

House File 978 - Introduced

HOUSE FILE 978

BY COMMITTEE ON WAYS AND MEANS

(SUCCESSOR TO HF 620)

A BILL FOR

1 An Act relating to the production of psilocybin and the
2 administration of psilocybin to persons with post-traumatic
3 stress disorder, and providing penalties.
4 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

1 Section 1. Section 124.401, subsection 5, Code 2025, is
2 amended by adding the following new paragraph:

3 NEW PARAGRAPH. *g.* A person may knowingly or intentionally
4 recommend, possess, use, dispense, deliver, transport, or
5 administer psilocybin if the recommendation, possession, use,
6 dispensing, delivery, transporting, or administering is in
7 accordance with the provisions of chapter 124F.

8 Sec. 2. NEW SECTION. **124F.1 Definitions.**

9 For the purposes of this chapter, unless the context
10 otherwise requires:

11 1. "*Active psilocybin*" means the psychoactive chemical with
12 the chemical abstracts service registry number 520-52-5.

13 2. "*Adulterant*" means a poisonous or deleterious substance
14 in a quantity that may be injurious to health.

15 3. "*Adverse event*" means an injury or suspected injury to
16 a patient that results in an escalation of care, harm to a
17 patient, or rescue of a patient and occurs during a psilocybin
18 administration session or within twenty-four hours from when
19 the administration session ended.

20 4. "*Community location*" means a public or private elementary
21 or secondary school, a church, a public library, a public
22 playground, or a public park.

23 5. "*Cultivation space*" means, quantified in square feet,
24 the horizontal area in which a psilocybin cultivation facility
25 cultivates psilocybin, including each level of horizontal area
26 if the psilocybin cultivation facility hangs, suspends, stacks,
27 or otherwise positions plants above other plants in multiple
28 levels.

29 6. "*Department*" means the department of health and human
30 services.

31 7. "*Family member*" means a parent, stepparent, spouse,
32 child, sibling, stepsibling, uncle, aunt, nephew, niece,
33 first cousin, mother-in-law, father-in-law, brother-in-law,
34 sister-in-law, son-in-law, daughter-in-law, grandparent, or
35 grandchild.

- 1 8. "*Independent psilocybin testing laboratory*" means a person
2 that does any of the following:
- 3 *a.* Conducts a chemical or other analysis of psilocybin or a
4 psilocybin product.
- 5 *b.* Acquires, possesses, and transports psilocybin or a
6 psilocybin product with the intent to conduct a chemical or
7 other analysis of the psilocybin or psilocybin product.
- 8 9. "*Independent psilocybin testing laboratory agent*"
9 means an individual who holds a valid psilocybin production
10 establishment agent registration card with a psilocybin testing
11 laboratory designation.
- 12 10. "*Inventory control system*" means a system described in
13 section 124F.2.
- 14 11. "*Licensing board*" means the psilocybin production
15 establishment licensing board created pursuant to section
16 124F.4.
- 17 12. "*Patient*" means an individual for whom a qualified
18 medical psilocybin provider recommends psilocybin.
- 19 13. "*Payment provider*" means an entity that contracts with
20 a psilocybin production establishment to facilitate transfer
21 of funds between the establishment and another business or
22 individual.
- 23 14. "*Psilocybin*" means a fresh mushroom containing
24 psilocybin or psilocin.
- 25 15. "*Psilocybin administration session*" means the time
26 period from when a qualified medical provider administers
27 psilocybin to a patient to the time the patient leaves the
28 qualified therapy provider location.
- 29 16. "*Psilocybin biomass*" means any part of a
30 psilocybin-containing fungus.
- 31 17. "*Psilocybin byproduct*" means any part of a
32 psilocybin-containing mushroom which is not used or intended
33 for sale.
- 34 18. "*Psilocybin cultivation facility*" means a person that
35 possesses psilocybin, grows or intends to grow psilocybin, and

1 sells or intends to sell psilocybin to a qualified therapy
2 provider.

3 19. "*Psilocybin cultivation facility agent*" means
4 an individual who holds a valid psilocybin production
5 establishment agent registration card with a cultivation
6 facility designation.

7 20. "*Psilocybin product*" means any portion of a
8 psilocybin-containing mushroom that has been dried and is
9 intended for oral consumption by a patient.

10 21. "*Psilocybin production establishment*" or "*establishment*"
11 means a psilocybin cultivation facility or an independent
12 psilocybin testing laboratory.

13 22. "*Psilocybin production establishment agent registration*
14 *card*" means a registration card issued by the department that
15 authorizes an individual to act as a psilocybin production
16 establishment agent, and that designates the type of psilocybin
17 production establishment for which an individual is authorized
18 to act as an agent.

19 23. "*Qualified medical psilocybin provider*" means a
20 physician and surgeon or osteopathic physician and surgeon
21 licensed pursuant to chapter 148, a physician assistant
22 licensed pursuant to chapter 148C, an advanced registered
23 nurse practitioner licensed under chapter 152, or an advanced
24 practice registered nurse under chapter 152E, who is registered
25 by the department under section 124F.24 to recommend treatment
26 with psilocybin.

27 24. "*Qualified therapy provider*" means a physician and
28 surgeon or osteopathic physician and surgeon licensed pursuant
29 to chapter 148, a physician assistant licensed pursuant
30 to chapter 148C, an advanced registered nurse practitioner
31 licensed under chapter 152, an advanced practice registered
32 nurse under chapter 152E, a psychologist licensed pursuant
33 to chapter 154B, or a social worker licensed pursuant to
34 chapter 154C who is registered by the department to administer
35 treatment with psilocybin.

1 25. "*Qualified therapy provider agent*" means an individual
2 who holds a valid qualified therapy provider agent registration
3 card.

4 26. "*Qualified therapy provider agent registration card*"
5 means a registration card issued by the department that
6 authorizes an individual to act as a qualified therapy provider
7 agent.

8 27. "*Qualified therapy provider location*" or "*provider*
9 *location*" means a facility with all of the following:

10 *a.* A single, secure public entrance.

11 *b.* A security system with a backup power source that detects
12 and records entry and provides notice of an unauthorized entry
13 to law enforcement when the facility is closed.

14 *c.* A lock or equivalent restrictive security feature on any
15 area where the psilocybin or psilocybin product is stored at
16 the facility.

17 Sec. 3. NEW SECTION. 124F.2 **Inventory control system.**

18 1. Each psilocybin production establishment and qualified
19 therapy provider shall maintain an inventory control system
20 that meets all of the requirements of this section.

21 2. An inventory control system shall do all of the
22 following:

23 *a.* Track, in real time, psilocybin and psilocybin product
24 using a unique identifier from the time psilocybin is ready to
25 be harvested.

26 *b.* Maintain in real time a record of the amount of
27 psilocybin or psilocybin product in the possession of the
28 establishment or provider.

29 *c.* Include a video recording system that is tamper proof and
30 does all of the following:

31 (1) Tracks all handling and processing of psilocybin or
32 psilocybin product in the establishment or provider location.

33 (2) Stores each video record for at least forty-five days.

34 3. A psilocybin production establishment or qualified
35 therapy provider shall allow the department, or a financial

1 institution designated by the department, to validate
2 transactions to access the inventory control system at any
3 time.

4 4. The department shall adopt rules pursuant to chapter
5 17A to implement this section, and the rules shall include
6 requirements for aggregate or batch records regarding the
7 planting and propagation of psilocybin before being tracked,
8 and which may include compatibility standards for inventory
9 control systems.

10 Sec. 4. NEW SECTION. 124F.3 Notice to prospective and
11 current public employees.

12 Prior to giving a current employee an assignment or duty that
13 arises from or directly relates to an obligation under this
14 chapter, or hiring a prospective employee whose assignments or
15 duties would include an assignment or duty that arises from or
16 directly relates to an obligation under this chapter, a state
17 employer or a political subdivision employer shall give the
18 employee or prospective employee a written notice that the
19 employee's or prospective employee's job duties may require the
20 employee or prospective employee to engage in conduct which is
21 in violation of the criminal laws of the United States.

22 Sec. 5. NEW SECTION. 124F.4 Psilocybin production
23 establishment licensing board.

24 1. a. There is created within the department the psilocybin
25 production establishment licensing board. The board shall
26 consist of the following members, appointed by the director of
27 the department:

28 (1) One member of the public with knowledge of psilocybin.

29 (2) One member with knowledge and experience in the
30 pharmaceutical or nutraceutical manufacturing industry.

31 (3) One member representing law enforcement.

32 (4) One member who is a chemist or researcher with
33 experience in manufacturing and who is associated with a
34 research university.

35 (5) One member who has a background in fungus or mushroom

1 cultivation and processing.

2 (6) The director or the director's designee, who shall serve
3 as the chairperson of the board and as a nonvoting member,
4 except to cast a deciding vote in the event of a tie.

5 b. A person is ineligible for appointment to the board if
6 any of the following apply:

7 (1) The person has any commercial or ownership interest in a
8 psilocybin production establishment.

