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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

AS AMENDED ON SECOND CONSIDERATION, HOUSE OF REPRESENTATIVES, MAY 8, 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 preliminary provisions, further providing for definitions; in medical marijuana controls, further providing for electronic tracking and 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 103 of the act of April 17, 2016 (P.L.84, No.16), known as the Medical Marijuana Act, is amended by adding definitions to read:

Section 103. Definitions.

The following words and phrases when used in this act shall have the meanings given to them in this section unless the

context clearly indicates otherwise:

"Accreditation body." An organization which meets all of the following criteria:

(1) Certifies the competency, expertise and integrity of a laboratory and operates in conformance with ~~the most recent~~ <--
~~version of International Organization for Standardization~~ ~~ISO/IEC 17011~~ STANDARDS ESTABLISHED BY EXPERTS FOR <--
COMPETENCY, CONSISTENT OPERATIONS AND IMPARTIALITY OF ORGANIZATIONS ACCREDITING ASSESSMENT BODIES AS adopted by the department after review. The department shall transmit notice of the adoption under this paragraph to the Legislative Reference Bureau for publication in the next available issue of the Pennsylvania Bulletin.

(2) Determines a laboratory's compliance with and conformance to the relevant standards ~~established by the~~ <--
~~International Organization for Standardization, including~~ ~~ISO/IEC 17025,~~ ESTABLISHED BY EXPERTS OF TESTING AND <--
CALIBRATION LABORATORIES as adopted by the department after review. The department shall transmit notice of the adoption under this paragraph to the Legislative Reference Bureau for publication in the next available issue of the Pennsylvania Bulletin.

(3) Is a signatory to the International Accreditation Cooperation Mutual Recognition Arrangement for Testing.

(4) Is not affiliated with a laboratory applicant for which it has or will issue a certificate of accreditation.

(5) Is not affiliated with, owned by, operated by or financed by a medical marijuana organization.

* * *

"Approved laboratory." An independent laboratory approved by

the department, in accordance with section 704, to identify, collect, handle and conduct tests on medical marijuana samples from a grower/processor, as part of the quality assurance testing and on medical marijuana samples from the department.

* * *

"Cooperative laboratory." A public or private independent laboratory that identifies, collects, handles and conducts tests on medical marijuana samples on behalf of the department. The term does not include an approved laboratory.

* * *

"Independent laboratory." A laboratory that:

(1) Is not owned, operated or affiliated with a medical marijuana organization.

(2) Does not employ a principal, financial backer, operator or employee of a medical marijuana organization.

(3) Is recognized by an accreditation body to test and evaluate products to an established product safety standard ~~free from commercial, financial or other pressures that may influence the results of the testing and evaluation process.~~ AND PROVIDE UNBIASED RESULTS. <--

* * *

"RESEARCH AND DEVELOPMENT TESTING." TESTING PERFORMED ON BEHALF OF A GROWER/PROCESSOR TO EVALUATE THE EFFECTIVENESS OF ENVIRONMENTAL CONTROLS IN ITS CULTIVATION AND PROCESSING PRACTICES AND TO ENHANCE MEDICAL MARIJUANA CROP YIELDS, RESILIENCE AND SUSTAINABILITY BY DEVELOPING MEDICAL MARIJUANA WITH IMPROVED TRAITS. <--

Section 2. Sections 701(c) and 704 of the act are amended to read:

Section 701. Electronic tracking.

* * *

(c) Access.--[Information] Except as provided in section ~~704(1)~~ 704(N), information maintained in electronic tracking systems under subsection (a) shall be confidential and not subject to the act of February 14, 2008 (P.L.6, No.3), known as the Right-to-Know Law. <--

* * *

Section 704. [Laboratory.] Laboratories.

[(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. 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.]

(a) Application and approval.--The following apply:

(1) An ~~owner or operator of an~~ independent laboratory may apply, in the form and manner prescribed by the department, for approval to test medical marijuana in accordance with the medical marijuana program. <--

(2) A nonrefundable initial application fee in the amount of $250 shall be paid by certified check or money order.

(3) The department may ~~designate the~~ ISSUE AN APPROVAL TO AN INDEPENDENT laboratory as an approved laboratory under this subsection if the department determines that an independent laboratory is financially and professionally suitable to conduct testing required under this act. ~~Nothing in this subsection shall be deemed to require the department to issue an approval to an independent laboratory.~~ <--

(4) An approval issued by the department to an independent laboratory is valid:

(i) For two years from the date of issuance.

(ii) Only for the location specified in the application and approval notice.

