1		BILL NO
2	INTRODUCED BY	
3		(Primary Sponsor)
4	A BILL FOR AN ACT	ENTITLED: "AN ALLOWING THE THERAPEUTIC USE OF PSILOCYBIN FOR CERTAIN
5	MENTAL HEALTH CO	ONDITIONS; ESTABLISHING REQUIREMENTS FOR THE CULTIVATION,
6	MANUFACTURE, PO	SSESSION, DISTRIBUTION, AND USE OF PSILOCYBIN TO INDIVIDUALS ELIGIBLE
7	TO USE THERAPEUTIC PSILOCYBIN; PROVIDING LEGAL PROTECTIONS AND LIMITATIONS;	
8	ESTABLISHING REPORTING REQUIREMENTS; ESTABLISHING A SPECIAL REVENUE ACCOUNT;	
9	PROVIDING RULEMAKING AUTHORITY; PROVIDING DEFINITIONS; AMENDING SECTIONS 45-9-101, 45-	
10	9-102, 45-9-103, 45-9-110, AND 45-10-107, MCA; AND PROVIDING EFFECTIVE DATES AND A	
11	TERMINATION DATE."	
12		
13	BE IT ENACTED BY	THE LEGISLATURE OF THE STATE OF MONTANA:
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15	NEW SECTION	<u>DN.</u> Section 1. Definitions. As used in [sections 1 through 11], the following definitions
16	apply:	
17	(1) "Adm	inistration session" means a session held at a therapeutic psilocybin treatment center in
18	which a participant purchases, consumes, and experiences the effects of psilocybin in a monitored setting	
19	under the supervision of a therapeutic psilocybin clinician.	
20	(2) "Cert	ified patient" means a resident of this state who is certified in accordance with [section 3]
21	to use therapeutic psilocybin.	
22	(3) "Culti	vator" means a person licensed to grow, harvest, manufacture, package, and label
23	psilocybin products for therapeutic use.	
24	(4) "Depa	artment" means the department of revenue provided for in 2-15-1301.
25	(5) "Integ	gration session" means a meeting between a certified patient and a therapeutic psilocybin
26	clinician that occurs after an administration session.	
27	(6) "Licer	nsee" means an individual or entity who has been granted a license under [sections 1
28	through 11].	



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(7) "Preparation session" means a meeting between a certified patient and a therapeutic psilocybin clinician that occurs before the patient participates in the administration session.

- (8) (a) "Psilocybin" means a naturally occurring psychedelic prodrug compound produced by fungi, including but not limited to members of the genus Psilocybe.
 - (b) The term includes psilocin, the substance into which psilocybin is converted in the human body.
- 6 (9) "Qualifying condition" means any of the following conditions as listed in the fifth edition of the 7 Diagnostic and Statistical Manual of Mental Disorders:
- 8 (a) posttraumatic stress disorder;
- 9 (b) an anxiety or depressive disorder; or
- 10 (c) a substance use disorder.
 - (10) "Therapeutic psilocybin" means psilocybin, concentrated psilocybin, and psilocybin-infused products for use by a certified patient as allowed under [sections 1 through 11].
 - (11) "Therapeutic psilocybin clinician" or "clinician" means an individual licensed by the department to certify a person for the use of therapeutic psilocybin, conduct preparation and integration sessions, and oversee a patient's use of therapeutic psilocybin.
 - (12) "Therapeutic psilocybin facilitator" or "facilitator" means an individual licensed by the department to monitor a certified patient's use of therapeutic psilocybin during an administration session.
- 18 (13) "Therapeutic psilocybin technician" or "technician" means an individual licensed by the 19 department to assist with administration sessions as allowed under [sections 1 through 11].
 - NEW SECTION. Section 2. Lawful use of therapeutic psilocybin. (1) A certified patient may use therapeutic psilocybin only at a therapeutic psilocybin treatment center.
 - (2) The use of therapeutic psilocybin must occur under the supervision of a therapeutic psilocybin clinician and only as part of a treatment regimen consisting of a preparation session, an administration session, and an integration session.
 - (3) A therapeutic psilocybin clinician must be on site during an administration session.
- 27 (4) The department may establish by rule additional requirements for preparation, administration, 28 and integration sessions.



