

THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 835 Session of 2023

INTRODUCED BY REGAN AND BREWSTER, JUNE 20, 2023

REFERRED TO LAW AND JUSTICE, JUNE 20, 2023

AN ACT

1 Amending the act of April 17, 2016 (P.L.84, No.16), entitled "An
 2 act establishing a medical marijuana program; providing for
 3 patient and caregiver certification and for medical marijuana
 4 organization registration; imposing duties on the Department
 5 of Health; providing for a tax on medical marijuana
 6 organization gross receipts; establishing the Medical
 7 Marijuana Program Fund; establishing the Medical Marijuana
 8 Advisory Board; establishing a medical marijuana research
 9 program; imposing duties on the Department of Corrections,
 10 the Department of Education and the Department of Human
 11 Services; and providing for academic clinical research
 12 centers and for penalties and enforcement," in preliminary
 13 provisions, further providing for definitions; in program,
 14 further providing for program established, for
 15 confidentiality and public disclosure, for lawful use of
 16 medical marijuana and for unlawful use of medical marijuana;
 17 in practitioners, further providing for practitioner
 18 registration, for practitioner restrictions, for issuance of
 19 certification and for duration; in patients, further
 20 providing for identification cards, for verification and for
 21 contents of identification card; in medical marijuana
 22 organizations, further providing for granting of permit, for
 23 relocation and for limitations on permits; in medical
 24 marijuana controls, further providing for electronic
 25 tracking, for grower/processors, for storage and
 26 transportation, for laboratory and for prices and providing
 27 for recalls; in dispensaries, further providing for
 28 dispensing to patients and caregivers and for facility
 29 requirements; in tax on medical marijuana, further providing
 30 for Medical Marijuana Program Fund; in Medical Marijuana
 31 Advisory Board, further providing for advisory board; in
 32 research program, further providing for establishment of
 33 medical marijuana research program, for medical marijuana
 34 research program administration and for approval; in academic
 35 clinical research centers and clinical registrants, further

1 providing for legislative findings and declaration of policy,
2 for definitions and for clinical registrants and providing
3 for termination of contract; and, in miscellaneous
4 provisions, further providing for applicability.

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

7 Section 1. The definitions of "certified medical use,"
8 "excipients," "harvest batch," "harvest lot," "patient,"
9 "process lot" and "serious medical condition" in section 103 of
10 the act of April 17, 2016 (P.L.84, No.16), known as the Medical
11 Marijuana Act, are amended and the section is amended by adding
12 a definition to read:

13 Section 103. Definitions.

14 The following words and phrases when used in this act shall
15 have the meanings given to them in this section unless the
16 context clearly indicates otherwise:

17 * * *

18 "Certified medical use." The acquisition, possession, use or
19 transportation of medical marijuana by a patient, or the
20 acquisition, possession, delivery, transportation or
21 administration of medical marijuana by a caregiver, for use [as
22 part of the treatment of the patient's serious medical
23 condition, as authorized in a certification under this act,
24 including enabling the patient to tolerate treatment for the
25 serious medical condition] by the patient as authorized in a
26 certification under this act.

27 * * *

28 "Excipients." Solvents, chemicals or materials reported by a
29 medical marijuana organization [and approved by] to the
30 department for use in the processing of medical marijuana.

31 * * *

32 ["Harvest batch." A specifically identified quantity of

1 medical marijuana plant that is uniform in strain, cultivated
2 utilizing the same growing practices, harvested at the same time
3 and at the same location and cured under uniform conditions.

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

6 * * *

7 "Office." The Office of Medical Marijuana within the
8 department.

9 "Patient." An individual who:

10 (1) has a [serious] medical condition;

11 (2) has met the requirements for certification under
12 this act; and

13 (3) is a resident of this Commonwealth.

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

21 (1) Cancer, including remission therapy.

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

24 (3) Amyotrophic lateral sclerosis.

25 (4) Parkinson's disease.

26 (5) Multiple sclerosis.

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

- 1 (7) Epilepsy.
- 2 (8) Inflammatory bowel disease.
- 3 (9) Neuropathies.
- 4 (10) Huntington's disease.
- 5 (11) Crohn's disease.
- 6 (12) Post-traumatic stress disorder.
- 7 (13) Intractable seizures.
- 8 (14) Glaucoma.
- 9 (15) Sickle cell anemia.
- 10 (16) Severe chronic or intractable pain of neuropathic
- 11 origin or severe chronic or intractable pain.
- 12 (17) Autism.
- 13 (18) Other conditions that are recommended by the
- 14 advisory board and approved by the secretary under section
- 15 1202.]