(5) An annual registration fee of $125 shall be paid by each approved laboratory.

(6) Fees payable under this section shall be deposited into the fund.

(7) A LABORATORY APPROVED BY THE DEPARTMENT PURSUANT TO 28 PA. CODE § 1171A.23 (RELATING TO APPROVAL OF LABORATORIES) PRIOR TO THE EFFECTIVE DATE OF THIS SECTION SHALL BE DEEMED AN APPROVED LABORATORY UNTIL ITS APPROVAL EXPIRES. A LABORATORY UNDER THIS PARAGRAPH SHALL BE SUBJECT TO THE REQUIREMENTS OF THIS ACT. <--

(b) Compliance testing.--A grower/processor shall contract with ~~approved laboratories as required by the department~~ AN APPROVED LABORATORY to test the medical marijuana produced by the grower/processor. The following shall apply: <--

(1) The department shall establish uniform medical marijuana testing standards and require that the approved ~~laboratory~~ LABORATORIES report testing results in a manner as the department shall determine, including: <--

(i) Requiring a test at harvest and at final processing.

(ii) Retesting of failed test results.

~~(2) 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.~~ <--

(2) NOTHING IN THIS SECTION SHALL BE CONSTRUED TO PREVENT A GROWER/PROCESSOR FROM ENGAGING ONE APPROVED LABORATORY TO COMPLETE ALL TESTING REQUIRED UNDER THIS SUBSECTION. <--

(c) Stability testing.--An approved 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 an approved laboratory 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.

(3) The stability testing results shall be reported to the department.

(4) IF A GROWER/PROCESSOR STORES HARVESTED MEDICAL MARIJUANA FOR A MINIMUM OF SIX MONTHS AFTER HARVEST TESTING AND BEFORE PROCESSING IT INTO A MEDICAL MARIJUANA PRODUCT, THE GROWER/PROCESSOR SHALL RETAIN A SAMPLE OF THE UNPROCESSED MEDICAL MARIJUANA AND REQUEST THAT AN APPROVED LABORATORY CONDUCT STABILITY TESTING. THE STABILITY TESTING UNDER THIS PARAGRAPH SHALL OCCUR EVERY SIX MONTHS UNTIL THE UNPROCESSED MEDICAL MARIJUANA IS PROCESSED INTO MEDICAL MARIJUANA PRODUCT OR UNTIL IT EXPIRES. <--

(d) Research and development testing.--An approved laboratory may collect samples from a grower/processor for research and development if requested. ~~Test results~~ RESULTS for research and development TESTING shall be reported to the department. ~~Testing~~ RESEARCH AND DEVELOPMENT TESTING for research and development shall not be a replacement for ~~compliance testing~~ ANY OTHER TESTING REQUIRED UNDER THIS SECTION. <--

(e) Audit testing.--The department, in its sole discretion, may conduct audit testing of medical marijuana samples collected from a grower/processor facility and medical marijuana products found at a dispensary facility using a cooperative laboratory or approved laboratory to identify, collect, handle and test the medical marijuana on the department's behalf.

(f) Standard operating procedures.--The following shall

apply:

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

(i) All sampling and testing procedures, including compliance testing, stability testing, research and development testing and quality assurance testing.

(ii) Quality control.

~~(iii) Any other operation as determined by the department.~~ <--

(2) An independent laboratory applying to be an approved laboratory under subsection (a) shall submit the laboratory's standard operating procedures to the department as part of the independent laboratory's application.

(3) An approved laboratory shall, within 30 days ~~of~~ AFTER the effective date of this paragraph, submit its standard operating procedures to the department. <--

(4) An approved laboratory shall notify the department in writing of any modifications to its standard operating procedures no less than 30 days prior to the modification.

(g) Enforcement procedures.--The department shall conduct announced or unannounced inspections or investigations to determine an approved laboratory's compliance with its standard operating procedures and this act. The department may require the approved laboratory to submit and adhere to a corrective action plan following an inspection.

(h) Accreditation body.--The department may engage with an accreditation body to fulfill the requirements under this section.

(i) Quality assurance testing.--The following shall apply:

(1) The department shall coordinate testing for quality

assurance purposes related to the department and compliance by each approved laboratory no less than once a year beginning January 1 after the effective date of this paragraph.

(2) The quality assurance testing may be announced or unannounced.

(3) Any fees for conducting tests as part of the quality assurance testing shall be the responsibility of each approved laboratory. The fees associated with the cost of the medical marijuana samples submitted as part of the testing shall be waived.