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2	<u>NEW</u>	SECTION. Section 3. Certification of patients application physician or clinician		
3	confirmation	(1) The department shall issue a card certifying a person for therapeutic psilocybin if the person		
4	is a Montana ı	is a Montana resident who is 18 years of age or older and submits:		
5	(a)	an application on a form prescribed by the department;		
6	(b)	a fee as required by the department by rule; and		
7	(c)	written confirmation from a physician or a therapeutic psilocybin clinician that a person has		
8	been diagnosed with a qualifying condition.			
9	(2)	The written confirmation must include:		
10	(a)	the name, date of birth, and address of the patient;		
11	(b)	a statement that the patient:		
12	(i)	has a qualifying condition;		
13	(ii)	is under the physician's or clinician's continuing care for the condition; and		
14	(iii)	is likely to benefit from the use of therapeutic psilocybin;		
15	(c)	the qualifying condition with which the patient has been diagnosed; and		
16	(d)	the physician's or clinician's name, address, telephone number, and signature.		
17	(3)	The department may require that the written confirmation be on a form provided by the		
18	department.			
19	(4)	The physician or therapeutic psilocybin clinician shall maintain a copy of the written		
20	confirmation in the patient's health record.			
21	(5)	A physician or clinician may not issue a certification for the physician's or clinician's therapeutic		
22	use of psilocybin.			
23				
24	NEW	SECTION. Section 4. Individual licensees requirements. (1) The department may issue		
25	the following licenses to individuals who meet the requirements of this section and related administrative rules:			
26	(a)	therapeutic psilocybin clinician;		
27	(b)	therapeutic psilocybin facilitator; and		
28	(c)	therapeutic psilocybin technician.		



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1	(2)	A person may be licensed as a therapeutic psilocybin clinician if the person is licensed under
2	Title 37 as:	
3	(a)	a physician;
4	(b)	a psychologist;
5	(c)	a clinical social worker;
6	(d)	a clinical professional counselor;
7	(e)	a marriage and famiy therapist; or
8	(f)	an advanced practice registered nurse with a clinical specialty in psychiatric mental health
9	nursing.	
10	(3)	A person may be licensed as a therapeutic psilocybin facilitator if the person is licensed under
11	Title 37 as:	
12	(a)	as an addiction counselor; or
13	(b)	a baccalaureate or master's level social worker.
14	(4)	A person may be licensed as a therapeutic psilocybin technician if the person does not have a
15	bachelor's degree in social work, counseling, or addiction counseling but has completed a department-	
16	approved there	apeutic psilocybin training program.
17	(5)	Applicants for licensure under this section must submit:
18	(a)	an application on a form prescribed by the department;
19	(b)	a fee as established by the department by rule; and
20	(c)	fingerprints to facilitate a fingerprint and background check by the department of justice and the
21	federal bureau of investigation.	
22	(6)	Licenses must be renewed annually.
23	(7)	A therapeutic psilocybin clinician shall:
24	(a)	work with a certified patient during preparation and integration sessions; and
25	(b)	be on site at a therapeutic psilocybin treatment center during an administration session.
26	(8)	A therapeutic psilocybin facilitator or technician may assist with an administration session only
27	under the supervision of a clinician.	
28	(9)	The department shall establish by rule:



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1 (a) additional requirements or limitations on activities performed by individuals licensed under this 2 section; and

- (b) training requirements for technicians and, as appropriate, other licensees. The technician training must include information on client safety, contraindications, mental and physical health, preparation, integration, ethics, and harm reduction.
- (10) The name, contact information, and other information relating to facilitators licensed by the department is public information and must be maintained on the department's website unless the facilitator notifies the department in writing that the facilitator does not want the information disclosed. A facilitator may cancel a request for nondisclosure at any time.