16 * * *

17 Section 2. Section 301(a) introductory paragraph, (4)(v),
18 (9), (13) and (14) of the act are amended, the subsection is
19 amended by adding a paragraph and the section is amended by
20 adding a subsection to read:

21 Section 301. Program established.

22 (a) Establishment.--A medical marijuana program for patients
23 suffering from [serious] medical conditions is established. The
24 program shall be implemented and administered by the department.
25 The department shall:

26 * * *

27 (4) Establish and maintain an electronic database to
28 include activities and information relating to medical
29 marijuana organizations, certifications and identification
30 cards issued, practitioner registration and electronic

1 tracking of all medical marijuana as required under this act
2 to include:

3 * * *

4 (v) [The] Two-way communication between the database
5 and the tracking system under section 701 [must include
6 information under section 801(a) and any other
7 information required by the department to be used by the
8 department and dispensaries to enable a dispensary to
9 lawfully provide medical marijuana. The tracking system
10 and database shall be capable of providing information in
11 real time. The database shall be capable of receiving
12 information from a dispensary regarding the disbursement
13 of medical marijuana to patients and caregivers. This
14 information shall be immediately accessible to the
15 department and other dispensaries to inhibit diversion
16 and ensure compliance with this act.] with immediate
17 access by the department and dispensaries to information,
18 including all of the following:

19 (A) Receipts as required under section 801(a)
20 and (c).

21 (B) Supply and form of medical marijuana
22 limitations requiring verification by dispensaries
23 under section 801(g).

24 (C) Any other information required by the
25 department to be used by the department and
26 dispensaries to enable a dispensary to lawfully
27 provide medical marijuana or to inhibit diversion and
28 ensure compliance with this act.

29 * * *

30 (9) Establish a program to authorize the use of medical

1 marijuana to conduct medical research relating to the use of
2 medical marijuana to treat [serious] medical conditions,
3 including the collection of data and the provision of
4 research grants.

5 * * *

6 (13) Develop recordkeeping requirements for all books,
7 papers, any electronic database or tracking system data and
8 other information of a medical marijuana organization.
9 Information shall be retained for a minimum period of [four
10 years] 180 days unless otherwise provided by the department.

11 [(14) Restrict the advertising and marketing of medical
12 marijuana, which shall be consistent with the Federal
13 regulations governing prescription drug advertising and
14 marketing.]

15 (15) Define and publish within 30 days of the effective
16 date of this paragraph guidelines for and monitor the
17 advertising and marketing of medical marijuana in accordance
18 with the following:

19 (i) Medical marijuana organizations must follow the
20 guidelines.

21 (ii) Advertising or marketing materials produced by
22 or for a medical marijuana organization shall:

23 (A) Not require preapproval by the department.

24 (B) Be free of names, colors and images that
25 would be attractive to individuals under 21 years of
26 age.

27 (C) Only be placed where the audience is
28 reasonably expected to be 21 years of age or older.

29 (D) Comply with local ordinances pertaining to
30 signs and advertising.

1 (iii) Permitted activities shall include the
2 development of and ability to provide and sell medical
3 marijuana organization branded materials.

4 * * *

5 (c) Office of Medical Marijuana.--The department shall
6 establish an Office of Medical Marijuana in accordance with the
7 following:

8 (1) The office shall oversee the Medical Marijuana
9 Program.

10 (2) A full-time director of the office shall be
11 appointed by the Governor, subject to the consent of a
12 majority of the members elected to the Senate.

13 Section 2.1. Section 302(a)(5) of the act is amended and the
14 section is amended by adding a subsection to read:

15 Section 302. Confidentiality and public disclosure.

16 (a) Patient information.--The department shall maintain a
17 confidential list of patients and caregivers to whom it has
18 issued identification cards. All information obtained by the
19 department relating to patients, caregivers and other applicants
20 shall be confidential and not subject to public disclosure,
21 including disclosure under the act of February 14, 2008 (P.L.6,
22 No.3), known as the Right-to-Know Law, including:

23 * * *

24 (5) Information relating to the patient's [serious]
25 medical condition.

26 * * *

27 (c) Administration.--Nothing in this section shall preclude
28 aggregation of de-identified data for research purposes,
29 operational key performance measures or sharing of the data for
30 the sole purpose of administering services to patients through a

1 service provider who is contractually obligated to not use the
2 data for anything other than services provided to a medical
3 marijuana organization.

4 Section 3. Section 303(b) (2), (3) and (8) of the act are
5 amended and the subsection is amended by adding paragraphs to
6 read:

7 Section 303. Lawful use of medical marijuana.

8 * * *

9 (b) Requirements.--The lawful use of medical marijuana is
10 subject to the following:

11 * * *

12 (2) [Subject to regulations promulgated under this act,
13 medical] Medical marijuana may only be dispensed to a patient
14 or caregiver in the following forms:

15 [(i) pill;

16 (ii) oil;

17 (iii) topical forms, including gels, creams or
18 ointments;

19 (iv) a form medically appropriate for administration
20 by vaporization or nebulization, excluding dry leaf or
21 plant form until dry leaf or plant forms become
22 acceptable under regulations adopted under section 1202;

23 (v) tincture; or

24 (vi) liquid.

25 (3) Unless otherwise provided in regulations adopted by
26 the department under section 1202, medical marijuana may not
27 be dispensed to a patient or a caregiver in dry leaf or plant
28 form.]

29 (i) Infused edible forms meant to be chewed,
30 dissolved, taken sublingually or swallowed. This includes

1 oil, tincture, capsules, tablets, gummies, liquids,
2 including beverages, and other ingestible forms.

