING LABORATORY LICENSE.—

957 (a) A laboratory that conducts testing of psilocybin
958 products as required by this section and s. 381.99 must have a
959 license to operate at the premises at which the psilocybin
960 products are tested.

961 (b) For purposes of this subsection, the department shall
962 adopt rules establishing the following:

963 1. Qualifications to be licensed under this section,
964 including accreditation of the applicant for licensure by the
965 department.

966 2. Processes for applying for and renewing a license.

967 (c) The department may inspect premises licensed under
968 this subsection to ensure compliance with this section, s.
969 381.99, and any department rule.

970 (d) Subject to the applicable provisions of ss. 120.569,
971 120.57, and 120.60, the department may refuse to issue or renew,
972 or may suspend or revoke, a license for a violation of this
973 section, s. 381.99, or any department rule.

974 (e) The department shall adopt rules pursuant to ss.
975 120.536(1) and 120.54 that establish a procedure for an initial

976 license and biennial renewal of such license. The department
977 shall renew the license biennially if the psilocybin testing
978 laboratory meets the requirements in this section, s. 381.99,
979 and any department rule.

980 (6) PERMIT REQUIRED TO WORK FOR OR ON BEHALF OF A
981 LICENSEE.—

982 (a) A licensee representative as defined in s. 381.99(1)
983 must have a valid permit issued by the department under this
984 section if the licensee representative participates in the:

985 1. Provision of psilocybin services at the premises;
986 2. Possession, manufacturing, transportation, delivery, or
987 selling of psilocybin products at the premises; or
988 3. Recording of the possession, manufacturing,
989 transportation, delivery, or selling of psilocybin products at
990 the premises.

991 (b) A licensee must verify that a person has a valid
992 permit issued by the department before allowing the person to
993 perform any work described in paragraph (a) at the premises.

994 (c) By February 1, 2023, the department shall begin
995 receiving applications and issuing permits to qualified
996 applicants to perform work as described in paragraph (a). For
997 purposes of this subsection, the department shall adopt rules
998 establishing all of the following:

999 1. Qualifications for performing work as described in
1000 paragraph (a).

1001 2. Duration of a permit issued under this subsection.

1002 3. Procedures for applying for and renewing a permit.

1003 (d)1. The department may require a person applying for a

1004 permit to successfully complete a course, made available by or

1005 through the department, which provides training on:

1006 a. Confirming identification;

1007 b. Detecting intoxication;

1008 c. Handling psilocybin products;

1009 d. If applicable, the manufacturing of psilocybin

1010 products;

1011 e. If applicable, the testing of psilocybin products;

1012 f. The requirements of this section, s. 381.99, and any

1013 department rules; or

1014 g. Any matter deemed necessary by the department to

1015 protect the public health, safety, and welfare.

1016 2. The department may not require a person applying for a

1017 permit to successfully complete a course more than once, except

1018 as part of a final order:

1019 a. Suspending a permit issued under this section, the

1020 department may require a permitholder to successfully complete

1021 the course as a condition of lifting the suspension.

1022 b. Revoking a permit issued under this section, the

1023 department shall require a permitholder to successfully complete

1024 the course before applying for a new permit.

1025 (e) A licensee may not employ a person younger than 21

1026 years of age at a premises. However, a licensee is not
 1027 prohibited from employing a person younger than 21 years of age
 1028 temporarily at the premises to make a service, maintenance, or
 1029 repair call or for other purposes independent of the operations
 1030 occurring on the premises.

1031 (7) GROUNDS FOR REFUSAL TO ISSUE A LICENSE OR PERMIT.—The
 1032 department may refuse to issue a license or, if applicable, a
 1033 permit to an applicant if the department finds that the
 1034 applicant:

1035 (a) Is younger than 21 years of age.

1036 (b) Has not completed any of the education or training
 1037 requirements required by this section.

1038 (c) Has not passed any examination required by this
 1039 section.

1040 (d) Has made false or fraudulent statements or
 1041 representations in the application.

1042 (e) Is incompetent or physically unable to manage the
 1043 premises proposed to be licensed.