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- NEW SECTION. Section 5. Therapeutic psilocybin cultivation and administration -- licensure -- limitations. (1) (a) Therapeutic psilocybin may be cultivated, manufactured, packaged, labeled, possessed, and administered only at a licensed therapeutic psilocybin treatment center.
- (b) Possession of psilocybin for any purposes at a location other than a therapeutic psilocybin treatment center is not protected by the provisions of [sections 1 through 11].
- (2) The department shall license an individual or entity as a cultivator or a therapeutic psilocybin treatment center if the individual or entity submits:
 - (a) an application on a form prescribed by the department;
- (b) a fee established by the department by rule;
 - (c) fingerprints to facilitate a fingerprint and background check by the department of justice and the federal bureau of investigation; and
 - (d) other materials as required by the department by rule.
- 23 (3) The department shall adopt rules establishing requirements for therapeutic psilocybin treatment 24 centers, including rules to ensure the safety and security of patients and the public.
 - (4) The department may conduct scheduled inspections of therapeutic psilocybin treatment centers.
 - (5) A therapeutic psilocybin treatment center may provide psilocybin only to a certified patient who has an agreement with the treatment center to obtain psilocybin from and use psilocybin at the treatment



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center. Psilocybin cultivated at the therapeutic psilocybin treatment center may be used only by certified patients having an agreement with the treatment center.

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- NEW SECTION. Section 6. Legal protections -- limitations. (1) Certified patients and licensees may not be subject to arrest, prosecution, or penalty in any manner or denied any right or privilege, including but not limited to civil penalty or disciplinary action by a business or occupational or professional licensing board, solely for participating in activities as authorized under [sections 1 through 11].
- 8 (2) A person in the custody of or under the supervision of the department of corrections or a youth 9 court may not be punished or otherwise penalized for conduct allowed under [sections 1 through 11].
- 10 (3) A person's certification as a patient or the person's participation in an activity authorized under
 11 [sections 1 through 11] may not be a consideration in a proceeding under Title 40, chapter 4, Title 41, chapter
 12 3, or Title 42.
 - (4) [Sections 1 through 11] do not permit:
 - (a) any individual to operate, navigate, or be in actual physical control of a motor vehicle, train, aircraft, motorboat, or other motorized form of transport while under the influence of psilocybin;
 - (b) consumption, possession, or transport of psilocybin outside of a therapeutic psilocybin treatment center; or
 - (c) delivery, distribution, or use of psilocybin by a person under 18 years of age.
- 19 (5) This section does not:
 - (a) bar the enforcement of a policy prohibiting an employee from performing the employee's duties while impaired by a controlled substance; or
 - (b) require a person or entity to perform or allow an act that would put the person or entity in direct violation of federal law or cause the person or entity to lose a federal contract or funding.

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- NEW SECTION. Section 7. Unlawful conduct -- penalties. (1) The department shall revoke and may not reissue the certification or license of an individual who:
- 27 (a) is convicted of a drug offense;
- 28 (b) allows another individual to be in possession of the individual's psilocybin; or



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1	(c)	is convicted of a felony offense or sexual offense after being certified or licensed under
2	[sections 1 through 11].	
3	(2)	A person commits the offense of fraudulent representation of therapeutic use of psilocyl

- (2) A person commits the offense of fraudulent representation of therapeutic use of psilocybin if the person knowingly or purposely fabricates or misrepresents a certification or license to a law enforcement officer.
- (3) A person who violates a provision of [sections 1 through 11] is punishable by a fine not to exceed \$500 or by imprisonment in a county jail for a term not to exceed 6 months, or both, unless otherwise provided in [sections 1 through 11] or unless the violation would constitute a violation of Title 45. An offense constituting a violation of Title 45 must be charged and prosecuted pursuant to the provisions of Title 45.
- (4) Review of a department action imposing a fine, suspension, or revocation under this section must be conducted as a contested case hearing under the provisions of the Montana Administrative Procedure Act.

