

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 2477 Session of
2018

INTRODUCED BY WATSON AND MARSICO, JUNE 11, 2018

AS AMENDED ON THIRD CONSIDERATION, IN SENATE, JUNE 21, 2018

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 academic
13 clinical research centers, further providing for chapter
14 heading, providing for legislative findings and declaration
15 of policy, further providing for definitions, providing for
16 academic clinical research centers, further providing for
17 clinical registrants and for research study and providing for
18 temporary regulations.

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

21 Section 1. Chapter 20 heading of the act of April 17, 2016
22 (P.L.84, No.16), known as the Medical Marijuana Act, is amended
23 to read:

CHAPTER 20

24
25 ACADEMIC CLINICAL RESEARCH CENTERS AND CLINICAL REGISTRANTS

26 Section 2. The act is amended by adding a section to read:

1 Section 2000. Legislative findings and declaration of policy.

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

4 (1) Patients suffering from serious medical conditions
5 deserve the ~~opportunity~~ BENEFIT OF RESEARCH CONDUCTED IN <--
6 CONJUNCTION WITH THE COMMONWEALTH'S MEDICAL SCHOOLS to
7 determine whether medical marijuana will improve their
8 conditions or symptoms.

9 (2) The Commonwealth has an interest in creating a
10 mechanism whereby the Commonwealth's medical schools and
11 hospitals can help develop research programs and studies in
12 compliance with ~~Federal law and the laws of this Commonwealth~~ <--
13 APPLICABLE LAW. <--

14 (b) Declaration of policy.--The General Assembly declares as
15 follows:

16 (1) It is the intention of the General Assembly to
17 create a mechanism whereby this Commonwealth's medical
18 schools and hospitals may provide advice to grower/processors
19 and dispensaries in the areas of patient health and safety,
20 medical applications and dispensing and management of
21 controlled substances, among other areas. It is the further
22 intention of the General Assembly to create a mechanism
23 whereby the Commonwealth may encourage research associated
24 with medical marijuana.

25 (2) It is the policy of the Commonwealth to allow, in
26 addition to the 25 grower/processors and 50 dispensaries
27 initially authorized under section 616, the operation of
28 additional grower/processors and dispensaries which will be
29 approved by the department as clinical registrants. A
30 clinical registrant is a grower/processor and a dispensary

1 which has a contractual relationship with a medical school
2 that operates or partners with a hospital to provide advice
3 about medical marijuana so that patient safety may be
4 enhanced.

5 Section 3. The definitions of "academic clinical research
6 center" and "clinical registrant" in section 2001 of the act are
7 amended to read:

8 Section 2001. Definitions.

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

12 "Academic clinical research center." An accredited medical
13 school within this Commonwealth that operates or partners with
14 an acute care hospital licensed within this Commonwealth that
15 has been approved and certified by the department to enter into
16 a contract with a clinical registrant.

17 "Clinical registrant." An entity that:

18 (1) [holds a permit as both a grower/processor and a
19 dispensary; and] is approved by the department as a clinical
20 registrant;

21 (2) has a contractual relationship with an academic
22 clinical research center under which the academic clinical
23 research center or its affiliate provides advice to the
24 entity, regarding, among other areas, patient health and
25 safety, medical applications and dispensing and management of
26 controlled substances[.]; and

27 (3) is approved by the department to hold a permit as
28 both a grower/processor and a dispensary.

29 Section 4. The act is amended by adding a section to read:

30 Section 2001.1. Academic clinical research centers.

1 (a) General rule.--An academic clinical research center must
2 be approved and certified by the department before the academic
3 clinical research center may contract with a clinical
4 registrant. The accredited medical school that is seeking
5 approval AND CERTIFICATION from the department ~~to be certified~~ <--
6 as an academic clinical research center must provide all
7 information required by the department, including information
8 for the individual who will be the primary contact for the
9 academic clinical research center during the department's review
10 of the application. The accredited medical school must also
11 provide all information required by the department for any
12 licensed acute care hospital that the accredited medical school
13 will operate or partner with during the time that it may be
14 approved and certified as an academic clinical research center
15 by the department.

16 (b) Posting and publication of list.--The department shall
17 post a list containing the name and address of each certified
18 academic clinical research center on the department's publicly
19 accessible Internet website and publish the list in the
20 Pennsylvania Bulletin.

