SENATE AMENDED

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THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 2477 Session of 2018

INTRODUCED BY WATSON AND MARSICO, JUNE 11, 2018

SENATOR FOLMER, STATE GOVERNMENT, IN SENATE, AS AMENDED, JUNE 20, 2018

AN ACT

Amending the act of April 17, 2016 (P.L.84, No.16), entitled "An act establishing a medical marijuana program; providing for patient and caregiver certification and for medical marijuana organization registration; imposing duties on the Department of Health; providing for a tax on medical marijuana organization gross receipts; establishing the Medical Marijuana Program Fund; establishing the Medical Marijuana Advisory Board; establishing a medical marijuana research program; imposing duties on the Department of Corrections, the Department of Education and the Department of Human Services; and providing for academic clinical research centers and for penalties and enforcement," in academic clinical research centers, further providing for chapter heading, providing for legislative findings and declaration of policy, further providing for definitions, providing for academic clinical research centers, further providing for clinical registrants and for research study and providing for temporary regulations.

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

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

CHAPTER 20

ACADEMIC CLINICAL RESEARCH CENTERS <u>AND CLINICAL REGISTRANTS</u>

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~~ BENEFIT OF RESEARCH CONDUCTED IN CONJUNCTION WITH THE COMMONWEALTH'S MEDICAL SCHOOLS 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~~ APPLICABLE LAW. <--

(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:

Section 2001. Definitions.

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 AND CERTIFICATION 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:

Section 2002. Clinical registrants.

[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~~ FOR 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) AN ENTITY SEEKING APPROVAL AS A CLINICAL REGISTRANT THAT DOES NOT ALREADY HOLD A PERMIT AS A GROWER/PROCESSOR OR A DISPENSARY SHALL SUBMIT THE APPLICATIONS REQUIRED UNDER CHAPTER 6. IN REVIEWING AN APPLICATION, THE DEPARTMENT SHALL <--

ENSURE THAT THE ENTITY MEETS ALL OF THE REQUIREMENTS FOR THE ISSUANCE OF A GROWER/PROCESSOR PERMIT OR A DISPENSARY PERMIT, AS APPLICABLE.

~~(3)~~ (4) 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)~~ (5) Except as provided in section 607(1)(vi) and (2)(vi), AN ENTITY SEEKING APPROVAL AS 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)~~ (6) The clinical registrant must have a minimum of $15,000,000 in capital. The department shall verify the capital requirement. <--

[(3)] ~~(6)~~ (7) 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).~~ <--

(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 TO, OR EXCHANGE SEEDS AND MEDICAL MARIJUANA PLANTS 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

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

Section 2003. Research study.

[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 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:

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

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

(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.