House of Representatives

General Assembly

File No. 237

February Session, 2022

Substitute House Bill No. 5396

House of Representatives, March 31, 2022

The Committee on Public Health reported through REP. STEINBERG of the 136th Dist., Chairperson of the Committee on the part of the House, that the substitute bill ought to pass.

AN ACT INCREASING ACCESS TO MENTAL HEALTH MEDICATION.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. (NEW) (*Effective July 1, 2022*) (a) As used in this section and section 2 of this act:

(1) "MDMA" means the synthetic psychoactive drug, 3,4-methylenedioxymethamphetamine, commonly known as ecstasy or molly, that acts as a serotonin receptor agonist and reuptake inhibitor of serotonin and dopamine.

(2) "Psilocybin" means a serotonin receptor agonist that occurs naturally in some mushroom species.

(3) "Qualified patient" means a resident of the state who is (A) a veteran, (B) a retired first responder, (C) a direct care health care worker, or (D) from a historically underserved community, and who has a serious or life-threatening mental or behavioral health disorder and without access to effective mental or behavioral health medication.

(4) "Qualified applicant" means a provider of mental or behavioral health services that has received approval from the federal Food and Drug Administration as an approved treatment site with an expanded access protocol that allows the provider access to an investigational drug for treatment use, including emergency use, pursuant to 21 CFR 312, as amended from time to time.

(5) "Approved treatment site" means the location where a qualified applicant that has been selected under subsection (e) of this section as a provider of MDMA-assisted or psilocybin-assisted therapy under the pilot program established pursuant to subsection (b) of this section will provide such therapy.

(b) There is established, within the Department of Mental Health and Addiction Services, a psychedelic-assisted therapy pilot program to provide qualified patients with the funding necessary to receive MDMA-assisted or psilocybin-assisted therapy as part of an expanded access program approved by the federal Food and Drug Administration pursuant to 21 CFR 312, as amended from time to time. The department shall cease to operate the pilot program when MDMA and psilocybin have been approved to have a medical use by the Drug Enforcement Administration, or any successor agency.

(c) There is established a Qualified Patients for Approved Treatment Sites Fund, "PAT Fund". The fund shall contain any moneys required by law to be deposited in the fund and may contain any other funds as provided in subsection (d) of this section. The Department of Mental Health and Addiction Services shall administer and use the fund for grants to qualified applicants to provide MDMA-assisted or psilocybin-assisted therapy to qualified patients under the pilot program established pursuant to subsection (b) of this section.

(d) For the fiscal year ending on June 30, 2023, and for each fiscal year thereafter, block grant funds allocated to the department pursuant to section 4-28b of the general statutes may be deposited in said fund, and the department may accept contributions from any source, public or private, for deposit in said fund.

(e) On or before November 29, 2022, a qualified applicant may apply to the Department of Mental Health and Addiction Services for selection as an approved treatment site. The department shall:

(1) Develop an application form for qualified applicants seeking selection as an approved treatment site and, not later than October 31, 2022, post such application on the department's Internet web site;

(2) Select up to three qualified applicants as approved treatment sites not later than December 28, 2022;

(3) Distribute one million five hundred thousand dollars from the PAT Fund equally amongst the approved treatment sites; and

(4) Distribute an additional one million five hundred thousand dollars from the PAT Fund equally amongst the approved treatment sites that, prior to March 31, 2023, provided proof of receipt of a one million five hundred thousand dollar matching grant from a private foundation to treat qualified patients. If no approved treatment site provides proof of receipt of such matching grant on or before March 31, 2023, the department shall distribute an additional one million five hundred thousand dollars from the PAT Fund equally amongst the approved treatment sites not later than March 31, 2024.

(f) Approved treatment sites shall collect and submit data to the Department of Mental Health and Addiction Services, including, but not limited to, its protocols for the provision of MDMA-assisted and psilocybin-assisted treatment, training on the facilitation of such treatment, implementation of facility standards, strategies for patient protection and mitigation of drug diversion. Approved treatment sites shall follow all applicable patient privacy laws in the collection and submission of data to the department. As used in this subsection, "drug diversion" means the transfer of a legally prescribed drug from the individual for whom it was prescribed to another individual for any illicit use.