21 Section 5. Sections 2002 and 2003 of the act are amended to
22 read:

23 Section 2002. Clinical registrants.

24 [Notwithstanding the limitations in section 616, the] (a)
25 Approval.--The department may [register] approve up to eight
26 clinical registrants. Each [entity] clinical registrant may
27 provide medical marijuana at not more than six separate
28 locations. The total number of locations authorized to dispense
29 medical marijuana under this section shall not exceed 48. [The
30 following apply with respect to this category of clinical

1 registrant:

2 (1) A] The grower/processor and dispensary permits
3 issued to clinical registrants approved under this section
4 shall be in addition to the 25 grower/processor and 50
5 dispensary permits issued by the department in accordance
6 with section 616(1) and (2). The limitations relating to
7 number and location in sections 616(1) and (2) and 603(d) do
8 not apply. A clinical registrant may not hold more than one
9 grower/processor and one dispensary permit. Once the
10 department approves the entity as a clinical registrant, the
11 entity shall comply with this chapter.

12 (b) Requirements.--The following shall apply to clinical
13 registrants:

14 (1) An entity seeking approval as a clinical registrant
15 shall submit an application to the department in such form
16 and manner as the department prescribes. The department shall
17 ensure that the applicant meets the requirements of this act
18 before approving the application to become a clinical
19 registrant.

20 (2) An entity may be issued a permit as a
21 grower/processor or dispensary before seeking approval as a
22 clinical registrant. An entity may also apply to be issued <--
23 FOR a permit as a grower/processor or a dispensary at the <--
24 same time the entity seeks approval from the department as a
25 clinical registrant.

26 (3) AN ENTITY SEEKING APPROVAL AS A CLINICAL REGISTRANT <--
27 THAT DOES NOT ALREADY HOLD A PERMIT AS A GROWER/PROCESSOR OR
28 A DISPENSARY SHALL SUBMIT THE APPLICATIONS REQUIRED UNDER
29 CHAPTER 6. IN REVIEWING AN APPLICATION, THE DEPARTMENT SHALL
30 ENSURE THAT THE ENTITY MEETS ALL OF THE REQUIREMENTS FOR THE

1 ISSUANCE OF A GROWER/PROCESSOR PERMIT OR A DISPENSARY PERMIT,
2 AS APPLICABLE.

3 ~~(3)~~ (4) When the department issues a permit as a <--
4 grower/processor or a dispensary to an entity seeking
5 approval as a clinical registrant, the issuance shall not be
6 construed to reduce the number of permits for
7 growers/processors and dispensaries authorized under section
8 616(1) and (2).

9 ~~(4)~~ (5) Except as provided in section 607(1)(vi) and (2) <--
10 (vi), AN ENTITY SEEKING APPROVAL AS a clinical registrant <--
11 must pay the fees and meet all other requirements under this
12 act for obtaining a permit as a grower/processor and a
13 dispensary.], except as provided under section 607(1)(vi) and <--
14 (2)(vi).

15 (2)] ~~The department shall ensure that a clinical~~ <--
16 ~~registrant meets all of the other requirements to hold a~~
17 ~~permit as a grower/processor and dispensary under Chapter~~
18 ~~6.~~ Upon approval of the department, a clinical registrant
19 shall be issued a grower/processor permit and a dispensary
20 permit and shall be a medical marijuana organization. As a
21 medical marijuana organization, a clinical registrant must
22 comply with all the provisions of this act relating to
23 medical marijuana organizations except as otherwise provided
24 in this chapter.

25 ~~(5)~~ (6) The clinical registrant must have a minimum of <--
26 \$15,000,000 in capital. The department shall verify the
27 capital requirement.

28 [(3)] ~~(6)~~ (7) The clinical registrant must comply with <--
29 all other requirements of this act regarding growing,
30 processing and dispensing medical marijuana. ~~This paragraph~~ <--

~~includes complying with sections 303(b)(1) and 616(6) and (7). A clinical registrant may not make a patient's participation in a research study or program a condition for dispensing medical marijuana under section 303(b)(1).~~

(8) A GROWER/PROCESSOR FACILITY OWNED BY A CLINICAL REGISTRANT MAY SELL ITS MEDICAL MARIJUANA PRODUCTS ONLY TO THE CLINICAL REGISTRANT'S DISPENSARY FACILITIES AND THE DISPENSARY FACILITIES OF OTHER CLINICAL REGISTRANTS. THE FACILITY MAY SELL SEEDS ~~AND~~, MEDICAL MARIJUANA PLANTS AND MEDICAL MARIJUANA PRODUCTS TO, OR EXCHANGE SEEDS ~~AND~~, MEDICAL MARIJUANA PLANTS AND MEDICAL MARIJUANA PRODUCTS WITH, ANY OTHER GROWER/PROCESSOR FACILITY HOLDING A PERMIT UNDER CHAPTER 6 OR THIS CHAPTER.