3 (ii) Infused nonedible forms, including gels,
4 creams, patches and ointments.

5 (iii) Forms for administration by inhalation,
6 vaporization or nebulization, including flower and plant
7 materials.

8 * * *

9 (8) Products packaged by a grower/processor or sold by a
10 dispensary shall [only] be identified by the name of the
11 grower/processor, the name of the dispensary, the form and
12 species of medical marijuana, the percentage of
13 tetrahydrocannabinol and cannabinal contained in the product
14 and any other labeling [required by the department.] deemed
15 necessary by the medical marijuana organization.

16 (9) Grower/processors and dispensaries may source and
17 sell ancillary devices used to administer medical marijuana.

18 (10) The department shall publish guidelines for
19 packaging and labeling of medical marijuana. Preapproval of
20 packaging and labels by the department shall not be required.
21 All packaging shall be childproof and free of names, colors
22 and images that would be attractive to individuals under 21
23 years of age and packaging that will be in contact with the
24 medical marijuana must be food grade.

25 Section 4. Sections 304(b), 401(a) and (c), 402(a), 403(a)
26 (2) and (3) and (b), 405, 501(c), (d), (e) and (h), 503.1, 508,
27 603(d) and 609(a) of the act are amended to read:

28 Section 304. Unlawful use of medical marijuana.

29 * * *

30 (b) Unlawful use described.--It is unlawful to:

1 [(1) Smoke medical marijuana.]

2 (2) Except as provided under subsection (c), incorporate
3 medical marijuana into edible form.]

4 (3) Grow medical marijuana unless the grower/processor
5 has received a permit from the department under this act.

6 (4) Grow or dispense medical marijuana unless authorized
7 as a health care medical marijuana organization under Chapter
8 19.

9 (5) Dispense medical marijuana unless the dispensary has
10 received a permit from the department under this act.

11 * * *

12 Section 401. Practitioner registration.

13 (a) Eligibility.--A physician included in the registry is
14 authorized to issue certifications to patients to use medical
15 marijuana. To be eligible for inclusion in the registry a
16 physician must:

17 (1) [A physician must apply] Apply for registration in
18 the form and manner required by the department.

19 (2) [The department must determine that the physician
20 is, by] By training or experience, be qualified to treat [a
21 serious medical condition] medical conditions. The physician
22 shall provide documentation of credentials, training or
23 experience as required by the department.

24 (3) [The physician must have] Have successfully
25 completed the course under section 301(a) (6).

26 * * *

27 (c) Practitioner requirements.--A practitioner included in
28 the registry shall have an ongoing responsibility to immediately
29 notify the department in writing if [the practitioner knows or
30 has reason to know that any of the following is true with

1 respect to a patient for whom the practitioner has issued a
2 certification:

3 (1) The patient no longer has the serious medical
4 condition for which the certification was issued.

5 (2) Medical marijuana would no longer be therapeutic or
6 palliative.

7 (3) The patient has died.]:

8 (1) The practitioner chooses to no longer certify an
9 individual.

10 (2) A patient for whom the practitioner issued a
11 certification has died.

12 Section 402. Practitioner restrictions.

13 (a) Practices prohibited.--The following apply with respect
14 to practitioners:

15 (1) A practitioner may not accept, solicit or offer any
16 form of remuneration from or to a prospective patient,
17 patient, prospective caregiver, caregiver or medical
18 marijuana organization, including an employee, financial
19 backer or principal, to certify a patient, other than
20 accepting a fee for service with respect to the examination
21 of the prospective patient to determine if the prospective
22 patient should be issued a certification to use medical
23 marijuana.

24 (2) A practitioner may not hold a direct or economic
25 interest in a medical marijuana organization.

26 [(3) A practitioner may not advertise the practitioner's
27 services as a practitioner who can certify a patient to
28 receive medical marijuana.]

29 * * *

30 Section 403. Issuance of certification.

1 (a) Conditions for issuance.--A certification to use medical
2 marijuana may be issued by a practitioner to a patient if all of
3 the following requirements are met:

4 * * *

5 (2) The practitioner has determined that the patient has
6 a [serious] medical condition and has included the condition
7 in the patient's health care record.

8 (3) The patient is under the practitioner's continuing
9 care [for the serious medical condition].

10 * * *

11 (b) Contents.--The certification shall include:

12 (1) The patient's name, date of birth and address.

13 (2) The specific [serious] medical condition of the
14 patient.

15 (3) A statement by the practitioner that the patient has
16 a [serious] medical condition and the patient is under the
17 practitioner's continuing care for the [serious] medical
18 condition.

19 (4) The date of issuance.

20 (5) The name, address, telephone number and signature of
21 the practitioner.

22 (6) Any requirement or limitation concerning the
23 appropriate form of medical marijuana and limitation on the
24 duration of use, if applicable, including whether the patient
25 is terminally ill.

