PRINTER'S NO. 2930

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 2208 Session of 2024

INTRODUCED BY FRANKEL, MADDEN, HILL-EVANS, HADDOCK, PARKER, SANCHEZ, KHAN, MAYES, CONKLIN AND OTTEN, APRIL 15, 2024

REFERRED TO COMMITTEE ON HEALTH, APRIL 15, 2024

AN ACT

Amending the act of April 17, 2016 (P.L.84, No.16), entitled "An act establishing a medical marijuana program; providing for patient and caregiver certification and for medical marijuana organization registration; imposing duties on the Department of Health; providing for a tax on medical marijuana organization gross receipts; establishing the Medical Marijuana Program Fund; establishing the Medical Marijuana Advisory Board; establishing a medical marijuana research program; imposing duties on the Department of Corrections, the Department of Education and the Department of Human Services; and providing for academic clinical research centers and for penalties and enforcement," in medical marijuana controls, further providing for laboratory; and, in Medical Marijuana Advisory Board, further providing for advisory board.

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. Section 704 of the act of April 17, 2016 (P.L.84, No.16), known as the Medical Marijuana Act, is amended to read:

Section 704. Laboratory.

(a) General testing.--A grower/processor shall contract with one or more independent laboratories to test the medical marijuana produced by the grower/processor. The department shall approve a laboratory under this subsection and require that the

laboratory report testing results in a manner as the department shall determine, including requiring a test at harvest and a test at final processing. A grower/processor may engage a single approved laboratory to perform both the harvest lot and finished product testing or a grower/processor may engage more than one approved laboratory to complete the harvest testing and final product testing. The possession by a laboratory of medical marijuana shall be a lawful use.

(b) Stability testing.--A laboratory shall perform stability testing to ensure the medical marijuana product's potency and purity. A grower/processor shall retain a sample from each medical marijuana product derived from a harvest batch and request that a sample be identified and collected by a laboratory approved under subsection (a) from each process lot to perform stability testing under the following conditions:

(1) The medical marijuana product is still in inventory at a dispensary in this Commonwealth as determined by the seed-to-sale system.

(2) The stability testing is done at six-month intervals for the duration of the expiration date period as listed on the medical marijuana product and once within six months of the expiration date.

(c) Standard operating procedures.--

(1) An approved testing laboratory shall maintain written standard operating procedures for each of the following:

(i) Confirmation of the validity of results of testing.

(ii) Quality control.

(iii) All sampling and testing procedures, including

required safety tests.

(iv) Any other operation as determined by the department.

(2) A laboratory applying for approval as a testing laboratory shall submit its standard operating procedures to the department as part of the laboratory's application.

(3) An approved testing laboratory shall submit its standard operating procedures to the department at the following time periods:

(i) for laboratories approved prior to the effective date of this paragraph, within 30 days of the effective date of this paragraph;

(ii) at each renewal of approval; and

(iii) within 30 days of a substantial change to the standard operating procedures.

(4) The department shall enter and conduct a reasonable inspection of an approved testing laboratory to ensure adherence to the standard operating procedures at least annually. The following shall apply:

(i) If the inspection results in the department identifying gaps in the standard operating procedure, the department shall submit its findings to the approved testing laboratory.

(ii) Failure to adhere to corrective actions within a reasonable time shall constitute a violation of this act and may result in penalties under section 1308(b) or (c). Nothing shall limit the department's ability to suspend or revoke an approval issued to a laboratory as prescribed in 28 Pa. Code Ch. 1171a (relating to laboratories).

(5) The department may engage with an independent accreditation body to fulfill the requirements under this subsection.

(d) Validity of results testing.--

(1) The department, in coordination with the Bureau of Laboratories, shall ensure that approved testing laboratories' results are valid no less than once a year beginning on January 1 after the effective date of this paragraph. The following apply:

(i) The department shall require approved testing laboratories to participate in an established method used to determine validity of results.

(ii) The department may engage an accredited proficiency testing provider to fulfill subparagraph (i).

(iii) Nothing shall prohibit the department from ensuring validity of results more than once within a calendar year.

(iv) A test issued by an accredited proficiency testing provider as required solely to maintain accreditation shall not fulfill the requirements of this subparagraph.

(2) If the results from an approved testing laboratory are found to be invalid, the following actions shall be taken by the department:

(i) A review of the approved testing laboratory's standard operating procedures.

(ii) Additional testing, as needed, to understand the cause for the anomalies and unanticipated errors.

(iii) The department may enter the approved testing laboratory for further investigation and shall issue its

findings. The department may engage with an independent accreditation body to fulfill the requirements under this subparagraph.

(3) Failure to participate or failure to adhere to corrective actions shall constitute a violation of this act and may result in penalties under section 1308(b) or (c). Nothing shall limit the department's ability to suspend or revoke an approval issued to a laboratory as prescribed in 28 Pa. Code Ch. 1171a.

(e) Trend analysis.--The department may utilize the seed-to-sale tracking system to conduct trend analysis for laboratory oversight.

(f) Accreditation.--The department shall determine the scope of accreditation an approved laboratory must receive and maintain. The department shall provide an approved laboratory reasonable time to receive any additional accreditation beyond the laboratory's most recent certificate of accreditation.

(g) State testing laboratory.--The department may establish and maintain a State testing laboratory. A State testing laboratory under this subsection shall be responsible for:

(1) Developing and maintaining a medical marijuana laboratory reference library that contains testing methodologies in the areas of:

(i) Potency.