Sec. 2. (NEW) (*Effective July 1, 2022*) (a) There is established the

Connecticut Psychedelic Treatment Advisory Board, which shall be part of the Department of Mental Health and Addiction Services.

(b) The board shall consist of the following members: (1) Two appointed by the speaker of the House of Representatives; (2) two appointed by the president pro tempore of the Senate; (3) one appointed by the minority leader of the House of Representatives; (4) one appointed by the minority leader of the Senate; (5) two appointed by the Office of the Governor; (6) one appointed by the Commissioner of Mental Health and Addiction Services; (7) one appointed by the Commissioner of Public Health; and (8) one appointed by the Commissioner of Consumer Protection. The board shall include members with experience or expertise in psychedelic research, psychedelic-assisted therapy, public health, access to mental and behavioral health care in underserved communities, veteran mental and behavioral health care, harm reduction and sacramental use of psychedelic substances.

(c) Notwithstanding the provisions of subsection (a) of section 4-9a of the general statutes, the speaker of the House of Representatives and the president pro tempore of the Senate shall select the chairpersons of the board from among the members of the board. The chairpersons shall oversee the establishment of and make recommendations regarding the voting procedures of the board.

(d) The administrative staff of the joint standing committee of the General Assembly having cognizance of matters relating to consumer protection shall serve as administrative staff of the board, with assistance as needed provided by employees of the Offices of Legislative Research and Fiscal Analysis.

(e) The board shall advise the Department of Mental Health and Addiction Services on the design and development of the regulations and infrastructure necessary to safely allow for therapeutic access to psychedelic-assisted therapy upon the legalization of MDMA, psilocybin and any other psychedelic compounds. In advising the department under this subsection, the board shall be responsible for: (1)

Reviewing and considering the data from the psychedelic-assisted therapy pilot program established under section 1 of this act to inform the development of such regulations; (2) advising the department on the necessary education, training, licensing and credentialing of therapists and facilitators, patient safety, harm reduction, the establishment of equity measures in both clinical and therapeutic settings, cost and insurance reimbursement considerations and standards of treatment facilities; (3) advising the department on the use of group therapy and other therapy options to reduce cost and maximize public health benefits from psychedelic treatments; (4) monitoring updated federal regulations and guidelines for referral and consideration by the state agencies of cognizance for implementation of such regulations and guidelines; (5) developing a long-term strategic plan to improve mental health care through the use of psychedelic treatment; (6) recommending equity measures for clinical subject recruitment and facilitator training recruitment; and (7) assisting with the development of public awareness and education campaigns.

(f) The board may establish committees and subcommittees necessary for the operation of the board.

Sec. 3. Section 21a-243 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective July 1, 2022*):

(a) The Commissioner of Consumer Protection shall adopt regulations for the efficient enforcement and operation of sections 21a-244 to 21a-282, inclusive.

(b) The Commissioner of Consumer Protection may, so far as may be consistent with sections 21a-244 to 21a-282, inclusive, adopt the regulations existing under the federal Controlled Substances Act and pertinent regulations existing under the federal food and drug laws and conform regulations adopted hereunder with those existing under the federal Controlled Substances Act and federal food and drug laws.

(c) The Commissioner of Consumer Protection, acting upon the advice of the Commission of Pharmacy, may by regulation designate,

after investigation, as a controlled substance, a substance or chemical composition containing any quantity of a substance which has been found to have a stimulant, depressant or hallucinogenic effect upon the higher functions of the central nervous system and having a tendency to promote abuse or physiological or psychological dependence or both. Such substances are classifiable as amphetamine-type, barbiturate-type, cannabis-type, cocaine-type, hallucinogenic, morphine-type and other stimulant and depressant substances, and specifically exclude alcohol, caffeine and nicotine. Substances which are designated as controlled substances shall be classified in schedules I to V by regulations adopted pursuant to subsection (a) of this section.