26 * * *

27 Section 405. Duration.

28 Receipt of medical marijuana by a patient or caregiver from
29 [a dispensary] dispensaries may not exceed a 90-day supply. [of
30 individual doses. During the last seven days of any 30-day

1 period during the term of the identification card, a patient may
2 obtain and possess a 90-day supply for the subsequent 30-day
3 period. Additional 90-day supplies may be provided in accordance
4 with this section for the duration of the authorized period of
5 the identification card unless a shorter period is indicated on
6 the certification.]

7 Section 501. Identification cards.

8 * * *

9 (c) Application.--A patient or a caregiver [may apply, in]
10 applying for an issuance of an identification card shall apply
11 in a form and manner prescribed by the department[, for issuance
12 or renewal of an identification card]. A caregiver must submit a
13 separate application for issuance [or renewal]. Each application
14 must include:

15 (1) The name, address and date of birth of the patient.

16 (2) The name, address and date of birth of a caregiver.

17 (3) The certification issued by the practitioner.

18 (4) The name, address and telephone number of the
19 practitioner and documentation from the practitioner that all
20 of the requirements of section 403(a) have been met.

21 (5) A one time \$50 processing fee. The department may
22 waive or reduce the fee if the applicant demonstrates
23 financial hardship.

24 (6) The signature of the applicant and date signed.

25 (7) Other information required by the department.

26 (d) Forms.--Application [and renewal] forms shall be
27 available on the department's publicly accessible Internet
28 website.

29 (e) Expiration.--An identification card of a patient or
30 caregiver shall not expire [within one year from the date of

1 issuance, upon the death of the patient, or as otherwise
2 provided in this section].

3 * * *

4 (h) Change in name or address.--A patient or caregiver who
5 has been issued an identification card shall notify the
6 department within 10 days of any change of name or address. [In
7 addition, the patient shall notify the department within 10 days
8 if the patient no longer has the serious medical condition noted
9 on the certification.]

10 Section 503.1. Verification.

11 The department shall verify the information in a patient or
12 caregiver's application [and on any renewal form].

13 Section 508. Contents of identification card.

14 An identification card shall contain the following:

15 (1) The name of the caregiver or the patient, as
16 appropriate. The identification card shall also state whether
17 the individual is designated as a patient or as a caregiver.

18 (2) The date of issuance [and expiration date].

19 (3) An identification number for the patient or
20 caregiver, as appropriate.

21 (4) A photograph of the individual to whom the
22 identification card is being issued, whether the individual
23 is a patient or a caregiver. The method of obtaining the
24 photograph shall be specified by the department by
25 regulation. The department shall provide reasonable
26 accommodation for a patient who is confined to the patient's
27 home or is in inpatient care.

28 [(5) Any requirement or limitation set by the
29 practitioner as to the form of medical marijuana.]

30 (6) Any other requirements determined by the department,

1 except the department may not require that an identification
2 card disclose the patient's [serious] medical condition.

3 Section 603. Granting of permit.

4 * * *

5 (d) Regions.--The department shall establish a minimum of
6 three regions within this Commonwealth for the purpose of
7 granting permits to grower/processors and dispensaries and
8 enforcing this act. The department shall approve permits for
9 grower/processors and dispensaries in a manner which will
10 provide an adequate amount of medical marijuana to patients and
11 caregivers in all areas of this Commonwealth. The department
12 shall consider the following when issuing a permit:

13 (1) Regional population.

14 [(2) The number of patients suffering from serious
15 medical conditions.]

16 (3) The types of serious medical conditions.]

17 (4) Access to public transportation.

18 (5) Any other factor the department deems relevant.

19 Section 609. Relocation.

20 (a) Authorization.--The department may approve an
21 application from a medical marijuana organization to relocate
22 within [this Commonwealth or] the same permitted region as
23 established in section 603(d) to add or delete activities or
24 facilities.

25 * * *

26 Section 5. Section 616(3) and (4) of the act are amended and
27 the section is amended by adding paragraphs to read:

28 Section 616. Limitations on permits.

29 The following limitations apply to approval of permits for
30 grower/processors and dispensaries:

1 * * *

2 (3) The department may not issue more than five
3 individual dispensary permits to one [person] entity.

4 (4) The department may not issue more than one
5 individual grower/processor permit to one [person] entity.

6 * * *

7 (8) After the initial issuance of permits, any
8 additional dispensary permits shall be awarded using the
9 competitive process and shall be issued in underserved
10 regions based upon patient distance to the nearest dispensary
11 and in counties without a dispensary permit as of the
12 effective date of this paragraph.

13 (9) If Federal or State law permits the sale of adult
14 use marijuana, each medical marijuana organization shall be
15 automatically issued a permit for growing/processing or
16 dispensing, based on the existing permit or permits, of both
17 medical and adult use marijuana products.

18 Section 6. Section 701(d) of the act is amended to read:

19 Section 701. Electronic tracking.

20 * * *

21 (d) Reports.--Within one year of the issuance of the first
22 permit to a grower/processor or dispensary, and every three
23 months thereafter in a form and manner prescribed by the
24 department, the following information shall be provided to the
25 department, which shall compile the information and post it on
26 the department's publicly accessible Internet website:

27 (1) The amount of medical marijuana sold in units by a
28 grower/processor during each three-month period.

