

AMENDMENTS TO HOUSE BILL NO. 1024

Sponsor: SENATOR REGAN

Printer's No. 1823

1 Amend Bill, page 1, lines 14 and 15, by striking out

2 "confidentiality and public disclosure and for"

3 Amend Bill, page 1, line 21, by striking out

4 "grower/processor" and inserting

5 grower/processors

6 Amend Bill, page 1, line 23, by inserting after

7 "requirements;"

8 in tax on medical marijuana, further providing for Medical

9 Marijuana Program Fund; in administration, further providing

10 for temporary regulations; in Medical Marijuana Advisory

11 Board, further providing for advisory board and for

12 regulations based on recommendations of advisory board; in

13 offenses related to medical marijuana, further providing for

14 disclosure of information prohibited;

15 Amend Bill, page 1, line 26, by striking out "; and," and

16 inserting

17 and providing for research initiative;

18 Amend Bill, page 1, line 27, by inserting after

19 "applicability"

20 ; and making a related repeal

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

22 and inserting

23 "caregiver,"

24 Amend Bill, page 2, line 2, by inserting after "care"

25 and "serious medical condition"

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

1 and inserting

2 definitions

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

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

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

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

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

11 (1) An individual designated by a patient.

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

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

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

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

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

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

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

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

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

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

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

1 for use in the processing of medical marijuana.

2 * * *

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

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

9 * * *

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

14 * * *

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

19 * * *

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

25 * * *

26 "Serious medical condition." Any of the following:

- 27 (1) Cancer, including remission therapy.
- 28 (2) Positive status for human immunodeficiency virus or
29 acquired immune deficiency syndrome.
- 30 (3) Amyotrophic lateral sclerosis.
- 31 (4) Parkinson's disease.
- 32 (5) Multiple sclerosis.
- 33 (6) Damage to the nervous tissue of the [spinal cord]
34 central nervous system (brain-spinal cord) with objective
35 neurological indication of intractable spasticity and other
36 associated neuropathies.
- 37 (7) Epilepsy.
- 38 (8) Inflammatory bowel disease.
- 39 (9) Neuropathies.
- 40 (10) Huntington's disease.
- 41 (11) Crohn's disease.
- 42 (12) Post-traumatic stress disorder.
- 43 (13) Intractable seizures.
- 44 (14) Glaucoma.
- 45 (15) Sickle cell anemia.
- 46 (16) Severe chronic or intractable pain of neuropathic
47 origin or severe chronic or intractable pain [in which
48 conventional therapeutic intervention and opiate therapy is
49 contraindicated or ineffective].
- 50 (17) Autism.
- 51 (18) Other conditions that are recommended by the

1 advisory board and approved by the secretary under section
2 1202.
3 "Synchronous interaction." A two-way or multiple-way
4 exchange of information between a patient and a health care
5 provider that occurs in real time via audio or video
6 conferencing.

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

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

9 and (7)

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

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

13 (7) A statement that the applicant:

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

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

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

26 (iv) Is able to comply with all applicable
27 Commonwealth laws and regulations relating to the
28 activities in which it intends to engage under this act.
29 * * *

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

32 Amend Bill, page 6, line 27, by inserting after "substances:"
33] the manufacture, delivery or possession with intent to
34 manufacture or deliver a controlled substance in violation of
35 the act of April 14, 1972 (P.L.233, No.64), known as The
36 Controlled Substance, Drug, Device and Cosmetic Act, or similar
37 law in any other jurisdiction:

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

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

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

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

13 department

14 Amend Bill, page 7, line 24, by striking out the comma after
15 "704" and inserting

16 and

17 Amend Bill, page 7, lines 24 and 25, by striking out "
18 802(a)(1), 2001.1(A), 2002(A) AND (B) and 2109(a)"

19 Amend Bill, page 8, line 1, by inserting after "Obtain"
20 and transport

21 Amend Bill, page 8, line 3, by inserting after "grow"
22 and process

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

25 to process medical marijuana

26 Amend Bill, page 8, lines 15 through 30; page 9, lines 1
27 through 5; by striking out "The department shall" in line 15,
28 all of lines 16 through 30 on page 8 and all of lines 1 through
29 5 on page 9 and inserting

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

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

36 (ii) The extracted material shall be processed into

1 a topical form.

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

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

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

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

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

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

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

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

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

36 Amend Bill, page 9, lines 24 through 30; page 10, lines 1
37 through 13; by striking out the period in line 24, all of lines
38 25 through 30 on page 9 and all of lines 1 through 13 on page 10
39 and inserting

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

43 (2) The Secretary of Agriculture shall, within 30 days
44 of the effective date of this subsection, transmit to the
45 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

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

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

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

8 Section 902. Medical Marijuana Program Fund.

9 * * *

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

19 Section 1107. Temporary regulations.

20 * * *

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

27 * * *

28 Section 1201. Advisory board.

29 * * *

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

32 * * *

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

36 (5) The written [report] reports under paragraph (4)
37 shall include recommendations and findings as to the
38 following:

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

41 (ii) Whether to change, add or reduce the types of
42 medical conditions which qualify as serious medical
43 conditions under this act.

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

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

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

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

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

9 Section 1202. [Regulations based on] Effectuating
10 recommendations of advisory board.

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

23 Section 1307. Disclosure of information prohibited.

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

30 (1) A medical marijuana organization.

31 (2) A health care medical marijuana organization or
32 university participating in a research study under Chapter
33 19.

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

36 (4) An employee or contractor of the department.

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

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

46 (1) The department shall:

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

1 within 90 days of the effective date of this paragraph.

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

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

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

14 permit

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

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

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

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

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

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

31 (b) Procedure.--An academic clinical research center shall
32 submit to the department for approval a completed written
33 research protocol of the planned research initiative. The
34 department shall grant approval or denial of the protocol within
35 15 days of its submissions. The following apply:

36 (1) The research initiative shall commence no later than
37 30 days from the date the department issues approval and
38 shall be completed no later than six months from the start
39 date of research initiative.

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

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

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

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

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

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

24 Section 10. Repeals are as follows:

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

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

29 Section 11. This act shall take effect as follows:

30 (1) The amendment or addition of sections 701(c.1) and
31 703(8) of the act shall take effect in 180 days.

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