CHAPTER 461

## **HUMAN SERVICES - BEHAVIORAL HEALTH**

HOUSE BILL 22-1344

BY REPRESENTATIVE(S) Neville and Ortiz, Bernett, Boesenecker, Cutter, Esgar, Exum, Gray, Herod, Hooton, Kennedy, Lindsay, Michaelson Jenet, Sirota, Titone, Valdez A., Woodrow, Young; also SENATOR(S) Cooke and Ginal, Buckner, Gonzales, Jaquez Lewis, Kolker, Lee, Moreno, Pettersen, Rankin, Rodriguez, Simpson, Smallwood, Story, Fenberg.

## AN ACT

CONCERNING THE LAWFUL USE OF A PRESCRIPTION DRUG THAT CONTAINS 3,4-METHYLENEDIOXYMETHAMPHETAMINE (MDMA) THAT IS APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION.

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

**SECTION 1. Legislative declaration.** (1) The general assembly finds and declares that:

- (a) The effects of post-traumatic stress disorder (PTSD) in patients, along with common comorbidities such as, but not limited to, disassociation, depression, and childhood trauma, represent a major public health crisis for which the currently available treatments are described by medical experts as modest at best;
- (b) Veterans, first responders, survivors of sexual assault, survivors of natural disasters, and other vulnerable populations who have experienced or witnessed a life-threatening or traumatic event are disproportionately likely to suffer from PTSD and common comorbidities;
- (c) According to the national center for PTSD, six percent of the population of the United States will have PTSD at some point in their lives and, in any given year, about fifteen million adults have PTSD;
- (d) The federal department of veterans affairs spent seventeen billion dollars on disability payments for more than one million veterans with PTSD;
  - (e) Results from a phase 3 clinical trial in 2021 demonstrated that

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- 3,4-methylenedioxymethamphetamine (MDMA)-assisted therapy for the treatment of patients with severe PTSD and other comorbidities can be highly effective if paired with talk therapy and counseling. In that clinical trial, two out of three study participants were no longer considered to have a PTSD diagnosis after treatment and eighty-eight percent experienced a clinically significant reduction in symptoms.
- (f) In 2015, the United States congress passed the "Improving Regulatory Transparency for New Medical Therapies Act", which gives the federal drug enforcement administration ninety days to schedule a substance under the federal "Controlled Substances Act" when it is approved for use by the federal food and drug administration; and
- (g) As of March 2022, it is widely expected that the federal food and drug administration will approve MDMA-assisted therapy for prescription use for PTSD as soon as 2023.
- (2) Therefore, the general assembly declares that it is in the best interests of the people of Colorado that behavioral health professionals in Colorado have the ability to provide MDMA-assisted therapy to treat patients with PTSD and other comorbidities if the federal food and drug administration ultimately approves it for prescription use.
- **SECTION 2.** In Colorado Revised Statutes, 18-18-203, **amend** (2)(c)(VII) as follows:
- **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:
- (VII) 3,4-methylenedioxymethamphetamine (MDMA); EXCEPT THAT 3,4-methylenedioxymethamphetamine (MDMA) does not include a PRESCRIPTION DRUG PRODUCT CONTAINING 3,4-METHYLENEDIOXYMETHAMPHETAMINE (MDMA) APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION AND PLACED ON A SCHEDULE OF THE FEDERAL "Controlled Substances Act", 21 U.S.C. sec. 801 et seq., as amended, other THAN SCHEDULE I, OR HAS BEEN EXEMPTED FROM ONE OR MORE PROVISIONS OF SUCH ACT, AND THAT IS INTENDED FOR PRESCRIBED USE AND DISPENSED BY A PHARMACY OR PRESCRIPTION DRUG OUTLET REGISTERED BY THE STATE OF COLORADO AND ONLY POSSESSED BY A PERSON AUTHORIZED TO POSSESS A CONTROLLED SUBSTANCE PURSUANT TO SECTION 18-18-302. ANY SUCH DRUG PRODUCT CONTAINING MDMA THAT IS APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION MUST BE CONTROLLED IN COLORADO IN THE SAME MANNER AS REQUIRED BY ANY FEDERAL CONTROL DESIGNATION PURSUANT TO THE FEDERAL "Controlled Substances Act", or any exemption from one or more Provisions of that act, and subject to the provisions set forth in part 1 of ARTICLE 280 OF TITLE 12 AND PART 3 OF THIS ARTICLE 18. NOTHING IN THIS SECTION

EXEMPTS A PERSON FROM ANY VIOLATION OF PART 4 OF THIS ARTICLE 18.

SECTION 3. Act subject to petition - effective date. This act takes effect at 12:01 a.m. on the day following the expiration of the ninety-day period after final adjournment of the general assembly; except that, if a referendum petition is filed pursuant to section 1 (3) of article V of the state constitution against this act or an item, section, or part of this act within such period, then the act, item, section, or part will not take effect unless approved by the people at the general election to be held in November 2022 and, in such case, will take effect on the date of the official declaration of the vote thereon by the governor.

Approved: June 8, 2022

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