1044 (f) Has been convicted of violating a federal law, state
 1045 law, or local ordinance if the conviction is substantially
 1046 related to the qualifications and ability of the applicant to
 1047 lawfully carry out activities under the license.

1048 (g) Does not have a good record of compliance with the
 1049 requirements of this section or s. 381.99.

1050 (h) Is not the legitimate owner of the premises proposed

1051 to be licensed or has not disclosed that other persons have
 1052 ownership interests in the premises proposed to be licensed.

1053 (i) Has not demonstrated financial responsibility
 1054 sufficient to adequately meet the requirements of the premises
 1055 proposed to be licensed.

1056 (j) Is unable to understand the laws of this state
 1057 relating to psilocybin products, psilocybin services, or the
 1058 rules adopted by the department relating to such products and
 1059 services.

1060 (8) GROUNDS FOR REVOCATION, SUSPENSION, OR RESTRICTION OF
 1061 A LICENSE OR PERMIT.—The department may revoke, suspend, or
 1062 restrict a license or, if applicable, a permit issued under this
 1063 section or require a licensee or licensee representative to
 1064 undergo training if the department finds or has reasonable
 1065 grounds to believe that:

1066 (a) The licensee or licensee representative:

1067 1. Has violated the requirements of this section,
 1068 including any code of professional conduct or code of ethics.

1069 2. Has made any false or fraudulent statement or
 1070 representation to the department in order to induce or prevent
 1071 action by the department.

1072 3. Is insolvent or incompetent or physically unable to
 1073 manage the premises of the licensee.

1074 4. Has misrepresented to a person or the public any
 1075 psilocybin products sold by the licensee or licensee

1076 representative.

1077 5. Since the issuance of the license or, if applicable,
1078 the permit, has been convicted of a felony, of violating any
1079 general or local laws of this state relating to psilocybin
1080 products, or of any misdemeanor or violation of any municipal
1081 ordinance committed on the premises.

1082 (b) There is any other reason that, at the discretion of
1083 the department, warrants revoking, suspending, or restricting
1084 the license or, if applicable, the permit.

1085 (9) OPERATING A PSILOCYBIN PRODUCT MANUFACTURING
1086 FACILITY.—

1087 (a) A licensed psilocybin product manufacturing facility
1088 may not manufacture psilocybin products outdoors.

1089 (b) The department shall adopt rules restricting the
1090 quantities of psilocybin products manufactured at a premises.
1091 The department shall take into consideration the demand for
1092 psilocybin services in this state, the number of psilocybin
1093 product manufacturing facilities applying for licenses, the
1094 number of licensed psilocybin product manufacturing facilities,
1095 and whether the availability of psilocybin products in this
1096 state is commensurate with the demand for psilocybin services.

1097 (c) A psilocybin product may not be sold or offered for
1098 sale within this state unless the psilocybin product complies
1099 with the minimum standards adopted by department rule. The
1100 department may prohibit the sale of a psilocybin product by a

1101 psilocybin product manufacturing facility or psilocybin service
1102 center for a reasonable period of time for the purpose of
1103 determining whether the psilocybin product complies with the
1104 minimum standards.

1105 (d)1. As is necessary to protect the public health,
1106 safety, and welfare, the department shall require a licensed
1107 psilocybin product manufacturing facility to test psilocybin
1108 products before selling or transferring the psilocybin products.

1109 2. The department may conduct random testing of psilocybin
1110 products for the purpose of determining whether a licensed
1111 psilocybin product manufacturing facility is in compliance with
1112 this section.

1113 3. The department may not require a psilocybin product to
1114 undergo the same test more than once, unless the psilocybin
1115 product is processed into a different type of psilocybin product
1116 or fundamentally altered.

1117 4. The testing of psilocybin products must be conducted by
1118 a licensed psilocybin testing laboratory.

1119 5. The department shall consider the cost of a potential
1120 testing procedure and how that cost will affect the overall cost
1121 of psilocybin products to the client.

1122 6. The department may not adopt rules that are more
1123 restrictive than are reasonably necessary to protect the public
1124 health, safety, and welfare.

