AMENDMENTS TO HOUSE BILL NO. 1024

Sponsor: SENATOR REGAN

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Amend Bill, page 1, lines 14 and 15, by striking out "confidentiality and public disclosure and for"

Amend Bill, page 1, line 21, by striking out "grower/processor" and inserting grower/processors

Amend Bill, page 1, line 23, by inserting after "requirements;"

in tax on medical marijuana, further providing for Medical Marijuana Program Fund; in administration, further providing for temporary regulations; in Medical Marijuana Advisory Board, further providing for advisory board and for regulations based on recommendations of advisory board; in offenses related to medical marijuana, further providing for disclosure of information prohibited;

Amend Bill, page 1, line 26, by striking out "; and," and inserting and providing for research initiative;

Amend Bill, page 1, line 27, by inserting after "applicability" ; and making a related repeal

Amend Bill, page 2, line 1, by striking out ""caregiver" and" and inserting "caregiver,"

Amend Bill, page 2, line 2, by inserting after "care"" and "serious medical condition"

Amend Bill, page 2, line 4, by striking out "a definition"

and inserting

definitions

Amend Bill, page 2, line 10, by inserting a bracket before "The"

Amend Bill, page 2, line 10, by striking out the bracket before "individual"

Amend Bill, page 2, line 10, by striking out "] person"

Amend Bill, page 2, line 12, by inserting after "marijuana."

] The term includes the following entities designated to deliver medical marijuana:

(1) An individual designated by a patient.

(2) If the patient is under 18 years of age, an individual under section 506(2).

(3) Individuals designated in writing, for purposes of section 502, by an organization that provides hospice, palliative or home health care services and:

(i) are employed by an organization that is licensed under the act of July 19, 1979 (P.L.130, No.48), known as the Health Care Facilities Act;

(ii) have significant responsibility for managing the health care and well-being of a patient; and

(iii) were designated by the organization to provide care to a patient who has provided authorization for the designation.

(4) Individuals designated in writing, for purposes of section 502, by a residential facility, including a long-term care nursing facility, a skilled nursing facility, an assisted living facility, a personal care home, an independent long-term care facility or an intermediate care facility for individuals with intellectual disabilities that:

(i) are licensed by the department or the Department of Human Services;

(ii) have significant responsibility for managing the health care and well-being of the patient; and

(iii) were designated by the residential facility to provide care to a patient who has provided authorization for the designation.

Amend Bill, page 2, lines 19 through 22, by striking out all of said lines and inserting

"Excipients." Solvents, chemicals or materials reported by a medical marijuana organization and approved by the department

for use in the processing of medical marijuana.

* * *

"Harvest batch." A specifically identified quantity of medical marijuana plant that is uniform in strain, cultivated utilizing the same growing practices, harvested at the same time and at the same location and cured under uniform conditions.

"Harvest lot." A specifically identified quantity of medical marijuana plant taken from a harvest batch.

* * *

"Medical marijuana product." The final form and dosage of medical marijuana that is grown, processed, produced, sealed, labeled and tested by a grower/processor and sold to a dispensary.

* * *

"Process lot." An amount of a medical marijuana product of the same type and processed using the same medical marijuana extract, standard operating procedures and the same or combination of different harvest lots.

* * *

"Research initiative." A nonpatient investigation not subject to Institutional Review Board or Research Approval Committee approval requirements of a patient-based research program, project or study, conducted by an academic clinical research center and its contracted clinical registrant.

* * *

"Serious medical condition." Any of the following:

(1) Cancer, including remission therapy.

(2) Positive status for human immunodeficiency virus or acquired immune deficiency syndrome.

(3) Amyotrophic lateral sclerosis.

(4) Parkinson's disease.

(5) Multiple sclerosis.

(6) Damage to the nervous tissue of the [spinal cord] central nervous system (brain-spinal cord) with objective neurological indication of intractable spasticity and other associated neuropathies.

(7) Epilepsy.

(8) Inflammatory bowel disease.

(9) Neuropathies.

(10) Huntington's disease.

(11) Crohn's disease.

(12) Post-traumatic stress disorder.

(13) Intractable seizures.

(14) Glaucoma.

(15) Sickle cell anemia.