29 (2) The [price] wholesale price by unit of amounts of
30 medical marijuana sold by grower/processors [as determined by

1 the department].

2 (3) The amount of medical marijuana purchased in units
3 by each dispensary in this Commonwealth.

4 (4) The [cost of amounts] wholesale price by unit of
5 medical marijuana [to] received in each dispensary in amounts
6 as determined by the department.

7 (5) The total amount and dollar value of medical
8 marijuana sold by each dispensary in the three-month period.

9 Section 7. Section 702(a)(1), (3) and (5) and (b)(2) of the
10 act are amended and subsection (a) is amended by adding
11 paragraphs to read:

12 Section 702. Grower/processors.

13 (a) Authorization.--Subject to subsection (b), a
14 grower/processor may do all of the following in accordance with
15 department regulations:

16 (1) Obtain and transport seed and immature plant
17 material from outside this Commonwealth [during at least one
18 30-day period per year as designated by the department] to
19 grow and process medical marijuana.

20 * * *

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

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

27 (ii) The extracted material shall be processed into
28 a topical form.

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

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

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

7 (3.1) Obtain industrial hemp-derived cannabidiol and
8 other cannabinoids from any commercial source within or from
9 outside of this Commonwealth.

10 * * *

11 (5) [Add] Produce medical marijuana products using
12 excipients or hemp or hemp-derived additives obtained or
13 cultivated in accordance with paragraph (4). Excipients must
14 be pharmaceutical [grade, unless otherwise approved by the
15 department. In determining whether to approve an added
16 substance, the department shall consider the following:

17 (i) Whether the added substance is] or food grade,
18 permitted by the United States Food and Drug
19 Administration for use in food or is Generally Recognized
20 as Safe (GRAS) under Federal guidelines[.

21 (ii) Whether the added substance constitutes a known
22 hazard such as], with residual limitations not to exceed
23 Federal guidelines for the subsequent dosage form under
24 the United States Pharmacopeia and the National
25 Formulary, and not a known hazard, including diacetyl,
26 CAS number 431-03-8, and pentanedione, CAS number 600-14-
27 6.

28 (6) Produce and sell medical marijuana products without
29 limitation or prior approval if the product:

30 (i) Is in compliance with paragraph (5).

1 (ii) Has all ingredients listed on the packaging.

2 (iii) Is in a form authorized by this act.

3 (b) Limitations.--

4 * * *

5 (2) For the purpose of paragraph (1), a grower/processor
6 shall maintain continuous video surveillance. A
7 grower/processor is required to retain the recordings onsite
8 or offsite for a period of no less than [180] 60 days, unless
9 otherwise required for investigative or litigation purposes.

10 * * *

11 Section 8. Sections 703(3), 704 and 705 of the act are
12 amended to read:

13 Section 703. Storage and transportation.

14 The department shall develop regulations relating to the
15 storage and transportation of medical marijuana among
16 grower/processors, testing laboratories and dispensaries which
17 ensure adequate security to guard against in-transit losses. The
18 tracking system developed by the department shall include all
19 transportation and storage of medical marijuana. The regulations
20 shall provide for the following:

21 * * *

22 [(3) Security systems that include a numbered seal on
23 the trailer.]

24 * * *

25 Section 704. Laboratory.

26 (a) [General testing] Contracting.--A grower/processor shall
27 contract with one or more independent laboratories to test the
28 medical marijuana produced by the grower/processor.

29 (a.1) Approved laboratories.--The department shall approve a
30 laboratory under this subsection and require that the laboratory

1 report testing results [in a manner as the department shall
2 determine, including requiring a test at harvest and a test at
3 final processing] within the State tracking system. The
4 possession by a laboratory of medical marijuana shall be a
5 lawful use.

6 (a.2) Samples.--

7 (1) A grower/processor shall submit a sample of final
8 products utilizing a statistically relevant sample for the
9 size of the batch to a contracted laboratory for testing.

10 (2) The batch size shall not be limited.

11 (3) Products may not be transferred for sale to a
12 dispensary without a passing test result.

13 (b) [Stability testing.--A laboratory shall perform
14 stability testing to ensure the medical marijuana product's
15 potency and purity.] Testing.--A grower/processor shall retain a
16 sample from each medical marijuana product [derived from a
17 harvest batch and request that a sample be identified and
18 collected by a laboratory approved under subsection (a) from
19 each process lot to perform stability testing] tested for sale
20 and submit the stability sample to a contracted laboratory to
21 perform stability testing to ensure the medical marijuana
22 product's potency and purity under the following conditions:

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

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

30 Section 705. Prices.

1 The department and the Department of Revenue shall monitor
2 the price of medical marijuana sold by grower/processors and by
3 dispensaries, including a [per-dose] unit price. If the
4 department and the Department of Revenue determine that the
5 prices are unreasonable or excessive, the department may
6 implement a cap on the price of medical marijuana being sold for
7 a period of six months. The cap may be amended during the six-
8 month period. If the department and the Department of Revenue
9 determine that the prices become unreasonable or excessive
10 following the expiration of a six-month cap, additional caps may
11 be imposed for periods not to exceed six months.

