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Medical Marijuana - Act 16 of 2016

Act 16 of 2016 creates a stand-alone act entitled the Medical Marijuana Act and establishes a program for the use of medical marijuana (MM) to be administered by the Department of Health (DOH).

SUMMARY: This legislation establishes a program for use of medical marijuana by patients with a “serious medical condition” which is defined as any of the following conditions: cancer; HIV/AIDS; amyotrophic lateral sclerosis (ALS); Parkinson’s disease; multiple sclerosis (MS); damage to the nervous tissue of the spinal cord with objective neurological indication of intractable spasticity; epilepsy; inflammatory bowel disease (IBD); neuropathies; Huntington’s disease; Crohn’s disease; post-traumatic stress disorder (PTSD); intractable seizures; glaucoma; sickle cell anemia; autism; and severe chronic or intractable pain of neuropathic origin or severe or intractable pain in which conventional therapeutic intervention and opiate therapy is contraindicated or ineffective.

The Act provides that DOH register two types of MM organizations: a grower/processor and a dispensary. Any of the following are permitted to become registered as either a grower/processor or a dispensary: an individual; a corporation; a partnership; an association; a trust; or other entity.

This legislation creates an advisory board within DOH, composed of fifteen members, seven permanent members and eight appointed by the Governor and legislative leaders in the House and Senate. The appointed members shall be knowledgeable about and have experience with issues relating to the care and treatment of individuals with serious medical conditions, geriatric or pediatric medicine or clinical research.

The permanent members are the: Secretary of Health; Commissioner of the Pennsylvania State Police (PSP); **Chairman of the State Board of Pharmacy**; Commissioner of the Bureau of the Professional and Occupational Affairs; Physician General; President of the PA Chiefs of Police Association; and President of the PA District Attorneys Association, or a designee from each department.

The board is given the task of reviewing Commonwealth law regarding MM, the experience in other states with respect to MM, and correspondence from individuals and organizations regarding MM. Two years after the MM program commences, the advisory board must submit a written report to the General Assembly and the Governor. That report must include recommendations with respect to the following areas:

- An assessment of the use of medical marijuana as a result of the enactment of this Act;
- An assessment of the benefits and risks to patients using medical marijuana under this Act, including adverse events;
- Recommendations for amendments to this Act for reasons of patient safety or to aid the general welfare of the citizens of this commonwealth;
- Whether to change the types of medical professionals who can certify patients to use MM;
- Whether to change, add to or reduce the types of medical conditions which qualify as “serious medical conditions”;
- Whether to change, add to or reduce the form and manner of consumption of MM permitted;

- Whether to change, add to or reduce the number of growers/processors or dispensaries;
- How to ensure affordable patient access to MM;
- Whether to permit MM to be dispensed in dry leaf or plant form, for administration by vaporization.

The Act gives DOH the authority to promulgate regulations to implement the recommendations of the advisory board, at the discretion of the secretary. Such regulations must be promulgated within 12 months of the acceptance of the report. The secretary must state in a notice to be published in the Pennsylvania Bulletin which recommendations will lead to regulations and the reasons why a particular recommendation was included or omitted. The legislation provides that DOH implement procedures for:

- Establishment of an electronic database to include activities and information relating to medical marijuana organizations, certifications, identification cards, practitioner registration and electronic tracking of all medical marijuana grown or sold. The electronic data base must permit use by dispensaries and the Department to ensure that MM is not diverted or otherwise used for an unlawful purpose;
- Issuance of identification cards to patients and caregivers;
- Review and approval of certifications for patients to use MM submitted by practitioners;
- Review and approval of applications to become growers/processors and dispensaries;
- Establishment of announced and unannounced inspections of growers/processors and dispensaries;
- Establishment of a four-hour course for practitioners regarding the latest scientific research on MM and establishment of a two-hour class for employees of growers/processors and dispensaries who come into contact with patients or who physically handle MM;
- Establishment of a dedicated telephone number and website regarding MM so that patients, caregivers and members of the public may obtain basic information about MM and the Act;
- Establishment of a manner and method to administer research studies of MM conducted by hospitals and universities within the Commonwealth.

Practitioner registration:

A doctor of medicine or a doctor of osteopathy may apply to DOH to become registered as a “practitioner.” A practitioner may certify patients to use MM. In order to become registered, DOH must determine that the physician is qualified by training or experience to treat the patient’s serious medical condition. The physician must also complete the four-hour course established by DOH. Before certifying a physician, DOH must check the information held by the Department of State to ensure the physician is the holder of an unexpired, unsuspended, and unrevoked Pennsylvania license to practice medicine.