9 (2) The person is associated with a business that has an
10 owner, officer, director, or employee whose family member
11 holds a license or has an interest in a psilocybin production
12 establishment.

13 (3) The person is employed or contracted to lobby on behalf
14 of a psilocybin production establishment.

15 c. The director shall ensure that no two members of the
16 board are employed by or represent the same business or
17 nonprofit organization.

18 d. Members of the board shall serve a term of four years,
19 except that initial members of the board shall be appointed
20 for staggered terms such that the director appoints two or
21 three board members every two years. The director shall fill a
22 vacancy on the board for the balance of the unexpired term.

23 e. The director may remove a member of the board for cause,
24 neglect of duty, inefficiency, or malfeasance.

25 f. Members of the board shall serve without compensation but
26 may be reimbursed for actual expenses.

27 2. The board shall meet as called by the chairperson to do
28 all of the following:

29 a. Review each license application for compliance with this
30 chapter and rules adopted by the department.

31 b. Conduct a public hearing to consider a license
32 application.

33 c. Make a determination on a license application.

34 3. The board shall hold a public hearing to review
35 a psilocybin production establishment's license if the

1 establishment changes ownership interest by more than twenty
2 percent, changes location, or as necessary based on the
3 recommendation of the department.

4 4. The board shall meet annually in December to consider
5 psilocybin production establishment license renewal
6 applications. A representative from each applicant for renewal
7 shall attend the meeting. The board shall consider the amount
8 of biomass the applicant produces, the amount of biomass the
9 applicant projects to produce, the current square footage of
10 growing area the applicant uses, and the square footage of
11 growing area the applicant projects to use.

12 5. The board is not subject to dissolution pursuant to
13 section 4A.5.

14 Sec. 6. NEW SECTION. 124F.5 Psilocybin production
15 establishment — license.

16 1. A person shall not operate a psilocybin production
17 establishment unless the person holds a psilocybin production
18 establishment license issued by the licensing board pursuant to
19 this chapter.

20 2. The department shall adopt rules pursuant to chapter 17A
21 to develop a process for soliciting and evaluating applications
22 for a psilocybin production establishment license.

23 3. An applicant for a psilocybin production establishment
24 license shall submit all of the following:

25 a. The proposed name of the establishment and the address
26 where the establishment will be located.

27 b. The name and address of any individual who has any of the
28 following:

29 (1) For a publicly traded company, a financial or voting
30 interest of two percent or greater in the proposed psilocybin
31 production establishment.

32 (2) For a privately held company, a financial or voting
33 interest in the proposed psilocybin production establishment.

34 (3) The power to direct the management or control of the
35 proposed psilocybin production establishment.

1 *c.* An operating plan, approved by the department, that
2 complies with section 124F.8 and any laws that the municipality
3 or county in which the person is located adopts regarding the
4 operation of psilocybin production establishments.

5 *d.* A statement that the applicant will obtain and maintain
6 a performance bond that a surety authorized to transact surety
7 business in this state issues in an amount of at least one
8 hundred thousand dollars for each psilocybin cultivation
9 facility license, or at least fifty thousand dollars for each
10 independent psilocybin testing laboratory license.

11 *e.* An application fee in an amount determined by the
12 department.

13 *f.* A description of any investigatory or adverse action
14 taken by a licensing jurisdiction, government agency, law
15 enforcement agency, or court in any state for any violation
16 or detrimental conduct in relation to any of the applicant's
17 psilocybin-related operations or businesses.

18 4. A psilocybin production establishment shall not be
19 located within one thousand feet of a community location or
20 in or within five hundred feet of an area that is zoned as
21 primarily residential. The board may grant a waiver to reduce
22 the proximity requirements in this subsection by up to twenty
23 percent if the board determines that it is not reasonably
24 feasible for the applicant to site the proposed psilocybin
25 production establishment without the waiver.

26 5. Upon the approval of an application for a license under
27 this section, the applicant shall pay to the department the
28 initial licensing fee, as determined by the department by rule,
29 and the department shall inform the department of public safety
30 of the license approval.

31 6. A psilocybin production establishment may be located
32 at the same location as a medical cannabidiol manufacturer
33 licensed pursuant to section 124E.6 if a separate license is
34 obtained for each.

35 7. If the licensing board receives more than one application

1 for a psilocybin production establishment within the same city
2 or town, the licensing board shall consult with the local
3 land use authority before approving any of the applications
4 pertaining to that city or town.

5 8. The licensing board shall not issue a license to operate
6 an independent psilocybin testing laboratory to any of the
7 following persons:

8 a. A person who holds a license or has an ownership interest
9 to operate a psilocybin cultivation facility.

10 b. A person who has an owner, officer, director, or employee
11 whose family member holds a license or has an ownership
12 interest in a psilocybin cultivation facility.

13 c. A person who has an ownership interest in a psilocybin
14 cultivation facility.

15 9. The licensing board shall not issue a license to operate
16 a psilocybin production establishment to an applicant if an
17 individual described in subsection 3, paragraph "b", has been
18 convicted of a misdemeanor for drug distribution, or convicted
19 of a felony, or is younger than twenty-one years old.

20 10. The licensing board may, at the discretion of the
21 licensing board, grant preference to an applicant who currently
22 holds a medical cannabidiol manufacturer license issued
23 pursuant to section 124E.6.

24 11. The licensing board may revoke a license issued pursuant
25 to this section if any of the following apply:

26 a. The psilocybin production establishment does not
27 begin operations within one year after the date on which the
28 licensing board issues the initial license.

29 b. An individual psilocybin production establishment
30 operated by the licensee has violated the same provision of
31 this chapter three times.

32 c. An individual described in subsection 3, paragraph "b",
33 is convicted of a misdemeanor for drug distribution, or is
34 convicted of a felony.

35 d. The licensee fails to cooperate with an investigation

1 of the psilocybin production establishment conducted by the
2 licensing board.

3 *e.* The psilocybin production establishment demonstrates
4 a willful or reckless disregard for the requirements of this
5 chapter or the rules of the department.

6 *f.* The licensing board determines that the psilocybin
7 production establishment no longer meets the minimum standards
8 for licensure and operation of the psilocybin production
9 establishment.

10 *g.* For an independent psilocybin testing laboratory,
11 the independent psilocybin testing laboratory fails to
12 substantially meet the performance standards adopted by the
13 department by rule.

14 12. If the municipality or county where the licensed
15 psilocybin production establishment will be located requires
16 a local land use permit, a person who is issued a psilocybin
17 production establishment license under this chapter shall
18 submit to the licensing board a copy of the licensee's approved
19 land use permit within one hundred twenty days after the date
20 on which the licensing board issues the license.

21 13. The department shall deposit fees imposed under this
22 section into the general fund of the state.

23 14. The department shall begin accepting applications under
24 this chapter on July 1, 2026.

25 15. The licensing board's authority to issue a license under
26 this section shall be plenary and not subject to review.

27 16. The licensing board shall not issue more than four
28 licenses to operate an independent psilocybin testing
29 laboratory.

30 17. The department may operate or partner with a research
31 university to operate an independent psilocybin testing
32 laboratory.

33 18. A psilocybin production establishment license shall not
34 be transferable or assignable.

35 19. If ownership of a psilocybin production establishment

1 changes by fifty percent or more, the psilocybin production
2 establishment shall submit a new application pursuant to this
3 section.

4 Sec. 7. NEW SECTION. **124F.6 Psilocybin production**
5 **establishment owners and directors — criminal background checks.**

6 1. The division of criminal investigation of the department
7 of public safety shall conduct a thorough investigation of
8 each applicant for a psilocybin production establishment
9 license as in a substantially similar manner as provided in
10 section 124E.19. The division shall report the results of the
11 investigation to the department.

12 2. The department shall collect a fee from the applicant,
13 determined by the department by rule, to cover the costs of the
14 investigation by the division of criminal investigation of the
15 department of public safety. The department shall remit the
16 fee to the division.

17 Sec. 8. NEW SECTION. **124F.7 License renewal.**

18 The licensing board shall renew a license issued pursuant
19 to section 124F.5 on an annual basis if all of the following
20 apply:

21 1. The licensee meets all of the requirements for initial
22 licensure.

23 2. The licensing board does not identify a significant
24 failure of compliance with this chapter or grounds for
25 revocation.

26 3. The licensee pays a renewal fee as determined by the
27 department by rule.

28 Sec. 9. NEW SECTION. **124F.8 Operating plan.**

29 A person applying for a psilocybin production establishment
30 license or license renewal shall submit to the department for
31 the department's review a proposed operating plan that includes
32 all of the following:

33 1. A description of the physical characteristics of the
34 proposed facility or, for a psilocybin cultivation facility, no
35 more than two facility locations, including a floor plan and an

1 architectural elevation.

2 2. A description of the credentials and experience of
3 each officer, director, and owner of the proposed psilocybin
4 production establishment, and of any highly skilled or
5 experienced prospective employee.

6 3. The psilocybin production establishment's employee
7 training standards.

8 4. A security plan.

9 5. A description of the psilocybin production
10 establishment's inventory control system.

