Second Regular Session Seventy-third General Assembly STATE OF COLORADO

REVISED

This Version Includes All Amendments Adopted on Second Reading in the Second House

LLS NO. 22-0590.01 Jane Ritter x4342

HOUSE BILL 22-1344

HOUSE SPONSORSHIP

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Public & Behavioral Health & Human Services

Health & Human Services

A BILL FOR AN ACT

| 101 | CONCERNING THE LAWFUL USE OF A PRESCRIPTION DRUG THAT |
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| 102 | CONTAINS 3,4-METHYLENEDIOXYMETHAMPHETAMINE (MDMA) |
| 103 | THAT IS APPROVED BY THE UNITED STATES FOOD AND DRUG |
| 104 | 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 http://leg.colorado.gov.)

The bill states that if the United States food and drug administration approves a prescription medicine that contains 3,4-methylenedioxymethamphetamine (MDMA), and if that medicine has

SENATE 2nd Reading Unamended April 28, 2022

HOUSE 3rd Reading Unamended April 8, 2022

HOUSE Amended 2nd Reading April 7, 2022

Shading denotes HOUSE amendment. Double underlining denotes SENATE amendment.

Capital letters or bold & italic numbers indicate new material to be added to existing statute.

Dashes through the words indicate deletions from existing statute.

been placed on a schedule of the federal "Controlled Substances Act", other than schedule I, or has been exempted from one or more provisions of such act, then thereafter prescribing, dispensing, transporting, possessing, and using that prescription drug is legal in Colorado.

1 Be it enacted by the General Assembly of the State of Colorado: 2 **SECTION 1. Legislative declaration.** (1) The general assembly 3 finds and declares that: 4 (a) The effects of post-traumatic stress disorder (PTSD) in 5 patients, along with common comorbidities such as, but not limited to, 6 disassociation, depression, and childhood trauma, represent a major 7 public health crisis for which the currently available treatments are 8 described by medical experts as modest at best; 9 Veterans, first responders, survivors of sexual assault, (b) 10 survivors of natural disasters, and other vulnerable populations who have 11 experienced or witnessed a life-threatening or traumatic event are 12 disproportionately likely to suffer from PTSD and common 13 comorbidities; 14 (c) According to the national center for PTSD, six percent of the 15 population of the United States will have PTSD at some point in their 16 lives and, in any given year, about fifteen million adults have PTSD; 17 (d) The federal department of veterans affairs spent seventeen 18 billion dollars on disability payments for more than one million veterans 19 with PTSD; 20 (e) Results from a phase 3 clinical trial in 2021 demonstrated that 3,4-methylenedioxymethamphetamine (MDMA)-assisted therapy for the 21 22 treatment of patients with severe PTSD and other comorbidities can be 23 highly effective if paired with talk therapy and counseling. In that clinical

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| 1 | trial, two out of three study participants were no longer considered to |
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| 2 | have a PTSD diagnosis after treatment and eighty-eight percent |
| 3 | experienced a clinically significant reduction in symptoms. |
| 4 | (f) In 2015, the United States congress passed the "Improving |
| 5 | Regulatory Transparency for New Medical Therapies Act", which gives |
| 6 | the federal drug enforcement administration ninety days to schedule a |
| 7 | substance under the federal "Controlled Substances Act" when it is |
| 8 | approved for use by the federal food and drug administration; and |
| 9 | (g) As of March 2022, it is widely expected that the federal food |
| 10 | and drug administration will approve MDMA-assisted therapy for |
| 11 | prescription use for PTSD as soon as 2023. |
| 12 | (2) Therefore, the general assembly declares that it is in the best |
| 13 | interests of the people of Colorado that behavioral health professionals in |
| 14 | Colorado have the ability to provide MDMA-assisted therapy to treat |
| 15 | patients with PTSD and other comorbidities if the federal food and drug |
| 16 | administration ultimately approves it for prescription use. |
| 17 | SECTION 2. In Colorado Revised Statutes, 18-18-203, amend |
| 18 | (2)(c)(VII) as follows: |
| 19 | 18-18-203. Schedule I. (2) Unless specifically excepted by |
| 20 | Colorado or federal law or Colorado or federal regulation or more |
| 21 | specifically included in another schedule, the following controlled |
| 22 | substances are listed in schedule I: |
| 23 | (c) Any material, compound, mixture, or preparation containing |
| 24 | any quantity of the following hallucinogenic substances, including any |
| 25 | salts, isomers, and salts of isomers of them that are theoretically possible |
| 26 | within the specific chemical designation: |
| 27 | (VII) 3,4-methylenedioxymethamphetamine (MDMA); EXCEPT |

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| 1 | THAT 3,4-METHYLENEDIOXYMETHAMPHETAMINE (MDMA) DOES NOT |
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| 2 | INCLUDE A PRESCRIPTION DRUG PRODUCT CONTAINING |
| 3 | 3,4-METHYLENEDIOXYMETHAMPHETAMINE (MDMA) APPROVED BY THE |
| 4 | FEDERAL FOOD AND DRUG ADMINISTRATION AND PLACED ON A SCHEDULE |
| 5 | of the federal "Controlled Substances Act", $21U.S.C.sec.801et$ |
| 6 | SEQ., AS AMENDED, OTHER THAN SCHEDULE I, OR HAS BEEN EXEMPTED |
| 7 | FROM ONE OR MORE PROVISIONS OF SUCH ACT, AND THAT IS INTENDED FOR |
| 8 | PRESCRIBED USE AND DISPENSED BY A PHARMACY OR PRESCRIPTION DRUG |
| 9 | OUTLET REGISTERED BY THE STATE OF COLORADO AND ONLY POSSESSED |
| 10 | BY A PERSON AUTHORIZED TO POSSESS A CONTROLLED SUBSTANCE |
| 11 | PURSUANT TO SECTION 18-18-302. ANY SUCH DRUG PRODUCT CONTAINING |
| 12 | MDMA THAT IS APPROVED BY THE FEDERAL FOOD AND DRUG |
| 13 | ADMINISTRATION MUST BE CONTROLLED IN COLORADO IN THE SAME |
| 14 | MANNER AS REQUIRED BY ANY FEDERAL CONTROL DESIGNATION |
| 15 | PURSUANT TO THE FEDERAL "CONTROLLED SUBSTANCES ACT", OR ANY |
| 16 | EXEMPTION FROM ONE OR MORE PROVISIONS OF THAT ACT, AND SUBJECT |
| 17 | TO THE PROVISIONS SET FORTH IN PART $\overline{1}$ OF ARTICLE $\overline{280}$ OF TITLE $\overline{12}$ AND |
| 18 | PART $\overline{3}$ OF THIS ARTICLE $\overline{18}$. Nothing in this section exempts a person |
| 19 | FROM ANY VIOLATION OF PART 4 OF THIS ARTICLE 18. |
| 20 | SECTION 3. Act subject to petition - effective date. This act |
| 21 | takes effect at 12:01 a.m. on the day following the expiration of the |
| 22 | ninety-day period after final adjournment of the general assembly; except |
| 23 | that, if a referendum petition is filed pursuant to section 1 (3) of article V |
| 24 | of the state constitution against this act or an item, section, or part of this |
| 25 | act within such period, then the act, item, section, or part will not take |
| 26 | effect unless approved by the people at the general election to be held in |

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- November 2022 and, in such case, will take effect on the date of the
- 2 official declaration of the vote thereon by the governor.

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