(16) Severe chronic or intractable pain of neuropathic origin or severe chronic or intractable pain [in which conventional therapeutic intervention and opiate therapy is contraindicated or ineffective].

(17) Autism.

(18) Other conditions that are recommended by the

advisory board and approved by the secretary under section 1202.

"Synchronous interaction." A two-way or multiple-way exchange of information between a patient and a health care provider that occurs in real time via audio or video conferencing.

Amend Bill, page 2, line 24, by striking out "302(b),"

Amend Bill, page 2, line 25, by inserting after "(4)"

and (7)

Amend Bill, page 2, lines 26 through 30; page 3, lines 1 through 15; by striking out all of said lines on said pages

Amend Bill, page 6, by inserting between lines 7 and 8

(7) A statement that the applicant:

[(i) Is of good moral character. For purposes of this subparagraph, an applicant shall include each financial backer, operator, employee and principal of the medical marijuana organization.]

(ii) Possesses the ability to obtain in an expeditious manner the right to use sufficient land, buildings and other premises and equipment to properly carry on the activity described in the application and any proposed location for a facility.

(iii) Is able to maintain effective security and control to prevent diversion, abuse and other illegal conduct relating to medical marijuana.

(iv) Is able to comply with all applicable Commonwealth laws and regulations relating to the activities in which it intends to engage under this act.

* * *

Amend Bill, page 6, line 26, by inserting a bracket before "the"

Amend Bill, page 6, line 27, by inserting after "substances:"

] the manufacture, delivery or possession with intent to manufacture or deliver a controlled substance in violation of the act of April 14, 1972 (P.L.233, No.64), known as The Controlled Substance, Drug, Device and Cosmetic Act, or similar law in any other jurisdiction:

Amend Bill, page 7, lines 1 through 4, by striking out "TO INDIVIDUALS" in line 1 and all of lines 2 through 4 and inserting

to an individual for whom it has been 10 or more years since the entry of a final disposition of a felony conviction related to the manufacture, delivery or possession with intent to manufacture or deliver a controlled substance in violation of the act of April 14, 1972 (P.L.233, No.64), known as The Controlled Substance, Drug, Device and Cosmetic Act, or similar law in any other jurisdiction, or one year since the individual's release from imprisonment for the felony conviction, whichever is later.

Amend Bill, page 7, line 9, by striking out "and"

Amend Bill, page 7, line 22, by striking out "advisory board" and inserting

department

Amend Bill, page 7, line 24, by striking out the comma after "704" and inserting

and

Amend Bill, page 7, lines 24 and 25, by striking out ", 802(a)(1), 2001.1(A), 2002(A) AND (B) and 2109(a)"

Amend Bill, page 8, line 1, by inserting after "Obtain"

and transport

Amend Bill, page 8, line 3, by inserting after "grow"

and process

Amend Bill, page 8, line 10, by inserting after "Commonwealth"

to process medical marijuana

Amend Bill, page 8, lines 15 through 30; page 9, lines 1 through 5; by striking out "The department shall" in line 15, all of lines 16 through 30 on page 8 and all of lines 1 through 5 on page 9 and inserting

(3) Apply solvent-based extraction methods and processes to medical marijuana plants that have failed a test conducted by an approved laboratory at harvest, subject to the following:

(i) The test failure shall be limited to yeast and mold.

(ii) The extracted material shall be processed into

a topical form.

(iii) The medical marijuana product must pass a final processed test under section 704.

(iv) The medical marijuana product shall be labeled as remediated.

(v) This paragraph shall expire upon the publication in the Pennsylvania Bulletin of a notice of the secretary's approval of the recommendations relating to a research initiative, as prescribed in section 2003.1.

(4) Obtain harvested hemp from a person holding a permit issued by the Department of Agriculture to grow or cultivate hemp under the 3 Pa.C.S. Ch. 15 (relating to controlled plants and noxious weeds) if the hemp received by a grower/processor is subject to the laboratory testing requirements of section 704.

(5) Add excipients or hemp or hemp-derived additives obtained or cultivated in accordance with paragraph (4). Excipients must be pharmaceutical grade, unless otherwise approved by the department. In determining whether to approve an added substance, the department shall consider the following:

(i) Whether the added substance is permitted by the United States Food and Drug Administration for use in food or is Generally Recognized as Safe (GRAS) under Federal guidelines.