NEW SECTION. Section 8. Recordkeeping. Licensees shall maintain records as required by the department by rule and make the records available to the department for inspection on request.

NEW SECTION. Section 9. Reporting requirement. (1) The department shall report annually, in accordance with 5-11-210, to the economic affairs interim committee and the legislature on activities carried out under [sections 1 through 11], including but not limited to:

- (a) the number of certified patients and their qualifying conditions;
- 21 (b) outcomes for certified patients as reported by therapeutic psilocybin treatment centers;
- 22 (c) the number and types of licensees;
- 23 (d) the results of inspections; and
- 24 (e) recommendations for legislative changes to the provisions of [sections 1 through 11].
- 25 (2) Licensees shall report information as required by the department for inclusion in the report.
- 26 (3) Information reported by licensees and by the department may contain only deidentified data.

28 <u>NEW SECTION.</u> **Section 10. Rulemaking authority.** (1) The department shall adopt rules to carry



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1 out the provisions of [sections 1 through 11], including but not limited to rules establishing:

- 2 (a) fees for the certification of patients and licensure of individuals and entities as allowed under 3 [sections 1 through 11];
 - (b) the process for submitting and approving certification and license applications;
- 5 (c) the training program to be completed by therapeutic psilocybin technicians;
- 6 (d) education and training requirements for other licensees;
- 7 (e) requirements for therapeutic psilocybin treatment centers that address the safety and security 8 of both patients and the public; and
- 9 (f) recordkeeping and reporting requirements for licensees.
- 10 (2) The fees established under this section must be commensurate with the costs of implementing 11 and administering the provisions of [sections 1 through 11].

NEW SECTION. Section 11. Therapeutic psilocybin special revenue account. (1) There is a therapeutic psilocybin account in the state special revenue fund established in 17-2-102 to the credit of the department.

- (2) Fees and fines collected pursuant to [sections 1 through 11] must be deposited in the account.

 Interest earned on the account must remain in the account.
- 18 (3) Money in the account may be used by the department for implementing and administering the 19 provisions of [sections 1 through 11].

Section 12. Section 45-9-101, MCA, is amended to read:

- "45-9-101. Criminal distribution of dangerous drugs. (1) Except as provided in Title 16, chapter 12, or [sections 1 through 11], a person commits the offense of criminal distribution of dangerous drugs if the person sells, barters, exchanges, gives away, or offers to sell, barter, exchange, or give away any dangerous drug, as defined in 50-32-101.
- (2) A person convicted of criminal distribution of dangerous drugs involving giving away or sharing any dangerous drug, as defined in 50-32-101, shall be sentenced as provided in 45-9-102.
 - (3) A person convicted of criminal distribution of dangerous drugs not otherwise provided for in



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subsection (1), (2), (4), or (5) shall be imprisoned in the state prison for a term not to exceed 25 years or be fined an amount of not more than \$50,000, or both.

- (4) A person who was an adult at the time of distribution and who is convicted of criminal distribution of dangerous drugs to a minor shall be sentenced as follows:
- (a) For a first offense, the person shall be imprisoned in the state prison for a term not to exceed 40 years and may be fined not more than \$50,000.
- (b) For a second or subsequent offense, the person shall be imprisoned in the state prison for a term not to exceed life and may be fined not more than \$50,000.
 - (5) If the offense charged results in the death of an individual from the use of any dangerous drug that was distributed, the person shall be imprisoned in the state prison for a term of not more than 100 years and may be fined not more than \$100,000.
 - (6) Practitioners, as defined in 50-32-101, and agents under their supervision acting in the course of a professional practice are exempt from this section."