11 6. Storage protocols to ensure that psilocybin is stored in
12 a manner that is sanitary and preserves the integrity of the
13 psilocybin.

14 7. For a psilocybin cultivation facility:

15 a. Psilocybin cultivation practices, including the
16 facility's intended pesticide and fertilizer use.

17 b. Square footage under cultivation and anticipated
18 psilocybin yield.

19 8. For an independent psilocybin testing laboratory:

20 a. Psilocybin and psilocybin product testing capacity.

21 b. Psilocybin and psilocybin product testing equipment.

22 c. Testing methods, standards, practices, and procedures for
23 testing psilocybin or psilocybin product.

24 Sec. 10. NEW SECTION. 124F.9 Psilocybin cultivation
25 facilities — number of licenses.

26 The licensing board shall not issue more than two licenses to
27 operate a psilocybin cultivation facility. If the recipient
28 of a license ceases operations for any reason, or otherwise
29 abandons the license, the board may grant the abandoned license
30 to another applicant.

31 Sec. 11. NEW SECTION. 124F.10 Psilocybin production
32 establishment agent — registration.

33 1. An individual shall not act as a psilocybin production
34 establishment agent unless the department registers the
35 individual as a psilocybin production establishment agent,

1 regardless of whether the individual is a seasonal, temporary,
2 or permanent employee.

3 2. None of the following individuals shall serve as a
4 psilocybin production establishment agent, have a financial
5 or voting interest of two percent or greater in a psilocybin
6 production establishment, or have the power to direct or
7 cause the management or control of a psilocybin production
8 establishment:

9 a. An advanced registered nurse practitioner licensed under
10 chapter 152 or an advanced practice registered nurse under
11 chapter 152E.

12 b. An individual licensed under chapter 148 to practice
13 medicine and surgery or osteopathic medicine and surgery.

14 c. A physician assistant licensed under chapter 148C.

15 3. An independent psilocybin testing laboratory agent may
16 not act as a psilocybin cultivation facility agent.

17 4. The department shall, within fifteen business days
18 from the date on which the department receives a complete
19 application from a psilocybin production establishment on
20 behalf of a prospective psilocybin production establishment
21 agent, register and issue a psilocybin production establishment
22 agent registration card to the prospective psilocybin
23 production establishment agent who successfully passes a
24 criminal background investigation as provided in section 124F.6
25 if the psilocybin production establishment does all of the
26 following:

27 a. Provides to the department the prospective psilocybin
28 production establishment agent's name and address.

29 b. Pays a fee to the department in an amount determined by
30 the department by rule.

31 5. The department shall designate, on an individual's
32 psilocybin production establishment agent registration card,
33 the type of psilocybin production establishment for which the
34 individual is authorized to act as an agent.

35 6. a. A psilocybin production establishment agent shall

1 comply with either a certification standard developed by the
2 department by rule, or a certification standard that the
3 department has reviewed and approved.

4 *b.* A certification standard described in paragraph "a" shall
5 include training in all of the following:

6 (1) Iowa medical psilocybin law.

7 (2) For a psilocybin cultivation facility agent, psilocybin
8 cultivation best practices.

9 (3) For an independent psilocybin testing laboratory agent,
10 psilocybin laboratory testing best practices.

11 7. A psilocybin production establishment agent registration
12 card shall expire two years from the date the department issued
13 the card. A psilocybin production establishment agent may
14 renew the agent's registration card if the agent is still
15 eligible to hold a psilocybin production establishment agent
16 registration card and pays a fee determined by the department
17 by rule.

18 8. *a.* A psilocybin production establishment agent shall
19 carry the individual's psilocybin production card with the
20 agent at all times when the agent is on the premises of
21 a psilocybin production establishment where the agent is
22 registered, or when the agent is transporting psilocybin or
23 psilocybin product.

24 *b.* If a psilocybin production establishment agent possesses
25 psilocybin or psilocybin product and produces the registration
26 card while handling or transporting psilocybin or psilocybin
27 product, there is a rebuttable presumption that the agent
28 possesses the psilocybin or psilocybin product legally and
29 a law enforcement officer does not have probable cause,
30 based solely on the agent's possession of the psilocybin or
31 psilocybin product, to believe that the individual is engaging
32 in illegal activity.

33 *c.* A psilocybin production establishment agent who fails to
34 carry the individual's psilocybin production card as required
35 by paragraph "a" is guilty of the following offenses:

1 (1) For a first offense, or second offense within a two-year
2 period, a simple misdemeanor punishable by a fine of one
3 hundred dollars.

4 (2) For a third or subsequent offense within a two-year
5 period, a simple misdemeanor punishable as provided by law.

6 *d.* For each violation of paragraph "c", the department may
7 assess the relevant psilocybin production establishment a fine
8 of up to five thousand dollars.

9 Sec. 12. NEW SECTION. 124F.11 **Psilocybin production**
10 **establishment — general operation requirements.**

11 1. A psilocybin production establishment shall operate in
12 accordance with the operating plan submitted by the psilocybin
13 production establishment pursuant to section 124F.8. A
14 psilocybin production establishment shall notify the department
15 prior to implementing a change to the establishment's operating
16 plan. The department shall inform the establishment of any
17 deficiencies in the new operating plan.

18 2. *a.* Except as provided in paragraph "b", a psilocybin
19 production establishment shall operate in a facility that
20 is accessible only by an individual with a valid psilocybin
21 production establishment agent registration card.

22 *b.* A psilocybin production establishment may authorize
23 an individual who is at least eighteen years of age and who
24 is not a psilocybin production establishment agent to access
25 the psilocybin production establishment if the psilocybin
26 production establishment tracks and monitors the individual at
27 all times while the individual is at the psilocybin production
28 establishment, and maintains a record of the individual's
29 access, including arrival and departure.

30 3. A psilocybin production establishment shall not employ
31 an individual who is younger than twenty-one years of age or
32 who has been convicted of a misdemeanor for drug distribution,
33 or convicted of a felony.

34 4. A psilocybin production establishment shall operate in a
35 facility that has all of the following:

1 *a.* A single, secure public entrance.

2 *b.* A security system with a backup power source that does
3 all of the following:

4 (1) Detects and records entry into the psilocybin
5 production establishment.

6 (2) Provides notice of an unauthorized entry to law
7 enforcement when the psilocybin production establishment is
8 closed.

9 (3) Secures any area where the psilocybin production
10 establishment stores psilocybin or a psilocybin product.

11 Sec. 13. NEW SECTION. 124F.12 **Inspections.**

12 1. The department may inspect the records and facility of a
13 psilocybin production establishment at any time during business
14 hours to determine if the psilocybin production establishment
15 complies with this chapter.

16 2. An inspection under this section may include all of the
17 following:

18 *a.* Inspection of a site, facility, vehicle, book, record,
19 paper, document, data, and other physical or electronic
20 information.

21 *b.* Questioning of any relevant individual.

22 *c.* Observation of an independent psilocybin testing
23 laboratory's methods, standards, practices, and procedures.

24 *d.* The sampling of a specimen of psilocybin or psilocybin
25 product sufficient for testing purposes.

26 *e.* Inspection of equipment, an instrument, a tool, or
27 machinery, including a container or label.

28 3. In conducting an inspection under this section, the
29 department may review and make copies of a book, record, paper,
30 document, data, or other physical or electrical information,
31 including financial data, sales data, shipping data, pricing
32 data, and employee data.

33 4. The department may impose a fee, or a license or
34 registration suspension or revocation, if a psilocybin
35 production establishment fails to comply with this section.

1 Sec. 14. NEW SECTION. 124F.13 Advertising.

2 1. A psilocybin production establishment shall not
3 advertise to the general public in any medium, except that a
4 psilocybin production establishment may advertise an employment
5 opportunity at the psilocybin production establishment.

6 2. The department shall adopt rules pursuant to chapter 17A
7 for standards relating to advertising by a qualified medical
8 psilocybin provider or qualified therapy provider. The rules
9 shall ensure that advertising by a qualified medical psilocybin
10 provider or qualified therapy provider does not imply that the
11 psilocybin may be used for recreational purposes.

12 Sec. 15. NEW SECTION. 124F.14 Psilocybin transportation.

13 1. No individual other than the following may transport
14 psilocybin or a psilocybin product:

15 a. A registered psilocybin production establishment agent.

16 b. A qualified therapy provider.

17 c. A registered qualified therapy provider agent.

18 d. An agent of the department conducting an inspection
19 pursuant to section 124F.12.

20 2. An individual transporting psilocybin or psilocybin
21 product shall be employed by the individual authorizing the
22 transportation and possess a manifest that includes all of the
23 following:

24 a. A unique identifier that links the psilocybin or
25 psilocybin product to a relevant inventory control system.

26 b. The origin and destination information for any psilocybin
27 or psilocybin product that the person is transporting.

28 c. The departure and arrival times of the individual
29 transporting the psilocybin or psilocybin product.