(d) The Commissioner of Consumer Protection may by regulation change the schedule in which a substance classified as a controlled substance in schedules I to V of the controlled substance scheduling regulations is placed. On or before December 15, 1986, and annually thereafter, the commissioner shall submit a list of all such schedule changes to the chairmen and ranking members of the joint standing committee of the General Assembly having cognizance of matters relating to public health.

(e) Notwithstanding the provisions of subsections (a) to (d), inclusive, of this section, not later than January 1, 2013, the Commissioner of Consumer Protection shall submit amendments to sections 21a-243-7 and 21a-243-8 of the regulations of Connecticut state agencies to the standing legislative regulation review committee to reclassify marijuana as a controlled substance in schedule II under the Connecticut controlled substance scheduling regulations, except that for any marijuana product that has been approved by the federal Food and Drug Administration or successor agency to have a medical use and that is reclassified in any schedule of controlled substances or unscheduled by the federal Drug Enforcement Administration or successor agency, the commissioner shall adopt the schedule designated by the Drug Enforcement Administration or successor agency.

(f) Notwithstanding the provisions of subsections (a) to (d), inclusive,

of this section, the Commissioner of Consumer Protection shall adopt the schedule designated by the Drug Enforcement Administration or successor agency for MDMA, as defined in section 1 of this act, and psilocybin, as defined in said section, if MDMA and psilocybin have been approved by said administration, or successor agency, to have a medical use and are reclassified in any schedule of controlled substances or unscheduled by said administration or successor agency.

[(f)**]** (g) A new or amended regulation under this chapter shall be adopted in accordance with the provisions of chapter 54.

[(g)**]** (h) In the event of any inconsistency between the contents of schedules I, II, III, IV and V of the controlled substance scheduling regulations and schedules I, II, III, IV and V of the federal Controlled Substances Act, as amended, the provisions of the federal act shall prevail, except (1) when the provisions of the Connecticut controlled substance scheduling regulations place a controlled substance in a schedule with a higher numerical designation, schedule I being the highest designation, or (2) as provided in subsection (e) of this section.

[(h)**]** (i) When a drug that is not a controlled substance in schedule I, II, III, IV or V, as designated in the Connecticut controlled substance scheduling regulations, is designated to be a controlled substance under the federal Controlled Substances Act, such drug shall be considered to be controlled at the state level in the same numerical schedule from the effective date of the federal classification. Nothing in this section shall prevent the Commissioner of Consumer Protection from designating a controlled substance differently in the Connecticut controlled substance scheduling regulations than such controlled substance is designated in the federal Controlled Substances Act, as amended from time to time.

[(i)**]** (j) The Commissioner of Consumer Protection shall, by regulation adopted pursuant to this section, designate the following substances, by whatever official, common, usual, chemical or trade name designation, as controlled substances and classify each such substance in the appropriate schedule:

(1) 1-pentyl-3-(1-naphthoyl)indole (JWH-018);

(2) 1-butyl-3-(1-naphthoyl)indole (JWH-073);

(3) 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200);

(4) 5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (CP-47,497);

(5) 5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol; CP-47,497 C8 homologue);

(6) Salvia divinorum; and

(7) Salvinorum A.

[(j)**]** (k) Notwithstanding the provisions of subsection (c) of this section, the Commissioner of Consumer Protection shall designate the following substances, by whatever official, common, usual, chemical or trade name designation, as controlled substances in schedule I of the controlled substances scheduling regulations:

(1) Mephedrone (4-methylmethcathinone); and

(2) MDPV (3,4-methyenedioxypyrovalerone).