The four hour course established by the DOH regarding the latest scientific research on medical marijuana, including the risks and benefits of medical marijuana, and other information deemed necessary by the department will also be available to pharmacists, certified nurse practitioners and physician assistants in addition to physicians. Successful completion of the course shall be approved as continuing education credits by the appropriate state board.

Patient certification:

A practitioner may issue a certification to a patient if the: practitioner is authorized to issue a certification as evidence by inclusion in the registry maintained by DOH; patient has a serious medical condition and the practitioner has included the condition in the patient’s healthcare record; patient is under the practitioner’s continuing care for the serious medical condition; practitioner determines that, in their professional opinion, the patient is likely to receive therapeutic or palliative benefit from use of MM.

The practitioner must consult the statewide prescription drug monitoring database prior to issuing or modifying a certification. The practitioner must provide a copy of the certification to the patient, to DOH for placement in the registry, and must also place a copy in the patient’s healthcare record. DOH must be able to receive

certifications in electronic form. A practitioner may not issue a certification for the practitioner's own use or for the use of a "family or household member." The term "family or household member" has the same meaning given to it under the Protection from Abuse Act.

Lawful use of MM:

The lawful use of MM is subject to the following limitations:

- MM may only be dispensed to a patient who is certified by a practitioner, or a caregiver, who is in possession of a valid identification card.
- Forms which are permitted are pill, oil, topical forms (gel, cream, or ointment), a form medically appropriate for administration by vaporization or nebulization, tincture, and liquid.
- For each patient, possession of MM by a patient or caregiver may not exceed a 30-day supply, except that, during the last seven-day period, a patient may possess a 30-day supply for the next 30-day period;
- No more than five patients may be under the care of a single caregiver;
- A patient may designate up to two caregivers;
- The form of MM must be in compliance with any limitation set by the practitioner;
- MM must be kept in the original package in which it was dispensed;
- A patient or caregiver shall possess an identification card whenever the patient or caregiver is in immediate possession of MM.

The legislation provides that it is unlawful to: smoke MM; sell MM products; or grow MM unless grower/processor has received a permit by the DOH. It is unlawful to incorporate MM into edible form, however, patients may incorporate MM products into food in order to aid ingestion.

Identification cards:

Upon review and approval of the certification issued to a patient by a practitioner, satisfactory review of the prescription drug monitoring program in the case of a caregiver and satisfactory review of the criminal history record information of a caregiver, DOH shall issue an identification card to a patient or caregiver. The identification card shall permit a patient or caregiver to access MM. An identification card expires within one year from the date of issuance.

Identification cards include the name of the patient or caregiver, as appropriate, date of issuance and the expiration date, identification number, and a photograph. An identification card may not include the serious medical condition of the patient.

Minors:

If a patient is under 18 years of age, the patient must have a caregiver. The caregiver must be a parent or legal guardian, a person designated by the parent or legal guardian, or an individual approved by the DOH if no parent or legal guardian is appropriate or available.

Growers/processors and dispensaries:

A grower/processor and dispensary may be an individual, a corporation, partnership, association, trust, or other entity which is registered by DOH. The grower/processor must contract with an independent laboratory to test the MM produced. DOH must approve the laboratory.

Initial permits will be granted for up to 25 growers/processors and 50 dispensaries. Each dispensary may provide MM at no more than 3 separate locations.

A grower/processor may also be a dispensary, but no more than five grower/processors can also register as a dispensary. Further, no single entity can hold more than five dispensary permits. DOH must establish at least three regions within the Commonwealth in order to ensure that the grower/processors and dispensaries are

geographically distributed across the Commonwealth. The DOH may adjust the boundaries as necessary every two years.

The dispensary may lawfully dispense MM to a patient or caregiver upon presentation of a valid identification card. The dispensary provides the patient or caregiver with a receipt regarding MM. The receipt includes: the name, address and any identification number assigned to the dispensary by the DOH, the name and address of the patient or caregiver, the date the MM was dispensed, any requirement of limitation by the practitioner as to the form of the MM, and the form and quantity of MM. A copy of the receipt is filed with DOH. No dispensary may sell a quantity of MM greater than that which the patient or caregiver is permitted to possess under the certification, or in a form or quantity prohibited by the Act. Before dispensing MM, the dispensary must consult the electronic database established by DOH in order to prevent diversion and other unlawful acts.

