

Pennsylvania's Medical Marijuana Act: Act 16



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Qualifying Medical Conditions



- terminal illness
- cancer
- HIV/AIDS
- amyotrophic lateral sclerosis (ALS)
- Parkinson's disease
- multiple sclerosis
- epilepsy
- inflammatory bowel disease
- neuropathies
- Huntington's disease
- Crohn's disease
- post-traumatic stress disorder (PTSD)

- intractable seizures
- glaucoma
- autism
- sickle cell anemia
- damage to the nervous tissue of the spinal cord with objective neurological indication of intractable spasticity
- severe chronic or intractable pain of neuropathic origin
- Or, if conventional therapeutic intervention and opiate therapy is contraindicated or ineffective

Certifying Physicians



A patient must be under the ongoing care of a physician who:

- registers with the Department of Health;
- completes a four-hour course;
- issues a certification during an in-person visit that states that the patient has a qualifying medical condition AND that the physician believes the patient could benefit from medical cannabis; and
- reports to the department if a patient no longer needs access to medical cannabis as a result of improved health or death.

Usage Limitations



- The only types of medical cannabis allowed initially are pills, oils, gels, creams, ointments, tinctures, liquid, and non-whole plant forms for administration through vaporization.
- Dispensaries cannot sell edibles, but medical cannabis products can be mixed into food or drinks to facilitate ingestion by a patient in a facility or residence.
- Vaporization is allowed.
- Smoking is prohibited.
- Following the issuance of the board's report, the Department of Health could promulgate a rule that would allow patients access to dry leaf cannabis.

Regulatory and Enforcement Authority: Department of Health



<ul style="list-style-type: none">• Issue permits	<ul style="list-style-type: none">• Register and monitor practitioners
<ul style="list-style-type: none">• Maintain database including the patient and practitioner directory and the tracking system	<ul style="list-style-type: none">• Promulgate regulations
<ul style="list-style-type: none">• Develop enforcement procedures, including announced and unannounced inspections	<ul style="list-style-type: none">• Develop a training course for doctors
<ul style="list-style-type: none">• Determine the minimum number and types of medical marijuana products to be produced by a grower/processor and dispensed by a dispensary	<ul style="list-style-type: none">• Develop a training course for principals and employees of marijuana organizations who will come in direct contact with patients or marijuana
<ul style="list-style-type: none">• Establish a research program	<ul style="list-style-type: none">• Develop record keeping requirements
<ul style="list-style-type: none">• Create and maintain public outreach programs	

The Advisory Board: Members



Secretary of Health	The commissioner of the Pennsylvania State Police
The chairman of the State Board of Pharmacy or a designee	The commissioner of Professional and Occupational Affairs or a designee
The Physician General	The president of the Pennsylvania Chiefs of Police Association or a designee
A patient advocated appointed by the governor	The president of the Pennsylvania District Attorneys Association
Appointees from: <ul style="list-style-type: none">• Governor• President pro tempore of the Senate• Majority Leader of the Senate• Minority Leader of the Senate• Speaker of the House• Majority Leader of the House• Minority Leader of the House	Appointees shall be knowledgeable and experienced in issues relating to care and treatment of individuals with serious medical conditions, geriatric or pediatric medicine, or clinical research.

Advisory Board Duties



- Examine and analyze the laws and regulations of Pennsylvania and other states
- Accept and review comments from the public
- Recommend whether to alter any fees for patients or businesses
- On May 17, 2018, issue a report including recommendations on:
 - Whether to change the types of medical professionals who can issue certifications;
 - Whether to change, add, or reduce the list of qualifying conditions;
 - Whether to change, add, or reduce the number of growers/processors or dispensaries;
 - How to ensure affordable patient access to medical marijuana; and
 - Whether to change the form of medical marijuana permitted under the act
 - Whether to permit medical marijuana to be dispensed in dry leaf or plant form, for administration by vaporization.

Effect of the Advisory Board Report



- The Secretary can either accept or reject the board's recommendations.

Dispensaries



<ul style="list-style-type: none">• 50 dispensary permits, which can each have three locations	<ul style="list-style-type: none">• Required assets: At the time of application, at least \$150,000 in capital, which must be on deposit with a financial institution
<ul style="list-style-type: none">• Physician or pharmacist must be on-site at all times during business hours	<ul style="list-style-type: none">• Tax: 5% on the sale of medical marijuana to a dispensary
<ul style="list-style-type: none">• If the dispensary has multiple locations, a registered nurse practitioner may be on-site instead at the additional locations	<ul style="list-style-type: none">• Maximum of five dispensary permits per person
<ul style="list-style-type: none">• Application fee: \$5,000, nonrefundable• Permit fee: \$30,000 for each location (up to three), refundable if permit is denied• Annual renewal fee: \$5,000	<ul style="list-style-type: none">• Dispensaries will be required to offer a minimum number of products and types of products, as determined by the health department