Sec. 4. (NEW) (*Effective July 1, 2022*) The Department of Consumer Protection shall consider for adoption any nonbinding federal guidelines from the federal Department of Health and Human Services regarding the practice of psychedelic-assisted therapy. The Connecticut Psychedelic Treatment Advisory Board established under section 2 of this act and members of the public may submit written comments to the department during a notice and comment period established by the department regarding adoption of and any suggested changes to such guidelines that may better meet the needs of state residents. The department shall post the procedures and deadline for submission of written comments during such notice and comment period on its Internet web site.

Sec. 5. Subdivision (29) of section 21a-240 of the 2022 supplement to the general statutes is repealed and the following is substituted in lieu thereof (*Effective July 1, 2022*):

(29) "Marijuana" means all parts of any plant, or species of the genus cannabis or any infra specific taxon thereof, whether growing or not; the seeds thereof; the resin extracted from any part of the plant; every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin, any product made using hemp, as defined in section 22-61*l*, which exceeds three-tenths per cent total THC concentration on a dry-weight basis; manufactured cannabinoids, synthetic cannabinoids, except as provided in subparagraph (E) of this subdivision; or cannabinon, cannabinol or cannabidiol and chemical compounds which are similar to cannabinon, cannabinol or cannabidiol in chemical structure or which are similar thereto in physiological effect, which are controlled substances under this chapter, except cannabidiol derived from hemp, as defined in section 22-61*l*, with a total THC concentration of not more than three-tenths per cent on a dry-weight basis. "Marijuana" does not include: (A) The mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture or preparation of such mature stalks, except the resin extracted from such mature stalks or fiber, oil or cake; (B) the sterilized seed of such plant which is incapable of germination; (C) hemp, as defined in section 22-61*l*, with a total THC concentration of not more than three-tenths per cent on a dry-weight basis; (D) any substance approved by the federal Food and Drug Administration or successor agency as a drug and reclassified in any schedule of controlled substances or unscheduled by the federal Drug Enforcement Administration or successor agency which is included in the same schedule designated by the federal Drug Enforcement Administration or successor agency; or (E) synthetic cannabinoids which are controlled substances that are designated by the Commissioner of Consumer Protection, by whatever official, common, usual, chemical or trade name designation, as controlled substances and are classified in the appropriate schedule in accordance with subsections **[**(i)**]** (j) and **[**(j)**]** (k) of section 21a-243, as amended by this

act;

Sec. 6. (*Effective July 1, 2022*) The sum of three million dollars is appropriated to the Department of Mental Health and Addiction Services from the General Fund, for the fiscal year ending June 30, 2023, for deposit in the Qualified Patients for Approved Treatment Sites Fund established under section 1 of this act.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*July 1, 2022*	New section
Sec. 2	*July 1, 2022*	New section
Sec. 3	*July 1, 2022*	21a-243
Sec. 4	*July 1, 2022*	New section
Sec. 5	*July 1, 2022*	21a-240(29)
Sec. 6	*July 1, 2022*	New section

Statement of Legislative Commissioners:
In Section 2(c), the phrase "Notwithstanding the provisions of subsection (a) of section 4-9a of the general statutes, the" was added for consistency with the controlling provision of the general statutes.

PH *Joint Favorable Subst. -LCO*

The following Fiscal Impact Statement and Bill Analysis are prepared for the benefit of the members of the General Assembly, solely for purposes of information, summarization and explanation and do not represent the intent of the General Assembly or either chamber thereof for any purpose. In general, fiscal impacts are based upon a variety of informational sources, including the analyst's professional knowledge. Whenever applicable, agency data is consulted as part of the analysis, however final products do not necessarily reflect an assessment from any specific department.

