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THE GENERAL ASSEMBLY OF PENNSYLVANIA

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HOUSE BILL

No. 2477 Session of  
2018

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INTRODUCED BY WATSON AND MARSICO, JUNE 11, 2018

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REFERRED TO COMMITTEE ON CHILDREN AND YOUTH, JUNE 11, 2018

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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.