12 Section 9. The act is amended by adding a section to read:

13 Section 706. Recalls.

14 (a) Public health or safety.--A grower/processor shall
15 develop and implement a recall process and shall regularly
16 evaluate the products marketed by the grower/processor for
17 quality issues and defects that may impact public health or
18 safety and determine if a recall is necessary.

19 (b) Process.--Each grower/processor shall have a process for
20 recalls that includes all the following:

21 (1) How to assess the need for the recall.

22 (2) A plan of action while conducting a recall.

23 (3) How to address the depth of the recall.

24 (4) Whether public warnings should be issued.

25 (5) A plan to extend the effectiveness checks for the
26 recall.

27 (c) Definitions.--As used in this section, the following
28 words and phrases shall have the meanings given to them in this
29 subsection unless the context clearly indicates otherwise:

30 "Recall." A voluntary action by a grower/processor to remove

1 a marketed product that is considered to be a risk to the public
2 health or safety.

3 Section 10. Sections 801(b), (d), (e), (f) and (h)
4 introductory paragraph, 802(a), 902(c)(3), 1201(a)(8) and (j)(5)
5 (i) and (ii), 1902(a) and (b), 1903, 1904 and 2000(a)(1) of the
6 act are amended to read:

7 Section 801. Dispensing to patients and caregivers.

8 * * *

9 (b) Requirements.--[A dispensary shall have a physician or a
10 pharmacist available, either in person or by synchronous
11 interaction, to verify patient certifications and to consult
12 with patients and caregivers at all times during the hours the
13 dispensary is open to receive patients and caregivers. If a
14 dispensary has more than one separate location, a physician
15 assistant or a certified registered nurse practitioner may
16 verify patient certifications and consult with patients and
17 caregivers, either in person or by synchronous interaction, at
18 each of the other locations in lieu of the physician or
19 pharmacist. A physician, a pharmacist, a physician assistant or
20 a certified registered nurse practitioner shall, prior to
21 assuming duties under this paragraph, successfully complete the
22 course established in section 301(a)(6). A physician may not
23 issue a certification to authorize patients to receive medical
24 marijuana or otherwise treat patients at the dispensary.] The
25 following shall apply:

26 (1) A dispensary shall verify patient certification upon
27 entry into the dispensary. The verification may be performed
28 by a pharmacy technician, certified medical assistant or
29 certified nurse aide with supervision of a physician or
30 pharmacist.

1 (2) A dispensary shall have a physician or a pharmacist
2 available, either in person or by synchronous interaction, to
3 supervise verification of patient certifications and to
4 consult with patients and caregivers at all times during the
5 hours the dispensary is open to receive patients and
6 caregivers.

7 (3) If a dispensary has more than one location:

8 (i) A physician assistant or certified registered
9 nurse practitioner may verify patient certifications and
10 consult with patients and caregivers, either in person or
11 by synchronous interaction, at each of the other
12 locations in lieu of the physician or pharmacist.

13 (ii) The dispensary shall maintain a minimum of a
14 one-to-one medical professional-to-location ratio except
15 for brief periods of time that may include lunch breaks,
16 bathroom breaks, unexpected emergencies and unexpected
17 time off, during which the dispensary is permitted to
18 have a medical professional cover no more than two
19 locations at one time, and the dispensary may be required
20 to show a documented customer service process that
21 prevents excessive wait times for patient consultation.
22 For purposes of this subparagraph, the term "medical
23 professional" shall mean a physician, pharmacist,
24 physician assistant or certified registered nurse
25 practitioner.

26 (4) A physician, pharmacist, physician assistant,
27 certified registered nurse practitioner, pharmacy
28 technician, certified medical assistant or certified
29 nurse aide shall, prior to assuming duties under this
30 subsection, successfully complete the course established

1 in section 301(a)(6).

2 (5) A physician may not issue a certification to
3 authorize patients to receive medical marijuana or
4 otherwise treat patients at the dispensary.

5 * * *

6 (d) Limitations.--No dispensary may dispense to a patient or
7 caregiver:

8 (1) a quantity of medical marijuana greater than [that
9 which the patient or caregiver is permitted to possess under
10 the certification] a 90-day supply of individual doses; or

11 (2) a form of medical marijuana prohibited by this act.

12 [(e) Supply.--When dispensing medical marijuana to a patient
13 or caregiver, the dispensary may not dispense an amount greater
14 than a 90-day supply until the patient has exhausted all but a
15 seven-day supply provided pursuant to a previously issued
16 certification until additional certification is presented under
17 section 405.]

18 (f) Verification.--Prior to dispensing medical marijuana to
19 a patient or caregiver, the dispensary shall verify any
20 discrepancy of the information in [subsections (e) and]
21 subsection (g) by consulting or receiving communication to the
22 dispensary tracking system under section 701(a)(2) which
23 connects to the electronic tracking system included in the
24 department's electronic database established under section
25 301(a)(4)(v) [and the dispensary tracking system under section
26 701(a)(2)].