1125 (e) The department shall adopt rules establishing

1126 standards for the labeling of psilocybin products, including:
 1127 1. Ensuring that psilocybin products have labeling that
 1128 communicates all of the following:
 1129 a. Health and safety warnings.
 1130 b. If applicable, activation time of the psilocybin
 1131 product.
 1132 c. Potency of the psilocybin product.
 1133 d. If applicable, the dosage of the psilocybin product and
 1134 the number of doses included in the psilocybin product package.
 1135 e. Content of the psilocybin product.
 1136 2. Labeling that is in accordance with applicable state
 1137 food labeling requirements for the same type of food product or
 1138 potable liquid when the food product or potable liquid does not
 1139 contain psilocybin.
 1140 3. Requiring that all psilocybin products sold or
 1141 transferred by a licensed psilocybin product manufacturing
 1142 facility are labeled in accordance with this section and s.
 1143 381.99.
 1144 4. Establishing different labeling standards for different
 1145 varieties and types of psilocybin products.
 1146
 1147 The department shall consider the cost of a potential
 1148 requirement and how that cost will affect the overall cost of
 1149 psilocybin products to the client.
 1150 (f)1. As is necessary to protect the public health,

1151 safety, and welfare, the department shall adopt rules
1152 establishing standards for the packaging of psilocybin products,
1153 including, but not limited to, ensuring that psilocybin products
1154 are not marketed in a manner that is untruthful or misleading or
1155 otherwise creates a significant risk of harm to the public
1156 health, safety, and welfare.

1157 2. The department shall require all psilocybin products
1158 sold or transferred by a licensed psilocybin product
1159 manufacturing facility or psilocybin service center to be
1160 packaged in accordance with the rules adopted under this
1161 subsection. The department:

1162 a. May establish different packaging standards for
1163 different varieties and types of psilocybin products.

1164 b. May consider the effect on the environment of requiring
1165 certain packaging of psilocybin products.

1166 c. Shall consider the cost of a potential requirement and
1167 how that cost will affect the overall cost of psilocybin
1168 products to the client.

1169 d. May not adopt rules that are more restrictive than are
1170 reasonably necessary to protect the public health, safety, and
1171 welfare.

1172 3. A licensee may not use or allow the use of a mark or
1173 label on the package of a psilocybin product that is kept for
1174 sale if the mark or label does not precisely and clearly
1175 indicate the nature of the package's contents or if the mark or

1176 label in any way might deceive a person about the nature,
1177 composition, quantity, age, or quality of the package's
1178 contents. The department may prohibit a licensee from selling a
1179 psilocybin product that in the department's judgment is
1180 deceptively labeled or contains injurious or adulterated
1181 ingredients.

1182 (g) The department shall adopt rules establishing the
1183 maximum concentration of psilocybin that is allowed in a single
1184 dose of a psilocybin product and the number of doses that are
1185 allowed in a psilocybin product package. The department shall
1186 require all psilocybin products sold or transferred by a
1187 psilocybin product manufacturing facility or psilocybin service
1188 center to meet the concentration and packaging standards adopted
1189 by the department.

1190 (10) OPERATING A PSILOCYBIN TESTING LABORATORY.—

1191 (a) The department shall develop rules for psilocybin
1192 testing laboratories including:

- 1193 1. Security standards.
- 1194 2. Minimum standards for licensee representatives.
- 1195 3. Sample collection method and process standards.
- 1196 4. Proficiency testing for psilocybin products for potency
1197 and contaminants unsafe for human consumption, as determined by
1198 department rule.
- 1199 5. Reporting content, format, and frequency.
- 1200 6. Audits and onsite inspections.

- 1201 7. Quality assurance.
- 1202 8. Equipment and methodology.
- 1203 9. Chain of custody.
- 1204 10. Any other standard the department deems necessary to
- 1205 protect the public health, safety, and welfare.

1206 (b)1. The department shall establish standards for testing
 1207 psilocybin products and identify appropriate tests for
 1208 psilocybin products, depending on the type of psilocybin product
 1209 and the manner in which the psilocybin product was manufactured,
 1210 which are necessary to protect the public health, safety, and
 1211 welfare. The standards may include testing for all of the
 1212 following:

- 1213 a. Microbiological contaminants.
- 1214 b. Pesticides.
- 1215 c. Other contaminants.
- 1216 d. Solvents or residual solvents.
- 1217 e. Psilocybin concentration.