30 3. A registered psilocybin production establishment
31 agent transporting psilocybin or psilocybin product without
32 a manifest as provided in subsection 2 is guilty of a simple
33 misdemeanor punishable by a fine of one hundred dollars.

34 However, if the registered psilocybin production establishment
35 agent is carrying more psilocybin or psilocybin product than is

1 indicated on the manifest, other than a de minimis amount, the
2 registered psilocybin production establishment agent is subject
3 to penalties as provided in chapter 124.

4 4. This section shall not prohibit the department from
5 taking administrative enforcement action against a psilocybin
6 production establishment or another person for failing to make
7 a transport in compliance with this section.

8 Sec. 16. NEW SECTION. 124F.15 **Psilocybin — excess and**
9 **disposal.**

10 1. As used in this section, "*psilocybin waste*" means waste
11 and unused material from the cultivation and production of
12 psilocybin or psilocybin product under this chapter.

13 2. A psilocybin production establishment shall do all of the
14 following:

15 a. Render psilocybin waste unusable and unrecognizable
16 before transporting it from the psilocybin production
17 establishment.

18 b. Dispose of the psilocybin waste in compliance with all
19 applicable state and federal laws.

20 3. A person shall not transport or dispose of psilocybin
21 waste other than as provided in this section.

22 Sec. 17. NEW SECTION. 124F.16 **Psilocybin production**
23 **establishment — local control.**

24 1. A local government shall allow a psilocybin production
25 establishment to operate in any zone designated for industrial
26 use unless the local government has designated by ordinance
27 at least one industrial zone for the operation of psilocybin
28 production establishments before a person submits an
29 application for the establishment of a psilocybin production
30 establishment to the local government.

31 2. A local government shall allow a psilocybin production
32 establishment to operate in any zone designated for
33 agricultural use unless the local government has designated by
34 ordinance at least one agricultural zone for the operation of
35 psilocybin production establishments before a person submits an

1 application for the establishment of a psilocybin production
2 establishment to the local government.

3 3. A psilocybin production establishment may operate on
4 land that a local government has not zoned.

5 4. A local government shall not do any of the following:

6 a. Revoke from, or refuse to issue a license or permit to,
7 a psilocybin production establishment on the sole basis that
8 the applicant or psilocybin production establishment violates
9 federal law regarding the legal status of psilocybin.

10 b. Require a certain distance between a psilocybin
11 production establishment and another psilocybin production
12 establishment or a retail tobacco store as defined in section
13 142D.2.

14 c. Enforce an ordinance against a psilocybin production
15 establishment that was not in effect on the date the psilocybin
16 production establishment submitted a complete application to
17 the local government.

18 Sec. 18. NEW SECTION. 124F.17 Psilocybin cultivation
19 facility — growing and harvesting.

20 1. A psilocybin cultivation facility shall use a unique
21 identifier that is connected to the facility's inventory
22 control system to identify all of the following:

23 a. Each unique harvest of psilocybin.

24 b. Each batch of psilocybin that the facility transfers to
25 an independent psilocybin testing laboratory.

26 c. Any psilocybin waste, as defined in section 124F.15, of
27 which the psilocybin cultivation facility disposes.

28 2. A psilocybin cultivation facility shall identify
29 psilocybin biomass as psilocybin byproduct or psilocybin
30 product before transferring the psilocybin biomass from the
31 facility.

32 3. A psilocybin cultivation facility shall destroy
33 psilocybin cultivation byproduct as provided in section
34 124F.15.

35 Sec. 19. NEW SECTION. 124F.18 Psilocybin cultivation

1 **facility — sales.**

2 1. A psilocybin cultivation facility shall not sell a
3 product other than a psilocybin product or educational material
4 related to the medical use of psilocybin.

5 2. A psilocybin cultivation facility shall not sell a
6 product to a person other than a qualified therapy provider or
7 a registered agent of a qualified therapy provider.

8 Sec. 20. NEW SECTION. **124F.19 Psilocybin cultivation**
9 **facility — labeling.**

10 1. A psilocybin cultivation facility shall label a
11 psilocybin or psilocybin product with the amount of active
12 psilocybin in the psilocybin or psilocybin product.

13 2. The department may adopt rules pursuant to chapter 17A to
14 establish labeling requirements for a psilocybin product.

15 Sec. 21. NEW SECTION. **124F.20 Independent psilocybin**
16 **testing laboratory — psilocybin and psilocybin product testing.**

17 1. The department shall adopt rules pursuant to chapter 17A
18 to do all of the following:

19 a. Identify the adulterant analyses required to be performed
20 on psilocybin or psilocybin product.

21 b. Determine the level of each adulterant that is safe for
22 human consumption.

23 c. Establish protocols for a recall of psilocybin or
24 psilocybin product by a psilocybin production establishment.

25 2. The department may require an independent psilocybin
26 testing laboratory to test for a toxin if the department
27 receives information indicating the potential presence of a
28 toxin, or the department's inspector has reason to believe a
29 toxin may be present based on the inspection of a facility.

30 3. A psilocybin production establishment may not transfer
31 psilocybin or psilocybin product to a qualified therapy
32 provider until an independent psilocybin testing laboratory
33 tests a representative sample of the psilocybin or psilocybin
34 product as provided by the department by rule.

35 4. Before the sale of a psilocybin product, an independent

1 psilocybin testing laboratory shall identify and quantify the
2 amount of active psilocybin present in the psilocybin product.

3 5. The department shall adopt rules pursuant to chapter
4 17A for standards, methods, practices, and procedures for the
5 testing of psilocybin and psilocybin products by an independent
6 psilocybin laboratory.

7 6. The department may require an independent psilocybin
8 testing laboratory to participate in a proficiency evaluation
9 that the department conducts, or that an organization that the
10 department approves conducts.

11 Sec. 22. NEW SECTION. 124F.21 Independent psilocybin
12 testing laboratory — inspections.

13 1. If an independent psilocybin testing laboratory
14 determines that the results of a laboratory test indicate that
15 a psilocybin or psilocybin product batch may be unsafe for
16 human use:

17 a. The independent psilocybin testing laboratory shall
18 report the laboratory test results and the psilocybin or
19 psilocybin product batch to the department and the psilocybin
20 cultivation facility from which the batch originated.

21 b. The department shall place a hold on the psilocybin or
22 psilocybin products to conduct a root cause analysis of the
23 defective batch and make a determination as to the root cause.
24 The psilocybin cultivation facility that grew the psilocybin
25 may appeal the determination of the department.

26 2. If the department determines that psilocybin or
27 psilocybin product prepared by a psilocybin cultivation
28 establishment is unsafe for human consumption, the department
29 may seize, embargo, or destroy the psilocybin or psilocybin
30 product batch as provided in section 124F.15.

31 3. If an independent psilocybin testing laboratory
32 determines that the results of a lab test indicate that the
33 active psilocybin content of psilocybin or a psilocybin product
34 batch diverges more than ten percent from the amount the label
35 indicates, the psilocybin cultivation facility shall not sell

1 the psilocybin or psilocybin product batch unless the facility
2 replaces the incorrect label with a label that correctly
3 indicates the active psilocybin content.

4 Sec. 23. NEW SECTION. 124F.22 Psilocybin electronic
5 verification system.

6 1. The department, in consultation with the department of
7 agriculture and land stewardship and the department of public
8 safety, shall adopt rules pursuant to chapter 17A for the
9 creation and operation of an electronic verification system
10 that, at minimum, does all of the following:

11 a. Allows a qualified medical psilocybin provider to access
12 dispensing information regarding a patient of the qualified
13 medical psilocybin provider, electronically recommend or renew
14 a recommendation for psilocybin or a psilocybin product,
15 connect with an inventory control system that a psilocybin
16 production establishment uses to track in real time and archive
17 purchases of any psilocybin or psilocybin product, and connect
18 with an inventory control system that a psilocybin production
19 establishment utilizes.

20 b. Allows access by all of the following:

21 (1) The department to the extent necessary to carry out the
22 department's functions and responsibilities.

23 (2) The department of inspections, appeals, and licensing
24 to carry out the functions and responsibilities related to
25 the participation of qualified medical psilocybin providers
26 and qualified therapy providers in the recommendation and
27 administration of psilocybin.

28 c. Creates a record each time a person accesses the system
29 that identifies the person who accessed the system and the
30 individual whose records the person accessed.

31 d. Keeps a current record of the total number of individuals
32 who have a psilocybin recommendation issued pursuant to section
33 124F.23.

34 2. The department may release limited data from the
35 electronic verification system for the purposes of conducting

1 research, issuing required reports, or for other official
2 department purposes.

3 3. *a.* A person who knowingly and intentionally releases any
4 information from the state electronic verification system in
5 violation of this section is guilty of a class "D" felony.

6 *b.* A person who negligently or recklessly releases any
7 information from the state electronic verification system in
8 violation of this section is guilty of a serious misdemeanor.

9 4. *a.* A person who obtains or attempts to obtain
10 information from the state electronic verification system by
11 misrepresentation or fraud is guilty of a class "D" felony.

