## HOUSE . . . . . . . . . . . . No.

## The Commonwealth of Massachusetts

PRESENTED BY:

Marjorie C. Decker

To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in General Court assembled:

The undersigned legislators and/or citizens respectfully petition for the adoption of the accompanying bill:

An Act establishing a pilot program for access to regulated psilocybin.

PETITION OF:

NAME:DISTRICT/ADDRESS:DATE ADDED:Marjorie C. Decker25th Middlesex1/17/2025

HOUSE . . . . . . . . . . . . . No.

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## The Commonwealth of Massachusetts

In the One Hundred and Ninety-Fourth General Court (2025-2026)

An Act establishing a pilot program for access to regulated psilocybin.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

- SECTION 1. (a) Notwithstanding any general or special law to the contrary, the

  department of public health shall develop a pilot program to allow for the research and

  development of psilocybin services for adults with post-traumatic stress disorder, end-of-life

  distress, depression, or other specified conditions, as determined by program criteria and needs in
- 5 designated geographic areas, as established by the department. This pilot shall be known as the
- 6 Psilocybin-Assisted Therapy Program.

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- (b) For the purposes of this act, the following terms shall have the following meanings,
   unless the context clearly requires otherwise:-
  - "Community-based providers", licensed healthcare and community-based organizations, including but not limited to, mental health clinics, hospice organizations, veterans' administration facilities and other community-based therapeutic care organizations that provide services and care to adults with post-traumatic stress disorder, end-of-life distress, depression, or other specified conditions, as determined by the department.

"Department", the department of public health.

- "Local pilot", the operation of the pilot within each of the designated sites.
- 16 "Pilot", the Psilocybin-Assisted Therapy Program, as established in this act.
  - "Psilocybin", a psychedelic compound produced by fungi, including but not limited to, members of the genus Psilocybe. Such term shall include psilocin, the substance into which psilocybin is converted in the human body.
  - (c) The pilot shall provide psilocybin therapy through pathways approved by the federal food and drug administration to test the effects of providing psilocybin services to adults in controlled, community-based settings under the supervision of university researchers with experience administering psychedelic substances in clinical trials. Individuals eligible to participate in the pilot program must be adults who are 21 years of age or older.
  - (d) The department shall establish professional standards for regulated psychedelic use and criteria for participation in the pilot, including the number of universities that may participate in the pilot; provided, that preference shall be given to universities within the Commonwealth's public university system. The department shall develop local training and certification frameworks for psilocybin facilitators to sustain capacity beyond the pilot's conclusion. A local pilot shall collect and provide data relevant to potential coverage for the cost of psilocybin-assisted therapy, as determined by the department.
  - (e) Upon selection to participate in the pilot, qualifying universities shall enter into an agreement with the department specifying, at minimum:

34 (i) The amount of funding available to the university, through funding mechanisms as 35 outlined in subsection (k), for the purpose of overseeing the applicable local pilot; 36 (ii) The conditions under which payments will be made to the university; 37 (iii) Data collection and sharing requirements; and (iv) Reporting requirements including, but not limited to, frequency and method of data 38 39 reporting and specific data to be reported to the department. 40 (f) The pilot shall collaborate with community-based providers that provide services to 41 conduct pilot studies of administering psilocybin services to adults with post-traumatic stress 42 disorder, end-of-life distress, depression, or other specified conditions, as determined by the 43 department. 44 (g) A university selected to participate in the pilot shall be responsible for: 45 (i) protocol design, except that the research design shall use naturally occurring 46 psilocybin if there is a federally legal source of natural psilocybin available for FDA-approved 47 research purposes; 48 (ii) securing institutional review board approvals; 49 (iii) training psilocybin facilitators; and 50 (iv) data collection and reporting as outlined in the university's agreement with the 51 department.

- 52 (h) A university overseeing a local pilot shall maintain strict protocols for participant 53 screening, ensuring facilitator qualifications and training, informed consent, dosing, and follow-54 up.
  - (i) The department shall report not later than 12 months after the effective date of this act and annually thereafter to the clerks of the house of representatives and the senate, the joint committee on public health and the joint committee on mental health, substance use, and recovery. The report shall be peer-reviewed and shall include a study of the statewide efficacy of the pilot, including local community impacts and the feasibility of coverage for psilocybin-assisted therapy under MassHealth, consistent with any applicable federal guidelines.
  - (j) The sharing of health information, records, and other data with and among pilot entities and other participating entities shall be permitted to the extent necessary for the activities and purposes set forth in this act. The department shall establish guidelines consistent with this act for protecting confidential patient information during the course of the pilot.
  - (k) The pilot may be funded by appropriation, grants, donations, trust funds, or other funding sources. The funds for establishing a pilot shall be used for:
- (i) program administration and oversight;

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- (ii) training and qualification of facilitators;
- 69 (iii) data collection, analysis, and reporting; and
- 70 (iv) community engagement and education initiatives.
  - (l) The department may establish additional guidelines pursuant to this section through notice and comment rulemaking in compliance with chapter 111 of the General Laws.

- 73 (m) The pilot shall have a total duration of no less than two years.
- SECTION 2. This Act shall take effect on January 1, 2026.