(ii) Whether the added substance constitutes a known hazard such as diacetyl, CAS number 431-03-8, and pentanedione, CAS number 600-14-6.

Amend Bill, page 9, lines 14 through 19, by striking out "the" in line 14 and all of lines 15 through 19 and inserting

a grower/processor shall maintain continuous video surveillance. A grower/processor is required to retain the recordings onsite or offsite for a period of no less than 180 days, unless otherwise required for investigative or litigation purposes.

Amend Bill, page 9, lines 24 through 30; page 10, lines 1 through 13; by striking out the period in line 24, all of lines 25 through 30 on page 9 and all of lines 1 through 13 on page 10 and inserting

and designated by the Secretary of Agriculture in consultation with the secretary for use by a grower/processor.

(2) The Secretary of Agriculture shall, within 30 days of the effective date of this subsection, transmit to the Legislative Reference Bureau for publication in the

Pennsylvania Bulletin an initial list of pesticides which may be used by grower/processors. The list shall be posted on the department's publicly accessible Internet website and shall be reviewed and updated by the Secretary of Agriculture, in consultation with the secretary, at least once annually and transmitted to the Legislative Reference Bureau for publication in the Pennsylvania Bulletin.

Amend Bill, page 11, line 7, by striking out the bracket before the comma after "determine"

Amend Bill, page 11, line 8, by striking out "] of"

Amend Bill, page 11, line 14, by striking out "harvest batch of"

Amend Bill, page 11, line 14, by inserting after "marijuana"
 product derived from a harvest batch

Amend Bill, page 11, line 16, by striking out "a harvest batch" and inserting
 each process lot

Amend Bill, page 11, line 18, by striking out "harvest batch of"

Amend Bill, page 11, line 18, by inserting after "marijuana"
 product

Amend Bill, page 11, line 28, by striking out "REMOTELY" and inserting
 by synchronous interaction

Amend Bill, page 12, line 5, by striking out "REMOTELY" and inserting
 by synchronous interaction

Amend Bill, page 12, by inserting between lines 20 and 21

Section 5. Section 802(a)(1) of the act is amended and the subsection is amended by adding a paragraph to read:

Amend Bill, page 12, by inserting between lines 26 and 27

(1.1) For the purposes of paragraph (1), a dispensary shall maintain continuous video surveillance. The dispensary

is required to retain the recordings onsite or offsite for a period of no less than 180 days, unless otherwise required for investigative or litigation purposes.

Amend Bill, page 12, by inserting between lines 27 and 28

Section 6. Sections 902(d), 1107(b), 1201(j)(4), (5) and (6), 1202, 1307, 2001.1(a) and 2002(a) and (b) of the act are amended to read:

Section 902. Medical Marijuana Program Fund.

* * *

(d) Repayment of initial funding.--The department shall repay from the fees, taxes and investment earnings of the fund to the General Fund any money appropriated for the initial planning, organization and administration by the department with respect to the establishment of the program at the time of the original enactment of this act. [Repayment shall take place within a 10-year period commencing one year after the date of publication in the Pennsylvania Bulletin of the final regulations.]

Section 1107. Temporary regulations.

* * *

(b) Expiration.--[The] Notwithstanding any other provision of law, the department's authority to adopt temporary regulations under subsection (a) shall expire [two years after the effective date of this section] May 31, 2022. Regulations adopted after this period shall be promulgated as provided by law.

* * *

Section 1201. Advisory board.

* * *

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

* * *

(4) To issue [two years after the effective date of this section a written report] written reports to the Governor, the Senate and the House of Representatives.

(5) The written [report] 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.

[(iv) Whether to change, add or reduce the number of growers/processors or dispensaries.]

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

[(vi) Whether to permit medical marijuana to be dispensed in dry leaf or plant form, for administration by vaporization.]

(6) The [final written report] written reports under this section shall be adopted at a public meeting. The [report] 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 1202. [Regulations based on] Effectuating recommendations of advisory board.

After receiving [the] a report of the advisory board under section 1201(j)(4), at the discretion of the secretary, the department may [promulgate regulations to] effectuate recommendations made by the advisory board by transmitting a notice to the Legislative Reference Bureau for publication in the Pennsylvania Bulletin. The secretary shall [issue notice] transmit notice to the Legislative Reference Bureau for publication in the Pennsylvania Bulletin within 12 months of the receipt of [the] a report of the advisory board. The notice shall include the recommendations of the advisory board and shall state the specific reasons for the decision of the secretary on whether or not to effectuate each recommendation.