OFA Fiscal Note

State Impact:

Agency Affected	Fund-Effect	FY 23 $	FY 24 $
Mental Health & Addiction Serv., Dept.	GF - Cost	3,000,000	See Below
Mental Health & Addiction Serv., Dept.	GF - Cost	at least 86,000	at least 86,000
State Comptroller - Fringe Benefits[1]	GF - Cost	at least 34,800	at least 34,800

Note: GF=General Fund

Municipal Impact: None

Explanation

The bill results in a cost to the Department of Mental Health and Addiction Services (DMHAS) associated with establishing a psychedelic-assisted therapy pilot program to provide grants to applicants to provide MDMA-assisted or psilocybin-assisted therapy to qualified patients, as part of an expanded access program approved by the federal Food and Drug Administration (FDA). Such grants will be funded through the Qualified Patients for Approved Treatment Sites Fund, known as the PAT Fund, established by the bill and administered by DMHAS. The bill appropriates $3 million to the PAT Fund in FY 23, with at least $1.5 million to be distributed to approved treatment sites that year. DMHAS may deposit other funds into the PAT Fund.

DMHAS will incur additional costs of at least $86,000 (with associated fringe benefits of $34,800) for a Behavioral Health Program

[1]The fringe benefit costs for most state employees are budgeted centrally in accounts administered by the Comptroller. The estimated active employee fringe benefit cost associated with most personnel changes is 40.53% of payroll in FY 23.

Manager to administer the grant program.

The bill makes technical, conforming, and other changes that have no fiscal impact.

The Out Years

The annualized ongoing fiscal impact identified above would continue into the future subject to inflation. The pilot program will end when MDMA and psilocybin have been approved to have a medical use by the Drug Enforcement Administration (DEA), or its successor.

OLR Bill Analysis

sHB 5396

AN ACT INCREASING ACCESS TO MENTAL HEALTH MEDICATION.

SUMMARY

This bill establishes a Psychedelic-Assisted Therapy Pilot Program within the Department of Mental Health and Addiction Services (DMHAS) to provide qualified patients with funding needed to receive MDMA (i.e., "Molly" or "ecstasy") -assisted or psilocybin-assisted therapy (hereafter "psychedelic-assisted therapy") as part of a U.S. Food and Drug Administration (FDA)-approved expanded access program. The pilot program ends when the U.S. Drug Enforcement Agency (DEA) approves MDMA and psilocybin for medical use. (MDMA is a synthetic psychoactive drug and psilocybin occurs naturally in some mushrooms. Both act as serotonin receptor agonists and MDMA also acts as a reuptake inhibitor of serotonin and dopamine.)

Under the bill, "qualified patients" include Connecticut residents who (1) are veterans, retired first responders, direct health care workers, or from a historically underserved community and (2) have serious or life-threatening mental or behavioral health disorders and lack access to effective mental or behavioral health medication.

Additionally, the bill:

1. establishes a Qualified Patients for Approved Treatment Sites Fund (PAT Fund) administered by DMHAS to give grants to certain qualified providers to provide psychedelic-assisted therapy under the pilot program;

2. establishes an 11-member Connecticut Psychedelic Treatment Advisory Board within DMHAS to advise the department on

various issues related to psychedelic-assisted therapy;

3. requires the Department of Consumer Protection (DCP) to adopt DEA's controlled substances schedule for MDMA and psylocibin if DEA approves them for medical use and either reclassifies or unschedules them;

4. requires DCP to consider adopting nonbinding federal guidelines on psychedelic-assisted therapy and allow for written comments from the advisory board and the public; and

5. appropriates $3 million to DMHAS from the General Fund in FY 23 for deposit into the PAT Fund.

The bill also makes technical and conforming changes.

EFFECTIVE DATE: July 1, 2022

PAT FUND

Fund Use

Starting FY 23, the bill permits (1) any federal block grant funds allocated to DMHAS to be deposited in the PAT Fund and (2) DMHAS to accept public or private contributions to the fund.

The bill requires DMHAS to use PAT funds to provide grants to qualified applicants to provide psychedelic-assisted therapy to qualified patients under the pilot program.

Under the bill, "qualified applicants" are mental or behavioral health services providers approved by the FDA as an approved treatment site with an expanded access protocol that allows the provider to access an investigational drug for treatment use, including emergency use.