(4) A test ~~issued~~ REQUIRED by an accreditation body ~~as required~~ solely to maintain accreditation shall not fulfill the requirements of this subsection. <--

(5) QUALITY ASSURANCE TESTING SHALL BE CONDUCTED USING INDUSTRY BEST PRACTICES AND STANDARDS AND SHALL BE UNIFORM AMONG ALL APPROVED LABORATORIES IN THE PROGRAM. <--

~~(5)~~ (6) Nothing ~~shall~~ IN THIS SECTION SHALL BE CONSTRUED TO prohibit the department from coordinating quality assurance testing more than once within a calendar year. <--

~~(6)~~ (7) If the department determines that an approved laboratory's test results are unsatisfactory, the department shall initiate an investigation which may include the following: <--

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

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

(iii) An inspection of the approved laboratory's facility, transportation vehicles, equipment,

instruments, tools and physical or electronic materials.

(iv) Interviews with the personnel, staff, directors or other responsible parties of the approved laboratory.

(v) The approved laboratory submitting a corrective action plan to the department for review. ~~The following shall apply:~~ <--

~~(A) The department shall approve or deny a corrective action plan within 30 days of receipt of the plan.~~

~~(B) The department may, in its sole discretion, allow the approved laboratory to submit a revised corrective action plan based on the reasons for the denial of the plan.~~

~~(C) The department shall approve or deny a revised corrective action plan within 30 days.~~

~~(D) The plan shall be implemented within 30 days of the approval of the department.~~

(J) CORRECTIVE ACTIONS.--THE FOLLOWING SHALL APPLY TO A CORRECTIVE ACTION PLAN REQUIRED BY THE DEPARTMENT: <--

(1) THE DEPARTMENT SHALL APPROVE OR DENY A CORRECTIVE ACTION PLAN WITHIN 30 DAYS OF RECEIPT OF THE PLAN.

(2) THE DEPARTMENT MAY, IN ITS SOLE DISCRETION, ALLOW THE APPROVED LABORATORY TO SUBMIT A REVISED CORRECTIVE ACTION PLAN BASED ON THE REASONS FOR THE DENIAL OF THE PLAN WITHIN 30 DAYS OF RECEIPT OF THE DENIAL.

(3) THE DEPARTMENT SHALL APPROVE OR DENY A REVISED CORRECTIVE ACTION PLAN WITHIN 30 DAYS OF RECEIPT OF THE PLAN.

(4) THE CORRECTIVE ACTION PLAN SHALL BE IMPLEMENTED WITHIN A PRACTICABLE TIME FRAME DETERMINED BY THE DEPARTMENT FOLLOWING APPROVAL.

~~(j)~~ (K) Lawful possession.--The possession of medical marijuana by an approved laboratory or cooperative laboratory to conduct compliance testing, stability testing, RESEARCH AND DEVELOPMENT TESTING, audit testing and quality assurance testing shall be lawful use. <--

~~(k)~~ (L) Violations.--In addition to any other requirements UNDER THIS ACT OR A REGULATION PROMULGATED UNDER THIS ACT, the following shall be considered to be violations of this section and may result in penalties under section 1308(b): <--

(1) Failure to comply with the department as part of an inspection or investigation.

(2) Failure to submit a corrective action plan as required by the department.

(3) Failure to implement a corrective action plan within ~~30 days of approval~~ THE TIMELINE DETERMINED by the department. <--

(4) Failure to participate in the required quality assurance testing.

(5) Failure to produce:

(i) Test results.

(ii) Satisfactory test results as part of the quality assurance testing.

(6) FRAUDULENT REPORTING OF LABORATORY TEST RESULTS. <--

~~(l) Sanctions. The department may revoke or suspend the approval to test medical marijuana of an approved laboratory found to be in violation of this act or a regulation promulgated under this act, violation of an order issued under this act or a regulation promulgated under this act or for conduct or activity which would have disqualified the approved laboratory from receiving approval to test medical marijuana.~~ <--

(M) SANCTIONS.--IN ADDITION TO THE PENALTIES PERMITTED UNDER <-- SUBSECTION (L), THE DEPARTMENT MAY IMPOSE THE FOLLOWING SANCTIONS:

(1) REVOKE OR SUSPEND THE APPROVAL TO TEST MEDICAL MARIJUANA OF AN APPROVED LABORATORY FOUND TO BE IN VIOLATION OF THIS ACT OR A REGULATION PROMULGATED UNDER THIS ACT.