27 * * *

28 (h) Safety insert.--When a dispensary dispenses medical
29 marijuana to a patient or caregiver for the first time, the
30 dispensary shall provide to that patient or caregiver, as

1 appropriate, a safety insert and the insert shall be available
2 to a patient upon request at any subsequent visit. The insert
3 shall be developed and approved by the department. The insert
4 shall provide the following information:

5 * * *

6 Section 802. Facility requirements.

7 (a) General rule.--

8 (1) A dispensary may dispense medical marijuana in an
9 indoor, enclosed, secure facility located within this
10 Commonwealth or in accordance with a curbside delivery
11 protocol as determined by the department.

12 (1.1) For the purposes of paragraph (1), a dispensary
13 shall maintain continuous video surveillance. If the
14 dispensary has more than one location, continuous video
15 surveillance may be performed on-site at the dispensary
16 location or remotely from a centralized security location if
17 the dispensary has a protocol and communication channel for
18 the centralized security location to communicate with each
19 dispensary location. The dispensary is required to retain the
20 recordings onsite or offsite for a period of no less than
21 [180] 60 days, unless otherwise required for investigative or
22 litigation purposes.

23 (2) A dispensary may not operate on the same site as a
24 facility used for growing and processing medical marijuana.

25 (3) A dispensary may not be located within 1,000 feet of
26 the property line of a public, private or parochial school or
27 a day-care center.

28 (4) A dispensary may sell medical devices and
29 instruments which are needed to administer medical marijuana
30 and the dispensary's brand logo products under this act

1 without prior approval of the department if the dispensary
2 conforms with the advertising guidelines in section 301(a)
3 (15).

4 (5) A dispensary may sell services [approved by the
5 department] related to the use of medical marijuana.

6 * * *

7 Section 902. Medical Marijuana Program Fund.

8 * * *

9 (c) Use of proceeds.--After any repayment made under
10 subsection (d), money in the fund is appropriated in accordance
11 with the following percentages:

12 * * *

13 (3) To the department, for further research related to
14 the use of medical marijuana, including the research program
15 established under Chapter 19, 30% of the revenue in the fund.
16 Funding shall be provided for research into the treatment of
17 [those serious] medical conditions [for which medical
18 marijuana is available for treatment within this Commonwealth
19 and for research into the use of medical marijuana to treat
20 other medical conditions] for which medical marijuana may
21 have legitimate medicinal value. Money shall be used to
22 subsidize the cost of, or provide, medical marijuana to
23 patients participating in the program. However, money in the
24 fund may not be expended on activity under Chapter 20.

25 * * *

26 Section 1201. Advisory board.

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

30 * * *

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

6 (i) The Governor.

7 (ii) The President pro tempore of the Senate.

8 (iii) The Majority Leader of the Senate.

9 (iv) The Minority Leader of the Senate.

10 (v) The Speaker of the House of Representatives.

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

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

15 * * *

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

18 * * *

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

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

23 [(ii) Whether to change, add or reduce the types of
24 medical conditions which qualify as serious medical
25 conditions under this act.]

26 * * *

27 Section 1902. Establishment of medical marijuana research
28 program.

29 (a) Program to be established.--The department shall
30 establish and develop a research program to study the impact of

1 medical marijuana on the treatment and symptom management of
2 [serious] medical conditions. The program shall not include a
3 clinical registrant or academic clinical research center under
4 Chapter 20.

5 (b) Department duties.--The department shall:

6 (1) Review all [serious] medical conditions which are
7 cited by a practitioner upon the practitioner's certification
8 that a patient be granted an identification card.

9 (2) Create a database of all [serious] medical
10 conditions, including comorbidities, which are cited by
11 practitioners in the certifications of patients. The database
12 shall also include the form of medical marijuana certified to
13 treat each [serious] medical condition.

14 (3) When the database contains 25 or more patients with
15 the same [serious] medical condition, petition the United
16 States Food and Drug Administration and the United States
17 Drug Enforcement Administration for approval to study the
18 condition and the impact of medical marijuana on the
19 condition.

20 (4) Concurrent with the request to the United States
21 Food and Drug Administration and United States Drug
22 Enforcement Administration, publicly announce the formation
23 of a research study to which a vertically integrated health
24 system and a university within this Commonwealth may submit a
25 request to participate.

26 (5) Upon approval of a research study by the United
27 States Food and Drug Administration and the United States
28 Drug Enforcement Administration, select a vertically
29 integrated health system or systems to conduct the research
30 study and designate the form or forms of medical marijuana

1 which will be used to treat the [serious] medical condition.

2 (6) Notify a patient who has been issued an
3 identification card:

4 (i) that the patient has been selected to
5 participate, at the patient's option, in a research study
6 to study medical marijuana as a treatment; and

7 (ii) where the patient may secure medical marijuana
8 through a health care medical marijuana organization at
9 no cost to the patient in accordance with subsection (c).