12 *b.* A person who obtains or attempts to obtain information
13 from the state electronic verification system for a purpose
14 other than a purpose authorized in this chapter is guilty of a
15 class "D" felony.

16 5. *a.* Except as provided in paragraph "b", a person who
17 knowingly and intentionally uses, releases, publishes, or
18 otherwise makes available to any other person information
19 obtained from the state electronic verification system for
20 any purpose other than a purpose specified in this section is
21 guilty of a class "D" felony.

22 *b.* This subsection shall not prohibit a person who
23 rightfully obtains information from the state electronic
24 verification system from including the information in
25 the person's medical chart or file for access by a person
26 authorized to review the medical chart or file, providing the
27 information to a person in accordance with the requirements of
28 the federal Health Insurance Portability and Accountability Act
29 of 1996, Pub. L. No. 104-191, or discussing or sharing that
30 information about the patient with the patient.

31 Sec. 24. NEW SECTION. 124F.23 **Psilocybin recommendation**
32 **— limitations — expiration.**

33 1. No more than five thousand individuals shall
34 simultaneously hold a psilocybin recommendation from a
35 qualified medical psilocybin provider.

1 2. An individual's psilocybin recommendation expires if the
2 individual has not received treatment from a qualified therapy
3 provider with psilocybin or a psilocybin product by the later
4 of one year from the date the qualified medical psilocybin
5 provider provided the recommendation, or one year from the date
6 of the individual's most recent administration of psilocybin or
7 a psilocybin product by a qualified therapy provider.

8 Sec. 25. NEW SECTION. 124F.24 Qualified medical psilocybin
9 provider registration — continuing education — treatment
10 recommendation.

11 1. An individual shall not recommend a medical psilocybin
12 treatment unless the department registers the individual as a
13 qualified medical psilocybin provider under this section.

14 2. The department shall, within fifteen days after the date
15 the department receives an application from an individual,
16 register and issue a qualified medical psilocybin provider
17 registration card to the individual if the individual does all
18 of the following:

19 a. Provides to the department the individual's name and
20 address.

21 b. Provides to the department a report detailing the
22 individual's completion of the applicable continuing education
23 requirements described in subsection 3.

24 c. Provides to the department evidence that the individual
25 holds a license that qualifies the individual as a qualified
26 medical psilocybin provider.

27 d. Pays an application fee as determined by the department
28 by rule.

29 e. For an applicant on or after January 1, 2026, provides
30 the information required by subsection 9.

31 3. a. An individual applying for initial registration
32 or renewal of a registration shall complete a continuing
33 education program as determined by the department by rule. The
34 continuing education program shall be offered by the department
35 or a continuing education provider approved by the department.

1 The continuing education program shall address all of the
2 following:

3 (1) This chapter.

4 (2) General information about psilocybin under federal and
5 state law.

6 (3) The latest scientific research on medical psilocybin,
7 including risks and benefits.

8 (4) Best practices for recommending the form and dosage of
9 psilocybin.

10 (5) Systems and receptors affected by psilocybin.

11 (6) Mechanisms of action.

12 (7) Drug interactions.

13 (8) Diagnostic criteria.

14 (9) Contraindications.

15 (10) Side effects and mitigation of side effects.

16 (11) Administrative set and setting, including physical
17 patient safety.

18 (12) Integration.

19 (13) Potential outcomes.

20 (14) Ethical considerations.

21 (15) Discharge safety planning.

22 *b.* An applicant for initial registration shall complete
23 sixteen hours of continuing education. A qualified medical
24 psilocybin provider shall complete four hours of continuing
25 education every two years.

26 4. A qualified medical psilocybin provider shall not
27 recommend psilocybin to a patient, or renew a recommendation
28 for psilocybin, unless the qualified medical psilocybin
29 provider has done all of the following:

30 *a.* Completed and documented in the patient's medical record
31 a thorough assessment of the patient's condition and medical
32 history based on the appropriate standard of care.

33 *b.* Verified that the patient has post-traumatic stress
34 disorder.

35 *c.* Verified that the patient is at least twenty-one years

1 old.

2 *d.* Met with the patient face to face if the qualified
3 medical psilocybin provider has not recommended a psilocybin
4 treatment to the patient in the past.

5 5. *a.* Except as provided in paragraph "*b*", an individual
6 shall not advertise that the individual recommends medical
7 psilocybin treatment.

8 *b.* A qualified medical psilocybin provider, or a clinic or
9 office that employs a qualified medical psilocybin provider,
10 may advertise the following:

11 (1) The provider's or clinic's name and logo.

12 (2) That the individual treats post-traumatic stress
13 disorder.

14 (3) That the individual is registered as a qualified medical
15 psilocybin provider and recommends medical psilocybin.

16 (4) A scientific study regarding medical psilocybin use.

17 6. *a.* A qualified medical psilocybin provider registration
18 card shall expire two years from the date the department issued
19 the card.

20 *b.* The department shall adopt rules pursuant to chapter 17A
21 for the renewal of a medical psilocybin provider registration
22 card.

23 7. The department may revoke a medical psilocybin provider
24 registration card if a qualified medical psilocybin provider
25 fails to maintain compliance with this section.

26 8. A qualified medical psilocybin provider shall not
27 receive any compensation or benefit for the qualified
28 medical psilocybin provider's medical psilocybin treatment
29 recommendation from a psilocybin production establishment or an
30 owner, officer, director, board member, employee, or agent of a
31 psilocybin production establishment.

32 9. On or before January 1 of each year, a qualified medical
33 provider shall report to the department all of the following:

34 *a.* That the qualified medical psilocybin provider, or the
35 entity that employs the qualified medical psilocybin provider,

1 represents online or in printed material that the qualified
2 medical psilocybin provider is a qualified medical psilocybin
3 provider or offers medical psilocybin recommendations to
4 patients, if applicable.

5 **b.** The fee amount that the qualified medical psilocybin
6 provider, or the entity that employs the qualified medical
7 psilocybin provider, charges a patient for a medical psilocybin
8 recommendation, either as an actual cash rate or, if the
9 psilocybin provider or entity bills insurance, an average cash
10 rate.

11 **Sec. 26. NEW SECTION. 124F.25 Standard of care — provider**
12 **not liable — no private right of action.**

13 1. A qualified medical psilocybin provider or a qualified
14 therapy provider who recommends or administers psilocybin in
15 compliance with this chapter shall not be subject to a civil or
16 criminal penalty, or license discipline, solely for violating
17 a federal law or regulation that prohibits recommending,
18 prescribing, possessing, or dispensing psilocybin or a
19 psilocybin product.

20 2. This chapter shall not be construed to reduce or
21 negate the duty of a qualified medical psilocybin provider or
22 qualified therapy provider to use reasonable and ordinary care
23 in the treatment of a patient.

24 **Sec. 27. NEW SECTION. 124F.26 Nondiscrimination for medical**
25 **care or government employment.**

26 1. For purposes of medical care, including an organ or
27 tissue transplant, a patient's use of psilocybin as provided in
28 this chapter is the equivalent of authorized use of any other
29 medication used at the discretion of a physician, and does
30 not constitute the use of an illicit substance or otherwise
31 disqualify an individual from needed medical care.

32 2. **a.** Except as provided in paragraph "b", the state or a
33 political subdivision of the state shall treat an employee's
34 use of medical psilocybin as provided in this chapter in
35 the same way the state or political subdivision treats an

1 employee's use of any prescribed controlled substance, and an
2 employee's medical psilocybin recommendation from a qualified
3 medical psilocybin provider in the same way the state or
4 political subdivision treats an employee's prescription for any
5 prescribed controlled substance.

6 *b.* A state or political subdivision employee who has a valid
7 medical psilocybin registration shall not be subject to adverse
8 action for failing a drug test due to psilocybin or psilocin
9 without evidence that the employee was impaired or otherwise
10 adversely affected in the employee's job performance due to the
11 use of medical psilocybin. This paragraph shall not apply in
12 any of the following circumstances:

13 (1) The employee's use of psilocybin jeopardizes federal
14 funding, a federal security clearance, or any other federal
15 background determination required for the employee's position.

16 (2) The employee's position is dependent on a license
17 or peace officer certification that is subject to federal
18 regulations, including 18 U.S.C. §922(g)(3).

19 (3) An employee who uses medical psilocybin during the
20 twelve hours immediately preceding the employee's shift or
21 during the employee's shift.

22 Sec. 28. NEW SECTION. 124F.27 Insurance — coverage
23 requirement.

24 This chapter shall not be construed to require an insurer,
25 a third-party administrator, or an employer to pay for or
26 reimburse an employee for psilocybin or psilocybin product.

27 Sec. 29. NEW SECTION. 124F.28 Approved drugs.

28 This chapter shall not be construed to restrict or otherwise
29 affect the prescription, distribution, or dispensing of a
30 product that the United States food and drug administration has
31 approved.

32 Sec. 30. NEW SECTION. 124F.29 Qualified therapy
33 provider registration — continuing education — psilocybin
34 administration.

35 1. An individual shall not administer a medical psilocybin

1 treatment unless the department registers the individual as
2 a qualified medical psilocybin therapist as provided in this
3 section.