Principals, financial backers, employees, or volunteers of growers/processors and dispensaries may not hold positions in these organizations if they have been convicted of any criminal offense related to the sale or possession of illegal drugs, narcotics or controlled substances.

DOH registers grower/processors and dispensaries. The applicant to become a grower/processor or a dispensary must provide a description of the business activities, must submit Commonwealth and federal criminal history record information, and must show the ability to maintain effective security and control to prevent diversion. In addition, the applicant is under a continuing duty to report to DOH any change in facts or circumstances affecting the application. The applicant must report any loss or theft of MM within 24 hours to the Pennsylvania State Police (PSP) and must submit to inspections, whether announced or unannounced, by DOH.

A grower/processor may only manufacture MM in an indoor, enclosed, secure facility located within the Commonwealth.

The following applies with respect to fees:

For a grower/processor:

- Initial permit fee of \$200,000, with an initial application fee of \$10,000;
- Annual renewal fee of \$10,000.
- DOH must verify, at time of initial application, that grower/processor has \$2 million in capital, with \$500,000 on deposit.

For a dispensary:

- Initial permit fee of \$30,000 for each location, with an initial application fee of \$5,000;
- Annual renewal fee of \$5,000.
- DOH must verify, at the time of initial application, that dispensary has \$150,000 in capital, which must be on deposit.

DOH may suspend or revoke registration as a grower/processor or dispensary if:

- DOH has evidence that a grower/processor or dispensary has failed to maintain effective control against diversion;
- The grower/processor or dispensary violates any provision of the Act or regulation promulgated by DOH;
- The grower/processor or dispensary has intentionally, knowingly, recklessly or negligently failed to comply with applicable laws of the Commonwealth relating to medical marijuana.

A grower/processor and a dispensary must file reports with DOH regarding their activities. DOH must determine the information needed and the frequency of reports. Each grower/processor and dispensary is required to adopt and maintain security, real-time inventory tracking, recordkeeping, record retention and surveillance systems related to MM. DOH must specify the nature of these systems.

A dispensary must have a physician or pharmacist on duty at all times the facility is open to receive patients and caregivers. A physician, pharmacist, physician's assistant, or certified nurse practitioner shall, prior to assuming duties at the dispensary, successfully complete the four hour training course discussed earlier. If a dispensary has more than one location, a certified registered nurse practitioner or physician assistant may be on duty, as opposed to a physician or pharmacist. A physician may not certify patients or otherwise treat patients at the dispensary. The dispensary may sell medical devices and instruments needed to administer MM. In addition, the dispensary may sell services related to medical marijuana as approved by the Department.

A grower/processor or a dispensary may not be located within 1,000 feet of a school or a day care center. However, the DOH may make adjustments to this rule in order to provide access to patients.

Clinical registrant:

A clinical registrant holds a permit as both a grower/processor and a dispensary and has a contractual relationship with a hospital/medical school. The clinical registrant, upon approval of DOH, may dispense medical marijuana to the hospital/medical school in order to conduct research projects. Under the amendment, the department may register up to eight clinical registrants. Each clinical registrant may provide medical marijuana at no more than six separate locations. The clinical registrant must have at least \$15 million in capital.

Excise tax on MM and Medical Marijuana Program Fund:

An excise tax of 5% is imposed on the gross receipts from the sale of MM by a grower/processor to a dispensary. The tax shall be paid by the grower/processor and shall not be paid by dispensary or the patient or caregiver. The proceeds of the tax are to be deposited in the Medical Marijuana Program Fund. This fund is established in the State Treasury. The money from the fund and any interest accrued must be used to pay back the initial appropriation.

In addition, the money in the Medical Marijuana Program Fund is distributed as follows:

- 55% for the operations of DOH as required by the Act of which 15% must be spent on the waiver of fees for identification cards, for the cost of providing MM to those who cannot afford MM, and for the cost of providing MM to patients taking part in the research study under the Act;
- 10% for drug abuse prevention, counseling and treatment services provided by the Department of Drug and Alcohol Programs;
- 30% for research relating to the safety and use of MM, including the research component set up in the Act;
- 5% for distribution to local police departments, through the PA Commission on Crime and Delinquency.

Other financial limitations are as follows:

- The sale of MM to a patient or caregiver is exempt from sales tax;
- DOH and the Department of Revenue shall monitor the price of medical marijuana sold by a grower/processor and by a dispensary, including the per-dose price. If both the DOH and Department of Revenue determine that prices are unreasonable or excessive, a cap may be placed on the price of medical marijuana for a period of six months. Additional caps may be imposed for periods not to exceed six months. DOH may set the maximum per-dose price of each form of MM sold by a grower/processor to a dispensary.