Section 13. Section 45-9-102, MCA, is amended to read:

- "45-9-102. Criminal possession of dangerous drugs. (1) Except as provided in Title 16, chapter 12, or-50-32-609, or [sections 1 through 11], a person commits the offense of criminal possession of dangerous drugs if the person possesses any dangerous drug, as defined in 50-32-101, [in an amount] greater than permitted or for which a penalty is not specified under Title 16, chapter 12, or [sections 1 through 11].
- (2) A person convicted of criminal possession of dangerous drugs shall be imprisoned in the state prison for a term not to exceed 5 years or be fined an amount not to exceed \$5,000, or both.
- (3) A person convicted of a first violation under this section is presumed to be entitled to a deferred imposition of sentence of imprisonment.

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- (4) Ultimate users and practitioners, as defined in 50-32-101, and agents under their supervision acting in the course of a professional practice are exempt from this section."
 - **Section 14.** Section 45-9-103, MCA, is amended to read:
- 28 "45-9-103. Criminal possession with intent to distribute. (1) Except as provided in Title 16,



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1 chapter 12, or [sections 1 through 11], a person commits the offense of criminal possession with intent to

- 2 distribute if the person possesses with intent to distribute any dangerous drug as defined in 50-32-101 [in an
- amount] greater than permitted or for which a penalty is not specified under Title 16, chapter 12, or [sections 1
- 4 through 11].
 - (2) A person convicted of criminal possession with intent to distribute shall be imprisoned in the state prison for a term of not more than 20 years or be fined an amount not to exceed \$50,000, or both.
 - (3) Practitioners, as defined in 50-32-101, and agents under their supervision acting in the course of a professional practice are exempt from this section."

- Section 15. Section 45-9-110, MCA, is amended to read:
- "45-9-110. Criminal production or manufacture of dangerous drugs. (1) Except as provided in Title 16, chapter 12, or [sections 1 through 11], a person commits the offense of criminal production or manufacture of dangerous drugs if the person knowingly or purposely produces, manufactures, prepares, cultivates, compounds, or processes a dangerous drug, as defined in 50-32-101.
- (2) A person convicted of criminal production or manufacture of dangerous drugs, as defined in 50-32-101, shall be imprisoned in the state prison for a term of not more than 25 years and may be fined an amount not to exceed \$50,000.
- than permitted or for which a penalty is not specified under Title 16, chapter 12, or [sections 1 through 11] or manufacture without the appropriate license pursuant to Title 16, chapter 12, or [sections 1 through 11] shall be imprisoned in the state prison for a term of not more than 5 years and may be fined an amount not to exceed \$5,000, except that if the total weight is more than a pound or the number of plants is more than 30, the person shall be imprisoned in the state prison for a term of not more than 25 years and may be fined an amount not to exceed \$50,000. "Weight" means the weight of the dry plant and includes the leaves and stem structure but does not include the root structure.
- (4) Practitioners, as defined in 50-32-101, and agents under their supervision acting in the course of a professional practice are exempt from this section."

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1	Section 16. Section 45-10-107, MCA, is amended to read:		
2	"45-10-107. Exemptions. The provisions of this part do not apply to:		
3	(1) practitioners, as defined in 50-32-101, and agents under their supervision acting in the course		
4	of a professional practice;		
5	(2) persons acting in compliance with Title 16, chapter 12, or [sections 1 through 11]; or		
6	(3) persons acting as employees or volunteers of an organization, including a nonprofit community		
7	based organization, local health department, or tribal health department, that provides needle and syringe		
8	exchange services to prevent and reduce the transmission of communicable diseases."		
9			
10	NEW SECTION. Section 17. Codification instruction. [Sections 1 through 11] are intended to be		
11	codified as an integral part of Title 50, and the provisions of Title 50 apply to [sections 1 through 11].		
12			
13	NEW SECTION. Section 18. Effective dates. (1) Except as provided in subsection (2), [this act] is		
14	effective on passage and approval.		
15	(2) [Sections 3, 4, and 5] are effective on the effective date of rules adopted by the department for		
16	issuing certifications and licenses as allowed under [sections 1 through 11].		
17			
18	NEW SECTION. Section 19. Termination. [Sections 1 through 16] terminate June 30, 2027.		
19	- END -		

