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:
Section 2000. Legislative findings and declaration of policy.

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

(1) Patients suffering from serious medical conditions deserve the opportunity to determine whether medical marijuana will improve their conditions or symptoms.

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

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

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

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

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


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

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

"Clinical registrant." An entity that:

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

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

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

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

Section 2001.1. Academic clinical research centers.

(a) General rule.--An academic clinical research center must
be approved and certified by the department before the academic.
clinical research center may contract with a clinical registrant. The accredited medical school that is seeking approval from the department to be certified as an academic clinical research center must provide all information required by the department, including information for the individual who will be the primary contact for the academic clinical research center during the department's review of the application. The accredited medical school must also provide all information required by the department for any licensed acute care hospital that the accredited medical school will operate or partner with during the time that it may be approved and certified as an academic clinical research center by the department.

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

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


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

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

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

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

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

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

(4) Except as provided in section 607(1)(vi) and (2)
(vi), a clinical registrant must pay the fees and meet all
other requirements under this act for obtaining a permit as a
grower/processor and a dispensary[, except as provided under
section 607(1)(vi) and (2)(vi).

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

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

[(3)] (6) The clinical registrant must comply with all
other requirements of this act regarding growing, 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).


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

(b) Procedures.--The department may, upon application,
approve the dispensing of medical marijuana by a clinical
registrant to the academic clinical research center for the
20180HB2477PN3658 - 6 -
purpose of conducting a research study. The department shall
develop the application and standards for approval of such
dispensing by the clinical registrant. The following apply to
the research study:

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

   (i) The reason for the research project, including
   the reason for the trial.
   (ii) The strain and strength of medical marijuana to
   be used [and the strength of the medical marijuana to be
   used] in the research study.
   (iii) The anticipated duration of the study.
   (iv) Evidence of approval of the trial by an
   accredited institutional review board[, including] and
   any other required regulatory approvals.
   (v) Other information required by the department,
   except that the department may not require disclosure of
   any information that would infringe upon the academic
   clinical research center's exclusive right to
   intellectual property or legal obligations for patient
   confidentiality.

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

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

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

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


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

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

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

Section 7. This act shall take effect immediately.