## First Regular Session Seventy-fifth General Assembly STATE OF COLORADO

## ENGROSSED

This Version Includes All Amendments Adopted on Second Reading in the House of Introduction HOUSE BILL 25-1063

LLS NO. 25-0315.01 Jacob Baus x2173

**HOUSE SPONSORSHIP** 

Hartsook and Brown,

Michaelson Jenet,

#### SENATE SPONSORSHIP

House Committees Health & Human Services

**Senate Committees** 

# A BILL FOR AN ACT

- 101 CONCERNING THE LAWFUL USE OF CRYSTALLINE POLYMORPH 102 PSILOCYBIN THAT IS APPROVED BY THE UNITED STATES FOOD
- 103 AND DRUG ADMINISTRATION.

## **Bill Summary**

(Note: This summary applies to this bill as introduced and does not reflect any amendments that may be subsequently adopted. If this bill passes third reading in the house of introduction, a bill summary that applies to the reengrossed version of this bill will be available at <u>http://leg.colorado.gov</u>.)

The bill makes a prescription medicine that contains crystalline polymorph psilocybin legal to prescribe, dispense, distribute, possess, use, and market in Colorado upon its approval by the United States food and drug administration.



1 Be it enacted by the General Assembly of the State of Colorado:

2 SECTION 1. Legislative declaration. (1) The general assembly
3 finds that:

4 (a) Treatment-resistant depression is defined by the federal food 5 and drug administration as depression that has failed to respond to 2 or 6 more medications of adequate dose and duration during a single 7 depressive episode;

8 (b) Serious public health implications are associated with 9 treatment-resistant depression, including a high cost of illness caused by 10 the need for higher intensity treatments, impaired psychosocial function, 11 a greater need for disability benefits, workplace absenteeism, negative 12 impact on caregivers, and increased suicidality;

13 (c) According to the largest study ever conducted on the
14 limitations of treating depression, treatment-resistant depression occurs
15 in approximately one-third of people treated for major depressive
16 disorder;

17 (d) Veterans are disproportionately likely to suffer from18 treatment-resistant depression and other mental health conditions;

(e) According to a recent psychiatric journal publication,
approximately 68% of psychiatric clinic outpatient veterans satisfied
criteria for treatment-resistant depression;

(f) According to a recent medical journal publication,
approximately half of active-duty service members with post-traumatic
stress disorder also suffer from major depressive disorder, which is the
parent indication of treatment-resistant depression; and

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(g) In clinical trials, crystalline polymorph psilocybin was shown

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to reduce depression scores significantly for patients with
 treatment-resistant depression when compared to active placebos.

3 (2) Therefore, the general assembly declares that it is in the best
4 interests of the people of Colorado that behavioral health professionals in
5 Colorado have the ability to provide crystalline polymorph psilocybin to
6 treat patients with treatment-resistant depression if the federal food and
7 drug administration ultimately approves it for prescription use.

8 SECTION 2. In Colorado Revised Statutes, 18-18-203, amend
9 (2)(c)(XXI) as follows:

10 18-18-203. Schedule I. (2) Unless specifically excepted by
Colorado or federal law or Colorado or federal regulation or more
specifically included in another schedule, the following controlled
substances are listed in schedule I:

(c) Any material, compound, mixture, or preparation containing
any quantity of the following hallucinogenic substances, including any
salts, isomers, and salts of isomers of them that are theoretically possible
within the specific chemical designation:

18 (XXI) Psilocybin; EXCEPT THAT PSILOCYBIN DOES NOT INCLUDE 19 A PRESCRIPTION DRUG PRODUCT CONTAINING CRYSTALLINE POLYMORPH 20 PSILOCYBIN APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION 21 AND PLACED ON A SCHEDULE OF THE FEDERAL "CONTROLLED SUBSTANCES 22 ACT", 21 U.S.C. SEC. 801 ET SEQ., OTHER THAN SCHEDULE I, OR EXEMPT 23 FROM ONE OR MORE PROVISIONS OF THAT ACT, AND THAT IS INTENDED FOR 24 PRESCRIBED USE AND DISPENSED BY A PHARMACY OR PRESCRIPTION DRUG 25 OUTLET REGISTERED BY THE STATE OF COLORADO AND ONLY POSSESSED 26 BY A PERSON AUTHORIZED TO POSSESS A CONTROLLED SUBSTANCE 27 PURSUANT TO SECTION 18-18-302. ANY PRESCRIPTION DRUG PRODUCT

1 CONTAINING CRYSTALLINE POLYMORPH PSILOCYBIN THAT IS APPROVED BY 2 THE FEDERAL FOOD AND DRUG ADMINISTRATION MUST BE CONTROLLED IN 3 COLORADO IN THE SAME MANNER AS REQUIRED BY ANY FEDERAL 4 CONTROL DESIGNATION PURSUANT TO THE FEDERAL "CONTROLLED 5 SUBSTANCES ACT", OR ANY EXEMPTION FROM ONE OR MORE PROVISIONS 6 OF THAT ACT; AND IS SUBJECT TO THE PROVISIONS SET FORTH IN PART 1 OF 7 ARTICLE 280 OF TITLE 12 AND PART 3 OF THIS ARTICLE 18. NOTHING IN 8 THIS SUBSECTION (2)(c)(XXI) EXEMPTS A PERSON FROM ANY VIOLATION 9 OF PART 4 OF THIS ARTICLE 18.

10 SECTION 3. Act subject to petition - effective date. This act 11 takes effect at 12:01 a.m. on the day following the expiration of the 12 ninety-day period after final adjournment of the general assembly; except 13 that, if a referendum petition is filed pursuant to section 1 (3) of article V 14 of the state constitution against this act or an item, section, or part of this 15 act within such period, then the act, item, section, or part will not take 16 effect unless approved by the people at the general election to be held in 17 November 2026 and, in such case, will take effect on the date of the 18 official declaration of the vote thereon by the governor.