4 2. The department shall, within fifteen days after the date
5 the department receives an application from an individual,
6 register and issue a qualified medical psilocybin therapist
7 registration card to the individual if the individual does all
8 of the following:

9 a. Provides to the department the individual's name and
10 address.

11 b. Provides to the department the address of the clinic
12 at which the individual will be administering psilocybin to
13 patients.

14 c. Provides to the department a report detailing the
15 individual's completion of the applicable continuing education
16 requirements described in subsection 3.

17 d. Certifies to the department that the individual has
18 installed and maintains an inventory control system.

19 e. Provides to the department evidence that the individual
20 holds a license that qualifies the individual as a qualified
21 medical psilocybin provider.

22 f. Pays an application fee as determined by the department
23 by rule.

24 g. Provides to the department an emergency transport plan
25 for patients who experience a medical emergency during the
26 course of treatment.

27 3. a. An individual applying for initial registration
28 or renewal of a registration shall complete a continuing
29 education program as determined by the department by rule. The
30 continuing education program shall be offered by the department
31 or a continuing education provider approved by the department.
32 The continuing education program shall address all of the
33 following:

34 (1) This chapter.

35 (2) General information about psilocybin under federal and

1 state law.

2 (3) The latest scientific research on medical psilocybin,
3 including risks and benefits.

4 (4) Best practices for recommending the form and dosage of
5 psilocybin.

6 (5) Systems and receptors affected by psilocybin.

7 (6) Mechanisms of action.

8 (7) Drug interactions.

9 (8) Diagnostic criteria.

10 (9) Contraindications.

11 (10) Side effects and mitigation of side effects.

12 (11) Administrative set and setting, including physical
13 patient safety.

14 (12) Integration.

15 (13) Potential outcomes.

16 (14) Ethical considerations.

17 (15) Discharge safety planning.

18 *b.* An applicant for initial registration shall complete
19 eighty hours of continuing education. A qualified therapy
20 provider shall complete four hours of continuing education
21 every two years.

22 4. A qualified therapy provider shall only administer
23 psilocybin to a patient when all of the following requirements
24 are met:

25 *a.* The patient has a recommendation issued by a qualified
26 medical psilocybin provider.

27 *b.* The qualified medical therapy provider has obtained and
28 reviewed the patient's mental health history.

29 *c.* The qualified therapy provider has provided the patient
30 with a safety data sheet created by the department which
31 outlines the potential risks of psilocybin use.

32 *d.* There are unexpired rescue medications on site, as
33 determined by the department by rule.

34 *e.* The administration session is video-recorded and the
35 video recording is preserved for one year from the date of the

1 session, or the patient gives written, informed consent waiving
2 the video-recording requirement.

3 *f.* The qualified therapy provider has a contractual
4 relationship with a licensed physician and surgeon or
5 osteopathic physician and surgeon who remains on call during
6 the course of the administration session in case the patient
7 requires nonemergency medical intervention.

8 5. A qualified therapy provider shall only administer
9 psilocybin or a psilocybin product in a qualified therapy
10 provider location.

11 6. *a.* Except as provided in paragraph "b", an individual
12 shall not advertise that the individual administers medical
13 psilocybin treatment.

14 *b.* A qualified therapy provider or clinic or office
15 that employs a qualified therapy provider may advertise the
16 following:

17 (1) The provider's or clinic's name and logo.

18 (2) That the individual treats post-traumatic stress
19 disorder.

20 (3) That the individual is registered as a qualified therapy
21 provider and administers medical psilocybin.

22 (4) A scientific study regarding medical psilocybin use.

23 7. *a.* A qualified therapy provider registration card
24 expires two years from the date the department issues the card.

25 *b.* The department shall adopt rules pursuant to chapter 17A
26 for the renewal of a qualified therapy provider registration
27 card.

28 8. Within seven days of the date on which an adverse event
29 occurs, a qualified therapy provider shall submit to the
30 department a report containing all of the following:

31 *a.* The age and sex of the patient.

32 *b.* The patient's preexisting health conditions, if any.

33 *c.* The amount of psilocybin administered to the patient.

34 *d.* Factors which contributed to the adverse event.

35 *e.* The nature and severity of the adverse event.

1 *f.* The ultimate outcome of the adverse event.

2 9. The department may revoke a qualified therapy provider
3 registration card if a qualified therapy provider fails to
4 maintain compliance with this section.

5 Sec. 31. NEW SECTION. 124F.30 **Qualified therapy provider**
6 **agent — registration.**

7 1. An individual shall not act as a qualified therapy
8 provider agent unless the department registers the individual
9 as a qualified therapy provider agent, regardless of whether
10 the individual is a seasonal, temporary, or permanent employee.

11 2. The department shall, within fifteen business days
12 after the date the department receives a complete application
13 from a qualified therapy provider agent, register and issue
14 a qualified therapy provider agent registration card to the
15 prospective agent who successfully passes a criminal background
16 investigation as provided in section 124F.6 if the prospective
17 agent does all of the following:

18 *a.* Provides to the department the prospective agent's name
19 and address.

20 *b.* Pays a fee to the department in an amount determined by
21 the department by rule.

22 3. *a.* A qualified therapy provider agent shall comply with
23 either a certification standard developed by the department
24 by rule, or a certification standard that the department has
25 reviewed and approved.

26 *b.* A certification standard described in paragraph "a" shall
27 include training in Iowa medical psilocybin law.

28 4. A qualified therapy provider agent registration card
29 shall expire two years from the date the department issued the
30 card. A qualified therapy provider agent may renew the agent's
31 registration card if the agent is still eligible to hold a
32 qualified therapy provider agent registration card and pays a
33 fee determined by the department by rule.

34 5. *a.* A qualified therapy provider agent shall carry the
35 individual's qualified therapy provider agent card with the

1 agent at all times when the agent is handling psilocybin or
2 psilocybin product.

3 *b.* If a qualified therapy provider agent possesses
4 psilocybin or psilocybin product and produces the registration
5 card in the agent's possession, there is a rebuttable
6 presumption that the agent possesses the psilocybin or
7 psilocybin product legally and a law enforcement officer does
8 not have probable cause, based solely on the agent's possession
9 of the psilocybin or psilocybin product, to believe that the
10 individual is engaging in illegal activity.

11 *c.* A qualified therapy provider agent who fails to carry
12 the individual's qualified therapy provider agent card with the
13 agent as required by paragraph "a" is guilty of the following
14 offenses:

15 (1) For a first offense, or a second offense within a
16 two-year period, a simple misdemeanor punishable by a fine of
17 one hundred dollars.

18 (2) For a third offense, or a subsequent offense within a
19 two-year period, a simple misdemeanor.

20 *d.* For each violation of paragraph "c", the department may
21 assess the relevant qualified therapy provider a fine of up to
22 two thousand five hundred dollars.

23 Sec. 32. NEW SECTION. 124F.31 **Reports.**

24 1. *a.* On or before November 1, 2025, and by November 1 of
25 each year thereafter, the department shall submit a report to
26 the general assembly including all of the following:

27 (1) The number of patients for whom psilocybin has been
28 recommended.

29 (2) The age and county of patients.

30 (3) The number of qualified medical psilocybin providers.

31 (4) The number of license applications and renewal
32 applications received.

33 (5) The number of licenses the department has issued in each
34 county.

35 (6) The number of licenses the department has revoked.

1 (7) The expenses incurred and revenues generated from the
2 medical psilocybin program.

3 (8) The number and nature of adverse events reported.

4 *b.* The department shall not include personally identifying
5 information in the report submitted pursuant to paragraph "a".

6 2. The department shall submit a report to the general
7 assembly regarding the efficacy of medical psilocybin,
8 including recommendations, by June 1, 2028.

9 Sec. 33. NEW SECTION. 124F.32 **Enforcement.**

10 1. If a person that is licensed or registered under this
11 chapter violates a provision of this chapter or rules adopted
12 by the department pursuant to this chapter, or fails to
13 comply with an enforcement action taken under this chapter,
14 the department may do any of the following, subject to the
15 requirements of this section:

16 *a.* Revoke the person's license or registration card.

17 *b.* Decline to renew the person's license or registration
18 card.

19 *c.* Assess an administrative fee, as determined by the
20 department by rule.

21 2. If the department finds that a person produced a
22 psilocybin or psilocybin product batch that contains a
23 substance, other than active psilocybin, that poses a
24 significant threat to human health the department shall do all
25 of the following:

26 *a.* Issue the person a written administrative citation.

27 *b.* Attempt to negotiate a stipulated settlement.

28 *c.* Seize, embargo, or destroy the psilocybin or psilocybin
29 product batch.

30 *d.* Order the person to cease and desist from the action that
31 creates a violation.

32 3. The department may, for a person subject to an
33 uncontested citation, a stipulated settlement, or a finding of
34 a violation in an adjudicative proceeding under this section,
35 if a fine is not already specified by law, assess a person who

1 is not an individual a fine of up to five thousand dollars per
2 violation.