10 (7) If the United States Food and Drug Administration
11 and the United States Drug Enforcement Administration reject
12 the proposal for the research study, take all reasonable
13 steps to collect and collate data on the [serious] medical
14 condition and the use of medical marijuana as a treatment for
15 the [serious] medical condition and consider submitting an
16 additional request to the United States Food and Drug
17 Administration and United States Drug Enforcement
18 Administration for a research study on the same condition.

19 * * *

20 Section 1903. Medical marijuana research program
21 administration.

22 (a) General rule.--The department shall establish a research
23 study for each [serious] medical condition. The department shall
24 engage universities within this Commonwealth to participate in
25 the collection, collation, analysis and conclusive findings of
26 the research studies. The department shall, by regulation,
27 establish the procedure to be used by health care medical
28 marijuana organizations with respect to:

29 (1) Real time inventory tracking.

30 (2) Real time tracking of the medical marijuana

1 dispensed.

2 (3) Recall of defective medical marijuana.

3 (b) Request for distributions.--The department shall
4 establish a form and procedure for universities selected to
5 participate in a research study to request distributions from
6 the fund to conduct research on medical marijuana, including
7 administrative costs. These distributions shall also be used to
8 pay for the cost of the medical marijuana so that it is not
9 borne by the patient participating in the research study. The
10 forms shall include, at a minimum, the following:

11 (1) The form or forms of medical marijuana to be
12 studied.

13 (2) The [serious] medical condition to be studied.

14 (c) Research reports.--

15 (1) A vertically integrated health system shall report
16 on the effectiveness of the use of medical marijuana for the
17 treatment of the [serious] medical condition studied and all
18 counterindications and noted side effects.

19 (2) The department shall notify the vertically
20 integrated health system and the university participating in
21 the research study of the data which is required to meet the
22 United States Food and Drug Administration's and the United
23 States Drug Enforcement Administration's approval for the
24 research study.

25 (3) The first report, including the data required under
26 paragraph (2), shall be submitted to the department and made
27 publicly available within 180 days of the initiation of a
28 research study for a specific [serious] medical condition.

29 (4) An annual report of the data required under
30 paragraph (2) shall be submitted to the department beginning

1 one year after the initiation of a research study for a
2 specific [serious] medical condition and each year
3 thereafter.

4 Section 1904. Approval.

5 A vertically integrated health system located in this
6 Commonwealth may petition the department to participate in a
7 research study to study a [serious] medical condition under
8 section 1903. Approval of the vertically integrated health
9 system as a health care medical marijuana organization by the
10 department shall authorize access within a region under section
11 603(d) to medical marijuana for all patients included in an
12 approved research study.

13 Section 2000. Legislative findings and declaration of policy.

14 (a) Legislative findings.--It is determined and declared as
15 a matter of legislative finding:

16 (1) Patients suffering from [serious] medical conditions
17 deserve the benefit of research conducted in conjunction with
18 the Commonwealth's medical schools to determine whether
19 medical marijuana will improve their conditions or symptoms.

20 * * *

21 Section 11. Section 2001 of the act is amended by adding a
22 definition to read:

23 Section 2001. Definitions.

24 The following words and phrases when used in this chapter
25 shall have the meanings given to them in this section unless the
26 context clearly indicates otherwise:

27 * * *

28 "Accredited medical school." An institution within this
29 Commonwealth that is accredited by the Liaison Committee of
30 Medical Education or the Commission on Osteopathic College

1 Accreditation or has gained pre-accreditation or provisional
2 accreditation so that the institution is authorized to enroll
3 students and is affiliated with an accredited institution of
4 higher education within this Commonwealth.

5 * * *

6 Section 12. Section 2002 of the act is amended by adding a
7 subsection to read:

8 Section 2002. Clinical registrants.

9 * * *

10 (c) Automatic permits.--If Federal or State law permits the
11 sale of adult use marijuana, each clinical registrant shall be
12 automatically issued permits for growing/processing and
13 dispensing, based on existing permits, of medical and adult use
14 marijuana.

15 Section 13. The act is amended by adding a section to read:
16 Section 2005. Termination of contract.

17 If an academic clinical research center does not renew or
18 terminates a contract with a clinical registrant, the clinical
19 registrant shall retain the grower/processor and dispensary
20 permits and shall be permitted to continue to operate its
21 grower/processor facility and all dispensaries if the facility
22 and dispensaries were operating for a minimum of two years prior
23 to the nonrenewal or termination of the clinical registrant's
24 contract with the academic clinical research center.

25 Section 14. Section 2109 of the act is amended by adding a
26 subsection to read:

27 Section 2109. Applicability.

28 * * *

29 (c) Required regulations.--If new temporary or permanent
30 regulations are required to implement changes made to this act,

1 the existing regulations issued by the department will remain in
2 effect until the revised regulations are issued. The department
3 shall transmit notice of the new or revised temporary or
4 permanent regulations to the Legislative Reference Bureau for
5 publication in the next available issue of the Pennsylvania
6 Bulletin within 60 days of the effective date of this
7 subsection.

8 Section 15. This act shall take effect in 30 days.