1218 2. The department shall also establish procedures for
 1219 determining batch sizes and for sampling psilocybin products,
 1220 including different minimum procedures and standards for
 1221 different varieties of psilocybin products.

1222 (c) In addition to the testing standards established under
 1223 paragraph (b), the department may require psilocybin products to
 1224 be tested in accordance with any applicable law or department
 1225 rule related to the production and processing of food products,

1226 potable liquids, or commodities.

1227 (d) A psilocybin testing laboratory may acquire psilocybin
1228 products only from a psilocybin product manufacturing facility
1229 or a psilocybin service center. A psilocybin testing laboratory
1230 may not sell, distribute, or transfer psilocybin products
1231 received from a psilocybin product manufacturing facility or
1232 psilocybin service center, except that a psilocybin testing
1233 laboratory may transfer a sample of a psilocybin product to
1234 another psilocybin testing laboratory in this state.

1235 (e) A psilocybin testing laboratory must properly dispose
1236 of all samples it receives, unless transferred to another
1237 psilocybin testing laboratory in this state, after all necessary
1238 tests have been conducted and any required storage period has
1239 elapsed, as established by department rule.

1240 (f) A psilocybin testing laboratory must use the computer
1241 software tracking system designated by the department under s.
1242 381.99(5) (a).

1243 (11) OPERATING A PSILOCYBIN SERVICE CENTER.—

1244 (a) The department shall adopt rules establishing the
1245 requirements, specifications, and guidelines for all of the
1246 following:

1247 1. Having a client complete, sign, and deliver a client
1248 information form to a psilocybin service center and a psilocybin
1249 service facilitator.

1250 2. Providing preparation sessions to a client.

- 1251 3. Holding and verifying the completion of a preparation
1252 session.
- 1253 4. Providing administration sessions to a client.
- 1254 5. Holding and verifying the completion of an
1255 administration session.
- 1256 6. Providing integration sessions to a client.
- 1257 7. Holding and verifying the completion of an integration
1258 session.
- 1259 (b)1. Before a client participates in a preparation
1260 session, the client must complete and sign a client information
1261 form, in a form and manner prescribed by the department in rule.
- 1262 2. A copy of the completed and signed client information
1263 form must be delivered to both of the following:
- 1264 a. The psilocybin service center at which the preparation
1265 session will be held.
- 1266 b. The psilocybin service facilitator who will conduct the
1267 preparation session.
- 1268 3. The client information form must:
- 1269 a. Solicit from the client such information as may be
1270 necessary to:
- 1271 (I) Enable a psilocybin service center and a psilocybin
1272 service facilitator to determine whether the client should
1273 participate in an administration session, including information
1274 that may identify risk factors and contraindications.
- 1275 (II) If applicable, assist the psilocybin service center

1276 and the psilocybin service facilitator in meeting any public
1277 health and safety standards and industry best practices during
1278 the administration session.

1279 b. Contain health and safety warnings and other
1280 disclosures as prescribed by the department in rule.

1281 (c)1. If a client information form is offered as evidence
1282 in any administrative or criminal proceeding involving a
1283 licensee or licensee representative for the sale or service of a
1284 psilocybin product to a client, the licensee or licensee
1285 representative is not guilty of any offense prohibiting a person
1286 from selling or serving a psilocybin product to a client unless
1287 it is demonstrated that a reasonable person would have
1288 determined that the responses provided by the client on the
1289 client information form were incorrect or altered.

1290 2. A licensee or licensee representative shall be entitled
1291 to rely upon all statements, declarations, and representations
1292 made by a client in a client information form unless it is
1293 demonstrated that:

1294 a. A reasonable person would have determined that one or
1295 more of the statements, declarations, and representations made
1296 by the client in the client information form were incorrect or
1297 altered; or

1298 b. The licensee or licensee representative violated this
1299 section or any department rules relating to the client
1300 information form.

1301 3. Except as otherwise provided by law, a licensee or
1302 licensee representative is not liable by virtue of any untrue
1303 statements, declarations, or representations relied upon in good
1304 faith by the licensee or licensee representative.