Section 1307. Disclosure of information prohibited.

(a) Offense defined.--In addition to any other penalty provided by law, an employee, financial backer, operator or principal of any of the following commits a misdemeanor of the third degree if the person discloses, except to authorized persons for official governmental or health care purposes, any information related to the use of medical marijuana:

(1) A medical marijuana organization.

(2) A health care medical marijuana organization or university participating in a research study under Chapter 19.

(3) A clinical registrant or academic clinical research center under Chapter 20.

(4) An employee or contractor of the department.

(b) Exception.--Subsection (a) shall not apply where disclosure is permitted or required by law or by court order. The department, including an authorized employee, requesting or obtaining information under this act shall not be subject to any criminal liability. The immunity provided by this subsection shall not apply to any employee of the department who knowingly and willfully discloses prohibited information under this act.

Amend Bill, page 14, lines 2 through 15, by striking out all of said lines and inserting

(1) The department shall:

(i) Open applications for the approval of up to two additional academic clinical research centers and issue approvals to qualified academic clinical research centers

within 90 days of the effective date of this paragraph.

(ii) Open applications for the approval of up to two additional clinical registrants within 120 days of the effective date of this paragraph and issue permits to qualified clinical registrants within 180 days from the date when applications are posted.

(2) If the statutory maximum number of approved academic clinical research centers or approved clinical registrants are not approved under paragraph (1), the department shall reopen the application process for the approval of academic clinical research centers and clinical registrants.

Amend Bill, page 14, line 26, by striking out "LICENSE" and inserting

permit

Amend Bill, page 15, lines 10 and 11, by striking out ", AND PROVIDED ALL RIGHTS OF OTHER GROWER/PROCESSOR PERMITTEES,"

Amend Bill, page 15, line 14, by inserting a bracket before "ONLY"

Amend Bill, page 15, line 14, by inserting a bracket after "ONLY"

Amend Bill, page 15, by inserting between lines 22 and 23

Section 7. The act is amended by adding a section to read:
Section 2003.1. Research initiative.

(a) Authority.--An academic clinical research center, in coordination with its contracted clinical registrant, may conduct a research initiative on the antimicrobial effects of applying solvent-based extraction methods and processes to microbial contamination of immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products.

(b) Procedure.--An academic clinical research center shall submit to the department for approval a completed written research protocol of the planned research initiative. The department shall grant approval or denial of the protocol within 15 days of its submissions. The following apply:

(1) The research initiative shall commence no later than 30 days from the date the department issues approval and shall be completed no later than six months from the start date of research initiative.

(2) Research initiative findings shall be provided to the department by the academic clinical research center within 15 days of the research initiative's conclusion.

(3) An academic clinical research center and its contracted clinical registrant shall present research initiative findings to the advisory board and the board's research subcommittee for the board's review and consideration under sections 1201 and 1202. The board shall issue a written report, with recommendations and findings regarding the use of solvent-based extraction methods and processes on microbial contamination by a clinical registrant or grower/processor. The secretary may approve the board's recommendation in accordance with section 1202.

(4) Prior to implementing a recommendation of the board under paragraph (3), as approved by the secretary, a clinical registrant or grower/processor shall seek approval from the department for a change in its grower/processor extraction process. The department shall inspect the site and facility equipment. Upon approval, the department shall issue a notice of final approval to implement the process.

Section 8. Section 2109(a) of the act is amended to read:

Amend Bill, page 15, line 30, by striking out all of said line and inserting

Section 9. The amendment of the definition of "serious medical condition" in section 103 of the act shall apply retroactively to May 18, 2016.

Section 10. Repeals are as follows:

(1) The General Assembly declares that the repeal under paragraph (2) is necessary to effectuate this act.

(2) Section 1736-A.1 of the act of April 9, 1929 (P.L.343, No.176), known as The Fiscal Code, is repealed.

Section 11. This act shall take effect as follows:

(1) The amendment or addition of sections 701(c.1) and 703(8) of the act shall take effect in 180 days.

(2) The remainder of this act shall take effect immediately.