Grower/Processors



<ul style="list-style-type: none">• The department will issue 25 combined grower/processor permits	<ul style="list-style-type: none">• One grower/processor permit per person
<ul style="list-style-type: none">• Application fee: \$10,000, nonrefundable• Permit fee: \$200,000 included with the application, refunded if permit is denied• Annual renewal fee: \$10,000	<ul style="list-style-type: none">• No more than five grower/processors can also have dispensary permits; if the department adds more grower/processor licenses, no more than 20% of those permits can also have a dispensary permit
<ul style="list-style-type: none">• Required assets: At the time of application, at least \$2,000,000 in capital, of which \$500,000 must be on deposit with a financial institution	<ul style="list-style-type: none">• All principals and employees who will handle marijuana or have contact with patients must complete a two-hour course

Testing



- Grower/processors are required to contract a Department of Health-approved independent laboratory to test medical marijuana.
- The laboratory is required to provide the department testing results, including a test at harvest and a test after final processing.
- Laboratories approved by the department will have legal protections for the possession of medical marijuana.

Permit Application Process



- For all principals, financial backers, and employees:
 - names;
 - a description of roles and responsibilities;
 - fingerprints and releases necessary for background checks; and
 - information relating to any similar license, permit, or other authorization obtained in another state, including any suspensions, revocations, or disciplinary action.
- A statement that the applicant (including all financial backers, operators, employees, and principals) is of good moral character, can swiftly acquire the necessary facilities, and can maintain effective security.
- Any other requirements developed during the regulatory process.

Permit Application Process



When evaluating an application, the department will consider whether the applicant:

- has the ability and intention to effectively maintain a secure facility;
- will comply with the laws of Pennsylvania; and
- has the financial ability and expertise to operate a facility that will function in the public interest.

Limitations on Locations of Marijuana Organizations



Marijuana businesses cannot be located within 1,000 feet of a public or private school or day care center. If the department determines this is preventing adequate patient access to medical cannabis, it can waive the prohibition for a specific location.

Pennsylvania will be divided into three zones based on:

- Regional population;
- The number of patients suffering from serious medical conditions;
- The types of serious medical conditions;
- Access to public transportation; and
- Any other factor the department deems relevant.

Price Caps



- If the department finds the price of medical marijuana is preventing patient access, it can establish a maximum price for a period of six months. The department can alter the price during the six-month period if necessary.
- The department can implement the temporary price caps whenever necessary.

Reporting Requirements



Within one year of the issuance of the first permit and every three months thereafter, all businesses must submit the following information to the department:

- The amount of medical marijuana sold by grower/processors during each three-month period;
 - The price of amounts of medical marijuana sold by grower/processors as determined by the department;
 - The amount of medical marijuana purchased by each dispensary in the Commonwealth;
 - The cost of amounts of medical marijuana to each dispensary as determined by the department; and
 - The total amount and dollar value of medical marijuana sold by each dispensary in each three-month period.
- * This information will be made public on the department website.
- * All records must be kept for four years.

Reporting Requirements



Medical marijuana organizations must:

- report to the department any change in facts or circumstances reflected in the application or any newly discovered or occurring fact or circumstance which is required to be included in the application, including a change in control of the organization.
- report to law enforcement, within 24 hours, any loss or theft of medical marijuana.

Tracking Requirements



Marijuana organizations must implement an electronic inventory tracking system accessible to the department. The system shall include :

- Seed-to-sale tracking;
- A daily log of each day's beginning inventory, acquisitions, amounts purchased and sold, disbursements, disposals, and ending inventory, including prices;
- A system for recall of defective medical marijuana; and
- A system to track the plant waste and disposal, including the name and address of any disposal service.

Tracking Requirements



Marijuana organizations also must track:

- Security and surveillance;
- Recordkeeping and record retention;
- The acquisition, possession, growing, and processing of medical marijuana;
- Delivery and transportation, including amounts and method of delivery; and
- Dispensing, including amounts, pricing, and amounts collected from patients and caregivers.

Shipping Requirements



The department shall develop regulations relating to the storage and transportation, such as:

- The manner in which trucks, vans, trailers, or other carriers will be secured;
- Security systems that include a numbered seal on the trailer;
- Obtaining copies of drivers' licenses and registrations and other information related to security and tracking;
- Use of GPS systems;
- Number of drivers or other security required to ensure against storage or in-transit losses;
- Recordkeeping for delivery and receipt of medical marijuana products; and
- Requirements to utilize any electronic tracking system required by the department.

Implementation Timeline



On May 17, 2016, Act 16 went into effect:

- Temporary certifications
- June-August: temporary regulations for grower/processors
- September-November: temporary regulations for practitioners
- December-February: temporary regulations for dispensaries

On May 17, 2018:

- Advisory board releases report
- DOH promulgates permanent regulations

Sunset Provision



All provisions related to dispensaries will expire three years after federal law removes marijuana from Schedule I of the Controlled Substances Act (if this even ever occurs).



Thank you, Philly, and good night!



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