ARIZONA HOUSE OF REPRESENTATIVES



Fifty-seventh Legislature First Regular Session

Senate: HHS DPA 5-0-2-0 | 3rd Read 23-4-3-0

SB 1555: psilocybin services; regulation; licensure
S/E: approved medication; rescheduling; controlled substance
Sponsor: Senator Shope, LD 16
Committee on Health & Human Services

Summary of the Strike-Everything Amendment to SB 1555

Overview

Allows any pharmaceutical composition of crystalline polymorph psilocybin to be prescribed in Arizona if approved by the U.S. Food and Drug Administration (FDA) and rescheduled by the U.S. Drug Enforcement Administration (DEA) to a schedule other than schedule I of the Controlled Substances Act (CSA) as a controlled substance. Contains a legislative intent and conditional enactment clause.

History

The CSA places drugs, substances and certain chemicals used to make drugs into one of five distinct schedules. The classification is based on the substance's medical use, potential for abuse and safety or dependency liability. The process to add, delete or change the schedule of a substance may be initiated by the DEA, the U.S. Department of Health and Human Services (HHS) or by a petition from an interested party (21 U.S.C. § 811).

The CSA also states that if the U.S. Secretary of HHS recommends that the U.S. Attorney General (U.S. AG) control the drug in schedule II, III, IV or V, the U.S. AG must issue an interim final rule controlling the drug no later than 90 days after the date the U.S. AG receives the: 1) scientific and medical evaluation and the scheduling recommendation from the Secretary; or 2) notification of the approval of the application from the Secretary. Federal law requires any person to apply, and gain approval, through the U.S. Secretary of HHS prior to introducing or delivering any new drug for introduction into interstate commerce (21 U.S.C. § 812).

The Arizona State Board of Pharmacy (Pharmacy Board) is required to: 1) adopt rules to protect the public regarding the practice of pharmacy, including the manufacturing and supplying of drugs or hazardous substances; 2) investigate compliance as to the quality and labeling of all drugs; and 3) license pharmacists and pharmacy interns. <u>Laws 2021</u>, <u>Chapter 61</u> authorized the Pharmacy Board to adopt the schedule I, II, III, IV and V controlled substances as listed in the CSA and require them to amend rules, as necessary, to reflect any changes in the schedule designations (<u>Title 36</u>, <u>Chapter 27</u>).

Psilocybin is a natural product found in numerous species of fungi and is known for its psychoactive properties (<u>National Library of Medicine</u>). Crystalline polymorph psilocybin is a characterization of psilocybin that can be synthetically formulated.

\square Prop 105 (45 votes)	□ Prop 108 (40 votes)	☐ Emergency (40 votes)	\Box Fiscal Note	

Provisions

- 1. Deems any FDA-approved pharmaceutical composition of crystalline polymorph psilocybin that is rescheduled by the DEA to a schedule other than a schedule I as a controlled substance and may be prescribed in Arizona. (Sec. 3)
- 2. Declares that it is the Legislature's intent that patients have rapid access to crystalline polymorph psilocybin as a treatment option if it is FDA-approved and rescheduled by the DEA. (Sec. 4)
- 3. Conditions the enactment of this legislation on the federal approval of crystalline polymorph psilocybin, by January 1, 2031, that is:
 - a) a newly approved prescription medication;
 - b) controlled under an issued federal interim final rule; and
 - c) published in the Federal Register. (Sec. 5)
- 4. Requires the Executive Director of the Pharmacy Board to notify in writing the Director of the Arizona Legislative Council by February 1, 2031, either:
 - a) the date on which the condition was met; or
 - b) that the condition was not met. (Sec. 5)
- 5. Makes conforming changes. (Sec. 1-2)