1305 (d)1. Before a client participates in an administration
1306 session, the client must attend a preparation session with a
1307 psilocybin service facilitator.

1308 2. A preparation session may be held at a psilocybin
1309 service center. The department may develop and adopt rules to
1310 allow preparation sessions to be conducted using telehealth as
1311 defined in s. 456.47(1).

1312 3. If a preparation session is completed in accordance
1313 with all applicable requirements, specifications, and
1314 guidelines, as determined by the department, the psilocybin
1315 service facilitator must certify, in a form and manner
1316 prescribed by the department, that the client completed the
1317 preparation session.

1318 (e)1. After a client completes and signs a client
1319 information form and completes a preparation session, the client
1320 may participate in an administration session, which must be held
1321 at a psilocybin service center. However, the department may
1322 develop and adopt rules to allow administration sessions to be
1323 conducted using telehealth as defined in s. 456.47(1).

1324 2. If an administration session is completed in accordance
1325 with all applicable requirements, specifications, and

1326 guidelines, as determined by the department, the psilocybin
1327 service facilitator must certify, in a form and manner
1328 prescribed by the department, that the client completed the
1329 administration session.

1330 3. A psilocybin service facilitator may not consume a
1331 psilocybin product during an administration session that the
1332 psilocybin service facilitator is supervising.

1333 (f)1. After a client completes an administration session,
1334 the psilocybin service facilitator who supervised the
1335 administration session must offer the client an opportunity to
1336 participate in an integration session. The client is not
1337 obligated to participate in an integration session.

1338 2. An integration session may be held at a psilocybin
1339 service center. However, the department may develop and adopt
1340 rules to allow integration sessions to be conducted using
1341 telehealth as defined in s. 456.47(1).

1342 3. If an integration session is completed in accordance
1343 with all applicable requirements, specifications, and
1344 guidelines, as determined by the department, the psilocybin
1345 service facilitator must certify, in a form and manner
1346 prescribed by the department, that the client completed the
1347 integration session.

1348 (g) A licensee or licensee representative may refuse to
1349 provide psilocybin services or cease providing psilocybin
1350 services to a client at its discretion. However, a psilocybin

1351 service center or a psilocybin service facilitator may not cease
1352 providing psilocybin services to a client during an
1353 administration session after the client has consumed a
1354 psilocybin product, except in the case of an emergency or as
1355 provided for in department rule.

1356 (h) A licensee representative or a psilocybin service
1357 facilitator may not disclose any information that may be used to
1358 identify a client or any communication made by a client during
1359 the course of providing psilocybin services or selling
1360 psilocybin products to the client, unless:

1361 1. The client, or his or her legal guardian or
1362 representative, gives consent to the disclosure;

1363 2. The client initiates legal action or makes a complaint
1364 against the psilocybin service center, the psilocybin service
1365 facilitator, or a licensee representative;

1366 3. The communication reveals the intent to commit a crime
1367 resulting in harm to the client or others;

1368 4. The communication reveals that a minor may have been a
1369 victim of a crime or physical, sexual, or emotional abuse or
1370 neglect; or

1371 5. In response to an inquiry by the department made during
1372 the course of an investigation into the conduct of the
1373 psilocybin service center, the psilocybin service facilitator,
1374 or a licensee representative.

1375 (12) INSPECTION OF RECORDS AND PREMISES; NOTICE.—

1376 (a) The department may request to view the records of a
1377 licensee for the purpose of determining compliance with this
1378 section and s. 381.99. The department shall provide a licensee
1379 48 hours' notice before inspecting the licensee's records. The
1380 department may not require the records of a licensee to be
1381 maintained on the licensee's premises.

1382 (b) The department may at any time inspect the premises of
1383 a licensee for compliance with this section and s. 381.99.

1384 (13) PROHIBITIONS.—

1385 (a) A person may not make false representations or
1386 statements to the department in order to induce or prevent
1387 action by the department.

1388 (b) A licensee may not maintain a noisy, lewd, disorderly,
1389 or insanitary premises or supply adulterated or otherwise
1390 harmful psilocybin products.

1391 (c) A licensee may not misrepresent to a person or to the
1392 public any psilocybin products.