3 4. The department shall not revoke a license or registration
4 issued under this chapter without first conducting a contested
5 case proceeding pursuant to chapter 17A.

6 5. Except where a criminal penalty is expressly provided for
7 a specific violation of this chapter, the following criminal
8 penalties apply:

9 a. Except as provided in paragraph "b", an individual who
10 violates a provision of this chapter is guilty of a simple
11 misdemeanor punishable by a fine of one hundred dollars.

12 b. An individual who intentionally or knowingly violates
13 a provision of this chapter, or violates a provision of this
14 chapter three or more times, is guilty of a serious misdemeanor
15 punishable by a fine of one thousand dollars.

16 EXPLANATION

17 The inclusion of this explanation does not constitute agreement with
18 the explanation's substance by the members of the general assembly.

19 This bill relates to the production of psilocybin and
20 administration of psilocybin to persons with post-traumatic
21 stress disorder. The bill requires a psilocybin production
22 establishment or a qualified therapy provider location,
23 defined in the bill, to include an inventory control system
24 that tracks psilocybin product, defined in the bill, in
25 real time; maintains access records; and includes a video
26 recording system. The bill requires a psilocybin production
27 establishment or qualified therapy provider location to allow
28 the department of health and human services (department) to
29 access the inventory control system at any time.

30 The bill requires a state employer or political subdivision
31 employer to inform an employee or prospective employee prior to
32 assigning a duty related to the administration of the bill that
33 the employee's or prospective employee's job duties may require
34 the employee or prospective employee to engage in conduct in
35 violation of the criminal laws of the United States.

1 The bill creates within the department the psilocybin
2 production establishment licensing board (board), with members
3 appointed by the director of the department. The board shall
4 consist of a member of the public with knowledge of psilocybin,
5 a member with knowledge and experience in the pharmaceutical
6 or nutraceutical manufacturing industry, a member representing
7 law enforcement, a member who is a chemist or researcher with
8 experience in manufacturing and who is associated with a
9 research university, a member who has a background in fungus or
10 mushroom cultivation and processing, and the director of the
11 department or the director's designee, who shall serve as the
12 chairperson of the board and a nonvoting member, except in the
13 case of a tied vote. The bill prohibits a person from serving
14 on the board if the person has certain financial interests
15 related to psilocybin. Members of the board shall serve a
16 term of four years, except that initial members of the board
17 shall be appointed for staggered terms such that the director
18 appoints two or three board members every two years. The
19 director shall fill vacancies in the board for the balance of
20 the unexpired term. Members of the board shall serve without
21 compensation, although they may be reimbursed for actual
22 expenses, and the director may remove a member of the board
23 for cause, neglect of duty, inefficiency, or malfeasance. The
24 board is not subject to automatic dissolution pursuant to Code
25 section 4A.5 (boards and governmental entities — dissolution).
26 The board shall meet as called by the chairperson to review
27 psilocybin license applications, conduct public hearings on
28 applications, and make determinations on license applications.
29 The bill requires the board to meet if a psilocybin production
30 establishment undergoes certain changes and annually to
31 consider license renewal applications. The bill prohibits a
32 person from operating a psilocybin production establishment
33 unless the person holds a license issued by the board. The
34 bill requires the department to adopt rules for solicitation
35 and evaluation of license applications. The bill also

1 requires an applicant for a license to submit the proposed
2 name and address of the establishment, the names and addresses
3 of certain persons associated with the establishment, an
4 operating plan, a statement that the applicant will obtain
5 a performance bond, an application fee, and a description
6 of any investigatory or adverse action previously taken
7 against the applicant in relation to any of the applicant's
8 psilocybin-related operations or businesses. The bill
9 prohibits a psilocybin production establishment from operating
10 within 1,000 feet of a community location, defined in the bill,
11 or 500 feet of an area that is zoned as primarily residential.
12 The bill allows the board to waive these limitations by up to
13 20 percent.

14 Upon approval of an application for a license, the bill
15 requires the applicant to pay an initial licensing fee and the
16 department to inform the department of public safety. The bill
17 allows a psilocybin production establishment to be located
18 at the same location as a medical cannabidiol producer and
19 the board may grant preference to an applicant who currently
20 holds a medical cannabidiol producer license. If the board
21 receives more than one application for a psilocybin production
22 establishment license in the same city or town, the board
23 shall consult with the local land use authority prior to
24 issuing a license. The bill prohibits the board from issuing
25 a license to certain persons. The bill allows the board to
26 revoke a license for certain violations. Fees collected by
27 the department shall be deposited into the general fund of the
28 state.

29 If the municipality or county where the psilocybin
30 production establishment will be located requires a land use
31 permit, the bill requires a licensee to submit a copy of an
32 approved land use permit within 120 days of issuance of the
33 license. The bill prohibits the board from issuing more than
34 four licenses to operate an independent psilocybin testing
35 laboratory and allows the board to operate an independent

1 psilocybin testing laboratory. A psilocybin production
2 establishment is not transferable or assignable, and the
3 board's authority to issue a license is plenary and not
4 subject to review. The bill requires the division of criminal
5 investigation of the department of public safety to conduct
6 a thorough investigation of each applicant for a psilocybin
7 production establishment license. The bill requires the board
8 to begin accepting license applications on July 1, 2026. The
9 board shall renew a license if the licensee continues to meet
10 the requirements for initial licensure, the board does not
11 identify a significant failure of compliance or grounds for
12 revocation, and the licensee pays a renewal fee.

13 The bill requires a person applying for a psilocybin
14 production establishment license or license renewal to submit a
15 proposed operating plan, including certain information about
16 the facility, the facility's officers and employees, a security
17 plan, a description of the inventory control system, and
18 storage protocols. The bill requires psilocybin cultivation
19 facilities and psilocybin testing laboratories to submit
20 additional information particular to the type of psilocybin
21 production establishment.

22 The bill prohibits a person from acting as a psilocybin
23 production establishment or qualified therapy provider agent
24 unless the person is registered as a psilocybin production
25 establishment agent with the board. The bill prohibits certain
26 persons from acting as a psilocybin production establishment
27 agent. The bill requires the board to issue a psilocybin
28 production establishment agent registration to a person if
29 the psilocybin production establishment that will employ
30 the agent submits an application and pays a fee on behalf
31 of the person. The prospective agent shall also undergo a
32 criminal background investigation. A psilocybin production
33 establishment agent shall comply with a certification standard
34 adopted by the board. A psilocybin production establishment
35 agent registration is valid for two years and may be renewed.

1 The bill requires a psilocybin production establishment agent
2 to carry the agent's registration card at all times while on
3 the premises of the psilocybin production establishment or when
4 transporting psilocybin. There is a rebuttable presumption a
5 person carrying a psilocybin production establishment agent
6 registration card while in possession of psilocybin possesses
7 the psilocybin legally. A psilocybin production establishment
8 agent who fails to carry a psilocybin production establishment
9 agent registration card while required to do so is guilty of a
10 simple misdemeanor punishable by a fine of \$100 for a first or
11 second offense in a two-year period and a simple misdemeanor
12 punishable as provided by law for a third or subsequent offense
13 in a two-year period. A simple misdemeanor is punishable by
14 confinement for no more than 30 days and a fine of at least
15 \$105 but not more than \$855. The board may fine a psilocybin
16 production establishment or qualified therapy provider that
17 employs a psilocybin production establishment agent a fine for
18 each violation.

19 The bill requires a psilocybin production establishment
20 to operate in accordance with the operating plan submitted
21 by the psilocybin production establishment and to inform the
22 department prior to implementing any changes to the plan.
23 The bill requires a psilocybin production establishment to
24 operate in a facility that is accessible only by an individual
25 with a valid psilocybin production establishment registration
26 card, except that a psilocybin production establishment may
27 authorize a person who is at least 18 years of age who is
28 not a psilocybin production establishment agent to access
29 the psilocybin production establishment if the psilocybin
30 production establishment tracks and monitors the individual at
31 all times. A psilocybin production establishment shall not
32 employ a person who is under 21 years of age or who has been
33 convicted of a misdemeanor for drug distribution or any felony.
34 The bill requires a psilocybin production establishment to have
35 a single, secure public entrance and a security system with a

1 backup power source.

2 The bill allows the department to inspect the facility and
3 records of a psilocybin production establishment at any time
4 during business hours. The bill grants certain investigational
5 powers to the department and allows the department to impose
6 a fee or suspend or revoke a license or registration for
7 failing to comply with an inspection. The bill prohibits a
8 psilocybin production establishment from advertising to the
9 general public, except to advertise an employment opportunity.
10 The bill requires the department to adopt rules for standards
11 relating to advertisement by qualified medical psilocybin
12 providers and qualified medical psilocybin therapists, defined
13 in the bill.