(9) A CLINICAL REGISTRANT MAY PETITION THE DEPARTMENT, ON A FORM PRESCRIBED BY THE DEPARTMENT, FOR APPROVAL TO SELL CERTAIN OF THE MEDICAL MARIJUANA PRODUCTS GROWN AND PROCESSED BY ITS GROWER/PROCESSOR FACILITY TO OTHER MEDICAL MARIJUANA ORGANIZATIONS HOLDING DISPENSARY PERMITS UNDER CHAPTER 6. THE PETITION MUST BE ACCOMPANIED BY A WRITTEN REPORT OF THE CLINICAL REGISTRANT'S RESEARCH FINDINGS WITH RESPECT TO THE MEDICAL MARIJUANA PRODUCTS WHICH ARE THE SUBJECT OF THE PETITION. THE DEPARTMENT SHALL APPROVE THE PETITION IF IT HAS BEEN DEMONSTRATED THAT THE MEDICAL MARIJUANA PRODUCTS HAVE A PRACTICAL EFFECT ON PATIENTS WHICH CHANGES A RECOMMENDATION WITHIN THE MEDICAL FIELD AS INDICATED IN THE REPORT SUBMITTED BY THE CLINICAL REGISTRANT.

(10) A DISPENSARY OWNED BY A CLINICAL REGISTRANT MAY DISPENSE MEDICAL MARIJUANA PRODUCTS TO A PATIENT OR CAREGIVER WHO PRESENTS A VALID IDENTIFICATION CARD TO AN EMPLOYEE WHO IS AUTHORIZED TO DISPENSE MEDICAL MARIJUANA PRODUCTS AT A

1 DISPENSARY LOCATION OPERATED BY THE CLINICAL REGISTRANT,
2 REGARDLESS OF WHETHER THE PATIENT IS A PARTICIPANT IN A
3 RESEARCH STUDY OR PROGRAM.

4 Section 2003. Research study.

5 [Notwithstanding any provision of this act to the contrary,
6 the] (a) Applicability.--The provisions of this section shall
7 apply upon publication of the notice under section 2108.

8 (b) Procedures.--The department may, upon application,
9 approve the dispensing of medical marijuana by a clinical
10 registrant to the academic clinical research center for the
11 purpose of conducting a research study. The department shall
12 develop the application and standards for approval of such
13 dispensing by the clinical registrant. The following apply to
14 the research study:

15 (1) The clinical registrant shall disclose the following
16 information to the department in its application:

17 (i) The reason for the research project, including
18 the reason for the trial.

19 (ii) The strain and strength of medical marijuana to
20 be used [and the strength of the medical marijuana to be
21 used] in the research study.

22 (iii) The anticipated duration of the study.

23 (iv) Evidence of approval of the trial by an
24 accredited institutional review board[, including] and
25 any other required regulatory approvals.

26 (v) Other information required by the department,
27 except that the department may not require disclosure of
28 any information that would infringe upon the academic
29 clinical research center's exclusive right to
30 intellectual property or legal obligations for patient

1 confidentiality.

2 (2) The academic clinical research center shall provide
3 its findings to the department within 365 days of the
4 conclusion of the research study or within 365 days of
5 publication of the results of the research study in a peer-
6 reviewed medical journal, whichever is later.

7 (3) The department shall allow the exchange of medical
8 marijuana seed between clinical registrants for the conduct
9 of research.

10 Section 6. The act is amended by adding a section to read:
11 Section 2004. Temporary regulations.

12 (a) Promulgation.--In order to facilitate the prompt
13 implementation of this chapter, the department shall promulgate
14 temporary regulations that shall expire not later than two years
15 following the publication of the temporary regulations. The
16 temporary regulations shall not be subject to:

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

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

22 (3) Sections 204(b) and 301(10) of the act of October
23 15, 1980 (P.L.950, No.164), known as the Commonwealth
24 Attorneys Act.

25 (b) Expiration.--The department's authority to adopt
26 temporary regulations under subsection (a) shall expire six
27 months after the effective date of this section. Regulations
28 adopted after this period shall be promulgated as provided by
29 law.

30 (c) Publication.--The department shall begin publishing

1 temporary regulations in the Pennsylvania Bulletin no later than
2 90 days after the effective date of this section.
3 Section 7. This act shall take effect immediately.