1393 (14) GENERAL LIABILITY INSURANCE.—As is necessary to
1394 protect the public health, safety and welfare, the department
1395 may require a licensee to maintain general liability insurance
1396 coverage in an amount that the department determines is
1397 reasonably affordable and available for the purpose of
1398 protecting the licensee against damages resulting from a cause
1399 of action related to activities carried out in accordance with
1400 the particular license held by the licensee.

1401 (15) INVESTIGATION AND ENFORCEMENT; DISCIPLINARY ACTION.-

1402 (a) The department may proceed with any investigation of,
1403 or any action or disciplinary proceeding against, a licensee or
1404 licensee representative or revise or render void an order
1405 suspending or revoking a license or permit. In cases involving
1406 the proposed denial of a license or permit, the applicant for
1407 licensure or permitting may not withdraw the application.

1408 (b) Section 120.569 applies to subpoenas issued by the
1409 department and to subpoenas issued by an authorized agent of the
1410 department.

1411 (c) In addition to any other disciplinary action that may
1412 be available to the department, the department may immediately
1413 restrict, suspend, or refuse to renew a license or permit issued
1414 under this section if circumstances create probable cause for
1415 the department to determine that a licensee or licensee
1416 representative has purchased or received a psilocybin product
1417 from an unlicensed source or that a licensee or licensee
1418 representative has stored, manufactured, transported, delivered,
1419 sold, or transferred a psilocybin product in a manner that is
1420 not allowed by the licensee's license.

1421 (16) ENFORCEABILITY OF CONTRACTS.-A contract is not
1422 unenforceable on the basis that possessing, manufacturing,
1423 transporting, delivering, distributing, dispensing, selling, or
1424 using psilocybin products is prohibited by federal law.

1425 (17) PROTECTIONS FOR LICENSEE REPRESENTATIVES.-It is an

1426 unlawful employment practice for a licensee to discharge,
1427 demote, suspend, or in any manner discriminate or retaliate
1428 against a licensee representative with regard to promotion,
1429 compensation, or other terms, conditions, or privileges of
1430 employment on the basis that the licensee representative has in
1431 good faith reported information to the department that the
1432 licensee representative believes is evidence of a violation of
1433 this section or s. 381.99.

1434 (18) RIGHTS OF DECEASED, INSOLVENT, OR BANKRUPT PERSONS OR
1435 LICENSEES.—The department may, by rule or order, provide for the
1436 manner and conditions under which psilocybin products left by a
1437 deceased, insolvent, or bankrupt person or licensee, or subject
1438 to a security interest, may be foreclosed, sold under execution,
1439 or otherwise disposed of. The business of a deceased, insolvent,
1440 or bankrupt person or licensee may be operated for a reasonable
1441 period after the death, insolvency, or bankruptcy. An obligor,
1442 as defined in s. 679.1021(1), may continue to operate at a
1443 premises for a reasonable period after default on the
1444 indebtedness by the debtor.

1445 Section 4. This act may not be construed to:

1446 (1) Require a federal or state government medical
1447 assistance program or private health insurer to reimburse a
1448 person for costs associated with the use of psilocybin products.

1449 (2) Amend or affect state or federal law pertaining to
1450 employment matters.

1451 (3) Amend or affect state or federal law pertaining to
1452 landlord-tenant matters.

1453 (4) Prohibit a recipient of a federal grant or an
1454 applicant for a federal grant from prohibiting the possession,
1455 manufacturing, transportation, delivery, sale, or use of
1456 psilocybin products to the extent necessary to satisfy federal
1457 requirements for the grant.

1458 (5) Prohibit a party to a federal contract or a person
1459 applying to be a party to a federal contract from prohibiting
1460 the possession, manufacturing, transportation, delivery, sale,
1461 or use of psilocybin products to the extent necessary to comply
1462 with the terms and conditions of the contract or to satisfy
1463 federal requirements for the contract.

1464 (6) Require a person to violate a federal law.

1465 Section 5. If any provision of this act or its application
1466 to any person or circumstance is held invalid, the invalidity
1467 does not affect other provisions or applications of the act
1468 which can be given effect without the invalid provision or
1469 application, and to this end the provisions of this act are
1470 severable.

1471 Section 6. This act shall take effect July 1, 2021.