14 The bill prohibits a person other than a psilocybin
15 production establishment agent, qualified therapy provider,
16 qualified therapy provider agent, or an agent of the department
17 conducting an inspection from transporting psilocybin. A
18 person transporting psilocybin must possess a manifest
19 including details about the psilocybin the person has been
20 authorized to transport. A psilocybin production establishment
21 agent who transports psilocybin without a manifest is guilty
22 of a simple misdemeanor punishable by a fine of \$100. A
23 psilocybin production establishment who transports an amount of
24 psilocybin in excess of the amount indicated in the manifest
25 is subject to penalties as provided in Code chapter 124
26 (controlled substances). The bill requires a person disposing
27 of psilocybin waste to render the psilocybin waste unusable
28 and unrecognizable and to dispose of it in compliance with
29 applicable state and federal law.

30 The bill requires a local government to allow a psilocybin
31 production establishment to operate in any zone designated for
32 industrial or agricultural use, unless the local government has
33 designated at least one industrial or agricultural zone for the
34 operation of a psilocybin production establishment prior to the
35 receipt of an application for the establishment of a psilocybin

1 production establishment by the local government. The bill
2 allows a psilocybin production establishment to operate on land
3 that has not been zoned. The bill prohibits local governments
4 from imposing certain restrictions on the establishment of a
5 psilocybin production establishment.

6 The bill requires a psilocybin cultivation facility to
7 use unique identifiers to identify certain classifications
8 of psilocybin. The bill prohibits a psilocybin cultivation
9 facility from selling any product other than a psilocybin
10 product or educational material related to psilocybin and from
11 selling to a person other than a qualified therapy provider or
12 a registered agent of a qualified therapy provider. The bill
13 includes certain labeling requirements for psilocybin products.

14 The bill requires the department to adopt rules for the
15 testing of psilocybin by an independent psilocybin testing
16 laboratory. The bill allows the department to require an
17 independent psilocybin testing laboratory to test for a toxin
18 if the department receives information about the presence
19 of the toxin. The bill prohibits a psilocybin production
20 establishment from transferring psilocybin to a qualified
21 therapy provider until a sample of the psilocybin has been
22 tested by an independent psilocybin testing laboratory. The
23 bill allows the department to require an independent psilocybin
24 testing laboratory to participate in a proficiency evaluation.
25 If an independent psilocybin testing laboratory determines that
26 a psilocybin product is unsafe for human use, the bill requires
27 the independent psilocybin testing laboratory to inform the
28 department and the psilocybin cultivation facility from which
29 the batch originated, and the department shall place a hold on
30 the sale and use of the psilocybin product until the department
31 completes an investigation.

32 The bill requires the department, in consultation with the
33 departments of agriculture and public safety, to adopt rules
34 for the creation and operation of an electronic verification
35 system. The electronic verification system shall, at a

1 minimum, allow a medical psilocybin provider to engage in
2 patient management; allow access by the department and the
3 department of inspections, appeals, and licensing; create a
4 record each time a person accesses the system; and keeps a
5 current record of the total number of individuals who have a
6 psilocybin recommendation. The bill allows the department to
7 release limited data from the electronic verification system
8 for research, reporting, and official department purposes. A
9 person who knowingly and intentionally releases information
10 from the electronic verification system in violation of the
11 bill is guilty of class "D" felony. A class "D" felony is
12 punishable by confinement for no more than five years and a
13 fine of at least \$1,025 but not more than \$10,245. A person
14 who negligently or recklessly releases information from the
15 electronic verification system in violation of the bill is
16 guilty of a serious misdemeanor. A serious misdemeanor is
17 punishable by confinement for no more than one year and a
18 fine of at least \$430 but not more than \$2,560. A person who
19 unlawfully obtains or attempts to obtain information from the
20 electronic verification system is guilty of a class "D" felony.

21 The bill limits the number of psilocybin recommendations
22 in the state to 5,000 patients. An individual's psilocybin
23 recommendation expires if the individual has not received
24 treatment from a qualified therapy provider with psilocybin
25 or a psilocybin product by the later of one year from the
26 day a qualified medical psilocybin provider provided the
27 recommendation or one year from the day of the individual's
28 most recent administration of psilocybin or a psilocybin
29 product by a qualified therapy provider. The bill prohibits
30 a person from recommending the use of psilocybin unless the
31 person is a qualified medical psilocybin provider, defined in
32 the bill as a physician and surgeon or osteopathic physician
33 and surgeon, a physician assistant, an advanced registered
34 nurse practitioner, or an advanced practice registered nurse
35 who is registered by the department to recommend treatment

1 with psilocybin. The bill requires the department to issue a
2 qualified medical psilocybin provider registration card to an
3 individual if the individual submits an application, provides
4 a report detailing the completion of continuing education
5 requirements regarding the use of psilocybin listed in the
6 bill, provides evidence that the person holds an appropriate
7 license, and pays an application fee.

8 The bill prohibits a qualified medical psilocybin provider
9 from recommending the use of psilocybin unless the qualified
10 medical psilocybin provider completes a thorough assessment
11 of the patient's condition and history, verifies that the
12 patient has post-traumatic stress disorder, verifies that the
13 patient is at least 21 years old, and meets with the patient
14 in person if the qualified medical psilocybin provider has not
15 previously recommended a psilocybin treatment to the patient.
16 The bill places restrictions on advertisements by qualified
17 medical psilocybin providers. A qualified medical psilocybin
18 provider registration card expires after two years and may be
19 renewed. The bill allows the department to revoke a qualified
20 medical psilocybin provider registration card for failure
21 to comply with the bill. The bill prohibits a qualified
22 medical psilocybin provider from receiving compensation from
23 certain persons involved in the production of psilocybin. A
24 qualified medical psilocybin provider shall not be subject to a
25 professional, civil, or criminal penalty solely for violating
26 a federal law or regulation that would prohibit recommending,
27 prescribing, possessing, or dispensing psilocybin.

28 The bill prohibits discrimination against a person in
29 the provision of medical care, including organ or tissue
30 transplantation, on the basis of the usage of psilocybin as
31 provided in the bill. The bill also prohibits the state or a
32 political subdivision of the state from discriminating against
33 an employee on the basis of the employee's use of psilocybin
34 as provided in the bill except under certain circumstances, as
35 provided in the bill.

1 The bill does not require an insurer, a third-party
2 administrator, or an employer to pay or reimburse for
3 psilocybin. The bill does not restrict the prescription,
4 distribution, or dispensing of a product that the United States
5 food and drug administration has approved.

6 The bill prohibits a person from administering a psilocybin
7 treatment unless the department registers the person as a
8 qualified medical psilocybin therapist, defined in the bill as
9 a physician and surgeon or osteopathic physician and surgeon, a
10 physician assistant, an advanced registered nurse practitioner,
11 an advanced practice registered nurse, a psychologist, or a
12 social worker. The department shall register a person as a
13 qualified medical psilocybin therapist if the person submits
14 an application, provides the address of the clinic where
15 psilocybin will be administered, provides a report detailing
16 the completion of continuing education requirements regarding
17 the use of psilocybin listed in the bill, certifies that the
18 individual has an inventory control system, provides evidence
19 that person has an appropriate license, pays an application
20 fee, and provides an emergency transport plan. A qualified
21 medical psilocybin therapist shall not administer psilocybin
22 to a patient unless the patient has a recommendation issued
23 by a qualified medical psilocybin provider, the qualified
24 medical psilocybin therapist has reviewed the patient's mental
25 health history, the qualified medical psilocybin therapist
26 has provided the patient with a safety sheet created by the
27 department, there are unexpired rescue medications on site, the
28 administration session is video-recorded, and the qualified
29 medical psilocybin therapist has a contractual relationship
30 with a licensed physician and surgeon or osteopathic physician
31 and surgeon who remains on call during the course of the
32 administration session in case a patient requires nonemergency
33 medical intervention.

34 A qualified therapy provider shall only administer
35 psilocybin in a qualified therapy provider location. The bill

1 places limits on advertising by qualified therapy providers. A
2 qualified therapy provider registration expires after two years
3 and may be renewed. The bill requires a qualified therapy
4 provider to submit a report to the department within seven days
5 after the occurrence of an adverse event, defined in the bill.
6 The bill allows the department to revoke a qualified therapy
7 provider registration if a qualified therapy provider fails to
8 maintain compliance with the requirements of the bill.

9 The bill requires the department to submit a report to the
10 general assembly on or before November 1, 2025, and annually by
11 November 1 thereafter, regarding participation in the medical
12 psilocybin program. The bill also requires the department to
13 submit a report regarding the medical efficacy of psilocybin
14 to the general assembly, including recommendations, by June 1,
15 2028.

16 The bill grants the department enforcement authority for the
17 enforcement of the bill, including by disciplining licenses
18 and registrations, imposing fees, and seizing and destroying
19 psilocybin. The department shall not revoke a license or
20 registration issued pursuant to the bill without first
21 conducting a contested case proceeding.

22 A person who violates a provision of the bill for which
23 another penalty is not provided is guilty of a simple
24 misdemeanor punishable by a fine of \$100, except that a person
25 who intentionally or knowingly violates a provision of the bill
26 for which no other penalty is provided three or more times is
27 guilty of a serious misdemeanor punishable by a fine of \$1,000.