Applications for Approved Treatment Sites

The bill requires DMHAS to (1) create an application form for qualitied applicants by October 31, 2022, and post it on the DMHAS website; (2) start accepting applications by November 29, 2022; and (3) select up to three applicants as approved treatment sites by December

28, 2022.

Fund Distributions

The bill requires DMHAS to distribute $1.5 million from the PAT Fund equally among the approved treatment sites.

DMHAS must also distribute an additional $1.5 million equally among approved treatment sites that, before March 31, 2023, provide proof that they received a $1.5 million matching grant from a private foundation to treat qualified patients.

If no approved treatment site provides this proof, the bill requires DMHAS to then distribute the additional $1.5 million from the PAT Fund equally among the approved treatment sites by March 31, 2024.

Data Collection

The bill requires approved treatment sites to collect and submit the following data to DMHAS:

1. their protocols for providing psychedelic-assisted therapy,
2. training on facilitating the treatment,
3. implementing facility standards, and
4. strategies for patient protection and to reduce the transfer of legally prescribed drugs from a prescription recipient to another person for illicit use.

The bill also requires approved treatment sites to follow applicable patient privacy laws when collecting and submitting the data.

CONNECTICUT PSYCHEDELIC TREATMENT ADVISORY BOARD

Duties

The bill establishes a 11-member Connecticut Psychedelic Treatment Advisory Board to advise DMHAS on the design and development of the necessary regulations and infrastructure to safely allow for therapeutic access to psychedelic-assisted therapy if MDMA, psilocybin, and any other psychedelic compounds are legalized.

Specifically, the advisory board must:

1. review and consider data from the psychedelic-assisted therapy pilot program to inform the development of the regulations;

2. advise DMHAS on necessary education, training, licensing, and credentialing of therapists and facilitators; patient safety and harm reduction; establishing equity measures in clinical and therapeutic settings; cost and insurance reimbursement considerations; and treatment facility standards;

3. advise DMHAS on using group therapy and other therapy options to reduce cost and maximize public health benefits from psychedelic treatments;

4. monitor updated federal regulations and guidelines for referral and consideration by the state agencies of cognizance for implementing them;

5. develop a long-term strategic plan to improve mental health care through psychedelic treatment;

6. recommend equity measures for clinical subject recruitment and facilitator training recruitment; and

7. help develop public awareness and education campaigns.

Membership

Under the bill, advisory board members include:

1. two members each appointed by the Senate president pro tempore and House speaker;

2. one member each appointed by the House and Senate minority leaders;

3. two members appointed by the governor; and

4. one member each appointed by the consumer protection, mental

health and addiction services, and public health commissioners.

The bill requires the advisory board to include members with experience or expertise in psychedelic research, psychedelic-assisted therapy, public health, access to mental and behavioral health care in underserved communities, veterans' mental and behavioral health care, harm reduction, and sacramental use of psychedelics.

Leadership and Administrative Staff

The bill requires the Senate president pro tempore and House speaker to select the advisory board chairpersons from among its members. The chairpersons must oversee establishing and making recommendations on the board's voting procedures.

The bill allows the board to have committees and subcommittees if they are needed for its operation.

Under the bill, the General Law Committee administrative staff serve as the advisory board's administrative staff, with assistance from the Office of Legislative Research and Office of Fiscal Analysis, if needed.

FEDERAL GUIDELINES ON PSYCHEDELIC-ASSISTED THERAPY

The bill requires DCP to consider adopting any nonbinding U.S. Department of Health and Human Services guidelines on the practice of psychedelic-assisted therapy.

It permits the Connecticut Psychedelic Treatment Advisory Board and the public to submit written comments to DCP during a notice and comment period the department establishes on (1) adopting the guidelines and (2) any suggested changes to them to better meet state residents' needs.

The bill requires DCP to post the procedures and deadline to submit written comments during the notice and comment period on its website.

COMMITTEE ACTION

Public Health Committee

Joint Favorable
Yea 31 Nay 0 (03/18/2022)