Other duties of DOH:

DOH must submit a written report every two years to the Governor, Attorney General of the Commonwealth, leadership of the House of Representatives and Senate, and chairmen of the standing committees with oversight responsibilities in the House of Representatives and Senate regarding:

- An assessment of the use of medical marijuana as a result of this Act;
- An assessment of the benefits and risks to patients receiving MM, including adverse events;

- Recommendations regarding amendments to the Act for patient safety or to aid the general welfare of the citizens of this Commonwealth.

The Department must promulgate regulations relating to transportation of medical marijuana and other regulations necessary to implement the Act. In addition, the Department must publish temporary regulations in the Pennsylvania Bulletin within six months of passage of the Act. The temporary regulations are in effect for 2 years, at which time all subsequent rulemaking must conform to the Regulatory Review Act.

In addition, this legislation places duties on DOH to increase participation by diverse groups with respect to registering as medical marijuana organizations.

Offenses related to MM:

The Act provides a number of offenses, which are specific in nature, including:

- Criminal diversion of MM by practitioners, patients, or caregivers
- Criminal retention of MM;
- Falsification of identification card;
- Adulteration of MM.

In addition, wrongful disclosure of information relating to MM is a criminal offense. Specifically, disclosure of information by an employee, financial backer, operator, or principal of the grower/processor or dispensary, a person associated with the research programs established under the Act, or an employee of DOH is graded as a misdemeanor of the third degree if the person discloses any information required to be kept confidential under the Act.

Any violation of the Act not included in a specific criminal provision is graded as a misdemeanor of the third degree for a first offense; punishable by a fine of no more than \$5,000 or to imprisonment of no more than six months.

A second or subsequent offense is graded as a misdemeanor of the third degree, and is punishable by a fine of no more than \$10,000 or to imprisonment for no less than six months or more than one year, or both.

DOH is authorized to levy a civil penalty for a violation of the Act, a violation of a regulation, or a violation of an order issued under this Act by DOH. Specifically, DOH may assess a civil penalty of not more than \$10,000 for each violation and an additional penalty of not more than \$1,000 for each day of continuing violation.

Miscellaneous provisions:

The growth, processing, manufacturing, acquisition, transportation, sale, dispensing, distribution, possession and consumption of MM shall not be deemed a violation of the Controlled Substances, Drug, Device and Cosmetic Act (Drug Act). If a provision of the Drug Act and this Act conflict, then the provisions of this Act take precedence.

Nothing in the Act is to be construed as requiring an insurer to provide coverage for MM. **No patient, caregiver, practitioner or employee, or principal of a grower/processor or dispensary shall be subject to arrest, prosecution or penalty in any manner, or denied any right or privilege, including civil penalty or disciplinary action by a Commonwealth licensing board or commission, solely for lawful use of MM.**

The fact that a person is a patient and is acting in accordance with the Act shall not by itself be considered by a court in a custody proceeding. In determining the best interest of the child in a custody proceeding, the provisions of 23 PACS Chapter 53 (relating to custody) shall apply.

The Act does not prevent the imposition of civil or criminal penalties for undertaking a task under the influence of MM such that the Act would constitute negligence, professional malpractice or professional misconduct.

Possessing or using MM in a state or county correctional facility by inmates is prohibited. Possessing or using MM in a youth development center by inmates is prohibited. The Department of Education must promulgate regulations within 18 months of the effective date regarding use of MM by students in schools, including pre-school. The Department of Human Services (DHS) must promulgate regulations regarding possession and use of MM by a child under the care of a child-care or social service center licensed by DHS and of employees in youth development centers. The Department of Corrections must adopt a written policy regarding MM use by employees of state correctional facilities. The governing authority of a county may adopt a resolution regarding MM use by employees of county correctional facilities.

It is not a violation of the Act or of the Drug Act if a parent or guardian of a child lawfully obtains MM from another state or country to be administered to the child. This provision expires two years after commencement of the program within the Commonwealth.

Data and information collected by DOH under the Act, including copies of identification cards and copies of certifications, shall be deemed exempt from public disclosure under the Right-to-Know Law. Applications to become registered with DOH as a grower/processor or dispensary are accessible under the Right-to-Know Law.

Provisions of this Act with respect to dispensaries expire three years after Congress removes marijuana from Schedule I from the federal Controlled Substances Act.