

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 2477 Session of
2018

INTRODUCED BY WATSON AND MARSICO, JUNE 11, 2018

REFERRED TO COMMITTEE ON CHILDREN AND YOUTH, JUNE 11, 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:

24 CHAPTER 20

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 to determine whether medical
6 marijuana will improve their conditions or symptoms.

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

12 (b) Declaration of policy.--The General Assembly declares as
13 follows:

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

23 (2) It is the policy of the Commonwealth to allow, in
24 addition to the 25 grower/processors and 50 dispensaries
25 initially authorized under section 616, the operation of
26 additional grower/processors and dispensaries which will be
27 approved by the department as clinical registrants. A
28 clinical registrant is a grower/processor and a dispensary
29 which has a contractual relationship with a medical school
30 that operates or partners with a hospital to provide advice

1 about medical marijuana so that patient safety may be
2 enhanced.

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

6 Section 2001. Definitions.

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

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

15 "Clinical registrant." An entity that:

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

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

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

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

28 Section 2001.1. Academic clinical research centers.

29 (a) General rule.--An academic clinical research center must
30 be approved and certified by the department before the academic

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

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

18 Section 5. Sections 2002 and 2003 of the act are amended to
19 read:

20 Section 2002. Clinical registrants.

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

29 (1) A] The grower/processor and dispensary permits
30 issued to clinical registrants approved under this section

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

9 (b) Requirements.--The following shall apply to clinical
10 registrants:

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

17 (2) An entity may be issued a permit as a
18 grower/processor or dispensary before seeking approval as a
19 clinical registrant. An entity may also apply to be issued a
20 permit as a grower/processor or a dispensary at the same time
21 the entity seeks approval from the department as a clinical
22 registrant.

23 (3) When the department issues a permit as a
24 grower/processor or a dispensary to an entity seeking
25 approval as a clinical registrant, the issuance shall not be
26 construed to reduce the number of permits for
27 growers/processors and dispensaries authorized under section
28 616(1) and (2).

29 (4) Except as provided in section 607(1)(vi) and (2)
30 (vi), a clinical registrant must pay the fees and meet all

1 other requirements under this act for obtaining a permit as a
2 grower/processor and a dispensary[, except as provided under
3 section 607(1) (vi) and (2) (vi).]

4 (2)]. The department shall ensure that a clinical
5 registrant meets all of the other requirements to hold a
6 permit as a grower/processor and dispensary under Chapter
7 6. Upon approval of the department, a clinical registrant
8 shall be issued a grower/processor permit and a dispensary
9 permit and shall be a medical marijuana organization. As a
10 medical marijuana organization, a clinical registrant must
11 comply with all the provisions of this act relating to
12 medical marijuana organizations except as otherwise provided
13 in this chapter.

14 (5) The clinical registrant must have a minimum of
15 \$15,000,000 in capital. The department shall verify the
16 capital requirement.

17 [(3)] (6) The clinical registrant must comply with all
18 other requirements of this act regarding growing, processing
19 and dispensing medical marijuana. This paragraph includes
20 complying with sections 303(b)(1) and 616(6) and (7). A
21 clinical registrant may not make a patient's participation in
22 a research study or program a condition for dispensing
23 medical marijuana under section 303(b)(1).

24 Section 2003. Research study.

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

28 (b) Procedures.--The department may, upon application,
29 approve the dispensing of medical marijuana by a clinical
30 registrant to the academic clinical research center for the

1 purpose of conducting a research study. The department shall
2 develop the application and standards for approval of such
3 dispensing by the clinical registrant. The following apply to
4 the research study:

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

7 (i) The reason for the research project, including
8 the reason for the trial.

9 (ii) The strain and strength of medical marijuana to
10 be used [and the strength of the medical marijuana to be
11 used] in the research study.

12 (iii) The anticipated duration of the study.

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

16 (v) Other information required by the department,
17 except that the department may not require disclosure of
18 any information that would infringe upon the academic
19 clinical research center's exclusive right to
20 intellectual property or legal obligations for patient
21 confidentiality.

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

27 (3) The department shall allow the exchange of medical
28 marijuana seed between clinical registrants for the conduct
29 of research.

30 Section 6. The act is amended by adding a section to read:

1 Section 2004. Temporary regulations.

2 (a) Promulgation.--In order to facilitate the prompt
3 implementation of this chapter, the department shall promulgate
4 temporary regulations that shall expire not later than two years
5 following the publication of the temporary regulations. The
6 temporary regulations shall not be subject to:

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

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

12 (3) Sections 204(b) and 301(10) of the act of October
13 15, 1980 (P.L.950, No.164), known as the Commonwealth
14 Attorneys Act.

15 (b) Expiration.--The department's authority to adopt
16 temporary regulations under subsection (a) shall expire six
17 months after the effective date of this section. Regulations
18 adopted after this period shall be promulgated as provided by
19 law.

20 (c) Publication.--The department shall begin publishing
21 temporary regulations in the Pennsylvania Bulletin no later than
22 90 days after the effective date of this section.

23 Section 7. This act shall take effect immediately.