(2) REVOKE OR SUSPEND THE APPROVAL TO TEST MEDICAL MARIJUANA OF AN APPROVED LABORATORY FOUND TO BE IN VIOLATION OF AN ORDER ISSUED UNDER THIS ACT OR A REGULATION PROMULGATED UNDER THIS ACT.

(3) REVOKE OR SUSPEND THE APPROVAL TO TEST MEDICAL MARIJUANA OF AN APPROVED LABORATORY FOR CONDUCT OR ACTIVITY WHICH WOULD HAVE DISQUALIFIED THE APPROVED LABORATORY FROM RECEIVING APPROVAL TO TEST MEDICAL MARIJUANA.

(4) SUSPEND AN APPROVED LABORATORY PENDING THE OUTCOME OF A HEARING IN A CASE WHICH THE APPROVAL TO TEST MEDICAL MARIJUANA COULD BE REVOKED.

(5) ORDER THE APPROVED LABORATORY TO CEASE AND DESIST TESTING MEDICAL MARIJUANA.

~~(m)~~ (N) Testing data and trend analysis.--The following <-- shall apply:

(1) An owner or operator of each approved laboratory shall ensure that the laboratory enters all of the following testing results into the seed-to-sale tracking system:

(i) Compliance testing.

(ii) Stability testing.

(iii) Research and development testing.

(iv) Quality assurance testing.

(2) The department may utilize the test results entered by the approved laboratory for the following purposes:

(i) To conduct trend analysis for laboratory oversight and compliance.

(ii) To review functionality of testing standards and methods.

(iii) To ensure compliance of medical marijuana products.

(iv) To ensure compliance by grower/processors.

(v) To release de-identified data to academic clinical research centers for research purposes only.

(vi) To compile and aggregate testing information to post on the department's publicly accessible Internet website.

(vii) To aid the department in any aspect of its regulatory efforts, including administrative action.

~~(n)~~ (O) Accreditation.--The department shall determine the scope of the 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. <--

~~(o)~~ (P) State testing laboratory.--The department may establish and maintain a State testing laboratory. A State testing laboratory under this section shall be responsible for all of the following: <--

(1) Developing and maintaining a medical marijuana laboratory reference library that contains testing methodologies, including all of the following:

(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 laboratories.

(3) Conducting ~~proficiency~~ QUALITY ASSURANCE testing of approved laboratories. <--

(4) ~~Remediation of~~ RESOLVING problems with approved laboratories. <--

(5) Conducting ~~compliance testing and~~ audit testing on medical marijuana samples analyzed by approved testing laboratories. <--

~~(p)~~ (Q) Materials.--Approved laboratories shall provide materials to the State testing laboratory reference library. <--

~~(q)~~ (R) Powers and duties of department.--The department shall: <--

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

(2) Within 90 days of the effective date of this paragraph, promulgate temporary regulations in accordance with the following:

(i) In order to facilitate the prompt implementation of this section, the department shall have the authority to promulgate temporary regulations which shall expire not later than two years following the publication of the temporary regulations in the Pennsylvania Bulletin under subparagraph (iii) and on the department's publicly accessible Internet website.

(ii) The department may promulgate temporary regulations not subject to:

(A) Sections 201, 202, 203, 204 and 205 of the act of July 31, 1968 (P.L.769, No.240), referred to as the Commonwealth Documents Law.

(B) Section 204(b) of the act of October 15, 1980 (P.L.950, No.164), known as the Commonwealth Attorneys Act.

(C) The act of June 25, 1982 (P.L.633, No.181), known as the Regulatory Review Act.

(iii) Within 90 days of the effective date of this paragraph, the department shall transmit the temporary regulations to the Legislative Reference Bureau for publication in the next available issue of the Pennsylvania Bulletin.

(iv) The ~~board's~~ DEPARTMENT'S authority to adopt temporary regulations under subparagraph (i) shall expire two years after publication of the temporary regulations. Regulations adopted after this period shall be promulgated as provided by law. <--

(3) Within 90 days of submitting the temporary regulations to the Legislative Reference Bureau, the department shall issue guidance to accompany the temporary regulations.

Section 3. Section 1201(b), (d), (e), (g), (h) and (i) of the act are amended and subsection (a) is amended by adding a paragraph 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:

* * *

(10) One member appointed by the Governor, who shall have experience and expertise in laboratory science and shall not be affiliated with, contracted with, an owner of, operator of or financed by an approved laboratory or medical marijuana organization.

(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.

* * *

(d) Voting; quorum.--The members under subsection (a)(1), (2), (3), (4), (5), (6) and (7) shall serve ex officio and all members 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.

* * *

(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.

* * *

Section 4. This act shall take effect in 90 days.