(ii) Homogeneity.

(iii) Detection of contaminants and the quantity of those contaminants.

(iv) Solvents.

(2) Establishing standard operating procedures for sample collection, preparation and analysis of medical

marijuana by approved testing laboratories.

(3) Conducting proficiency testing of approved testing laboratories.

(4) Remediation of problems with approved testing laboratories.

(5) Conducting compliance testing on medical marijuana samples analyzed by approved testing laboratories.

(h) Materials.--Approved testing laboratories shall provide materials to the State testing laboratory reference library.

(i) Memorandum of understanding.--The department may enter into a memorandum of understanding with the Department of Agriculture to test medical marijuana at an existing State-run laboratory if doing so would be a more economic and efficient alternative to establishing a State testing laboratory under subsection (g).

(j) Powers and duties of department.--The department shall:

(1) Hire sufficient staff with the proper expertise to conduct the requirements of this act.

(2) Promulgate regulations to facilitate the implementation of this act and oversight of laboratories.

Section 2. Section 1201 of the act is amended to read:

Section 1201. Advisory board.

(a) Establishment.--The Medical Marijuana Advisory Board is established within the department. The advisory board shall consist of the following members:

(1) The secretary or a designee.

(2) The Commissioner of the Pennsylvania State Police or a designee.

(3) The chairman of the State Board of Pharmacy or a designee.

(4) The Commissioner of Professional and Occupational Affairs or a designee.

(5) The Physician General or a designee.

(6) The president of the Pennsylvania Chiefs of Police Association or a designee.

(7) The president of the Pennsylvania District Attorneys Association or a designee.

(8) One member to be appointed by each of the following, which members shall be knowledgeable and experienced in issues relating to care and treatment of individuals with a serious medical condition, geriatric or pediatric medicine or clinical research:

(i) The Governor.

(ii) The President pro tempore of the Senate.

(iii) The Majority Leader of the Senate.

(iv) The Minority Leader of the Senate.

(v) The Speaker of the House of Representatives.

(vi) The Majority Leader of the House of Representatives.

(vii) The Minority Leader of the House of Representatives.

(9) One member appointed by the Governor, who shall be a patient, a family or household member of a patient or a patient advocate.

(10) One member appointed by the Governor, who shall have experience and expertise in laboratory science.

(b) Terms.--Except as provided under subsection (g), the members appointed under subsection (a)(8) [and], (9) and (10) shall serve a term of four years or until a successor has been appointed and qualified, but no longer than six months beyond

the four-year period.

(c) Chair.--The secretary, or a designee, shall serve as chair of the advisory board.

(d) Voting; quorum.--The members under subsection (a)(1), (2), (3), (4), (5), (6) and (7) shall serve ex officio and shall have voting rights. A majority of the members shall constitute a quorum for the purpose of organizing the advisory board, conducting its business and fulfilling its duties. A vote of the majority of the members present shall be sufficient for all actions of the advisory board unless the bylaws require a greater number.

(e) Attendance.--A member of the advisory board appointed under subsection (a)(8) [or], (9) or (10) who fails to attend three consecutive meetings shall forfeit his seat unless the secretary, upon written request from the member, finds that the member should be excused from a meeting for good cause. A member who cannot be physically present may attend meetings via electronic means, including video conference.

(f) Governance.--The advisory board shall have the power to prescribe, amend and repeal bylaws, rules and regulations governing the manner in which the business of the advisory board is conducted and the manner in which the duties granted to it are fulfilled. The advisory board may delegate supervision of the administration of advisory board activities to an administrative secretary and other employees of the department as the secretary shall appoint.

(g) Initial terms.--The initial terms of members appointed under subsection (a)(8) [and], (9) and (10) shall be for terms of one, two, three or four years, the particular term of each member to be designated by the secretary at the time of

appointment. All other members shall serve for a term of four years.

(h) Vacancy.--In the event that any member appointed under subsection (a)(8) [or], (9) or (10) shall die or resign or otherwise become disqualified during the member's term of office, a successor shall be appointed in the same way and with the same qualifications as set forth in this section and shall hold office for the unexpired term. An appointed member of the advisory board shall be eligible for reappointment.

(i) Expenses.--A member appointed under subsection (a)(8) [or], (9) or (10) shall receive the amount of reasonable travel, hotel and other necessary expenses incurred in the performance of the duties of the member in accordance with Commonwealth regulations, but shall receive no other compensation for the member's service on the board.

(j) Duties.--The advisory board shall have the following duties:

(1) To examine and analyze the statutory and regulatory law relating to medical marijuana within this Commonwealth.

(2) To examine and analyze the law and events in other states and the nation with respect to medical marijuana.

(3) To accept and review written comments from individuals and organizations about medical marijuana.

(4) To issue written reports to the Governor, the Senate and the House of Representatives.

(5) The written reports under paragraph (4) shall include recommendations and findings as to the following:

(i) Whether to change the types of medical professionals who can issue certifications to patients.

(ii) Whether to change, add or reduce the types of

medical conditions which qualify as serious medical conditions under this act.

(iii) Whether to change the form of medical marijuana permitted under this act.

(v) How to ensure affordable patient access to medical marijuana.

(6) The written reports under this section shall be adopted at a public meeting. The reports shall be a public record under the act of February 14, 2008 (P.L.6, No.3), known as the Right-to-Know Law.

Section 3. This act shall take effect in 90 days.