Final Report

As prepared, presented, and adopted by
The Pennsylvania Medical Marijuana Advisory Board

April 9, 2018

Pennsylvania Medical Marijuana Advisory Board
Final Report

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Introduction

This document, the official report of the Commonwealth of Pennsylvania Medical Marijuana Advisory Board (Board), serves to comply with the requirements of Act 16 of 2016, Chapter 12 (35 P.S. §§ 10231.1201-10231.1202), which defines the responsibilities and duties of the Board. Specifically, the Board was charged with the responsibility of issuing a written report to the Governor, Senate and House of Representatives within two years of the effective date of the section establishing the Board. The report has been formulated through a collaborative effort involving all fifteen (15) members.

In addition to monthly meetings, members participated in three work groups focused on regulatory, medical and patient/caregiver issues. Work groups explored a wide range of issues including, but not limited to, the five board "duties" detailed within Chapter 12 of Act 16 of 2016. A fourth work group was established to collate the various recommendations from each of the work groups into the final document. Multiple board meetings were held to provide a forum for open discussion concerning the recommendations of each work group as a foundation for arriving at the consensus-based recommendations that comprise this report.

This report includes specific recommendations and, where appropriate, the rationale for those recommendations. Prior to its formal adoption, the overall report and its specific recommendations were presented and discussed at an open Board meeting on April 9, 2018. The report that follows is the result of the overall process utilized by the Board in order to comply with the directives detailed within Act 16 of 2016, Chapter 12.

The Pennsylvania Medical Marijuana Program and Recommendations

I. ACT 16

A History of Medical Marijuana and Act 16 in Pennsylvania

Pennsylvania has a long history with marijuana dating back to when William Penn first founded the commonwealth in 1619. From the very early days, Penn specifically intended for farmers to grow hemp here; in fact, one of the first laws passed under the General Assembly in 1683 encouraged farmers to grow hemp. In the next two years, Pennsylvania produced large amounts of the plant, which Penn noted would be among the four staples of trade. By 1729, the mass production of hemp created the capitol of hemp, Hempfield Township in Lancaster County. The township is named for the "vast quantities of hemp raised there," which continued in the commonwealth well into the late 1930s when the perception of the drug began to change with the "Reefer Madness" scare.

Encouraged by this propaganda film, Governor Gifford Pinchot signed a law banning marijuana in Pennsylvania in 1933. Many farmers continued to grow hemp, though, because their farms had grown the plant for years, and at that time, there was no way to distinguish between "industrial hemp" and cannabis. For this reason, many farmers were arrested for continuing to grow their hemp plants. The perception of marijuana changed again when many local governments began approving measures to reduce these marijuana penalties. These marijuana laws are continuing to change.

The term "medical marijuana" is a defined term under the Act 16, meaning marijuana for certified medical use as permitted by that Act. The whole unprocessed marijuana plant or its basic extracts are used to treat a disease or symptom. The marijuana plant contains chemicals that may help treat a range of illnesses or symptoms, prompting a growing number of states – including Pennsylvania – to legalize marijuana for medical use. Studies have shown that medical marijuana can assist patients suffering from serious medical conditions by alleviating pain and improving their quality of life.

The movement toward medical marijuana legislation in Pennsylvania began prior to 2009. The first bill to be presented to the general assembly regarding medical marijuana, House Bill 1393, occurred on April 30, 2009 by Democratic Representative Mark Cohen from Philadelphia[1]. The goal was to allow medical use of marijuana and repeal provisions of law that prohibit and penalize marijuana use. This bill was referred to Health and Human Services on the same date it was presented but did not go any further. Since then, there have been a total of eight bills regarding the use of medical marijuana prior to the passage of Act 16 of 2016 (Senate Bill 3) in April 2016.

[1] Pennsylvania General Assembly. 2009. Regular Session 2009-2010 House Bill 1393. Retrieved from http://www.legis.state.pa.us/cfdocs/billinfo/billinfo.cfm?syear=2009&sind=0&body=H&type=B&bn=1393

Senate Bill 1182, in 2014, had the most impact prior to Senate Bill 3. It passed the Senate in a 43-7 vote and laid the groundwork for future victories. Though it passed the Senate, it did not make it past the Judiciary Committee in the House[2].

Various groups, individuals and advocates continued in their efforts to promote legislation on behalf of adult and minor patients. It was their steadfast belief that these patients could obtain relief from their illnesses through the use of medical marijuana.

Senate Bill 3 reintroduced the use of medical marijuana in the Commonwealth of Pennsylvania. The Senate had first approved the bill on May 12, 2015, and it was subsequently revised and approved by the House on March 14-16, 2016. The Senate made technical changes to the bill and sent it back to the House on April 12, and it received final approval in the House on April 13, 2016[3]. On April 17, 2016, Governor Tom Wolf signed into law Senate Bill 3, Pennsylvania's Medical Marijuana Act, making Pennsylvania the 24th state to legalize the use of medical marijuana. The bill went into effect thirty days later on May 17, 2016.

Pennsylvania's Medical Marijuana Act, Act 16 established a medical marijuana program, imposing duties on the Department of Health. Act 16 regulates patient and caregiver participation and for medical marijuana organization registration, provides for a tax on grower/processor gross receipts, and established the Medical Marijuana Program Fund. It further established the Medical Marijuana Advisory Board, a medical marijuana research program, and academic clinical research centers. It also regulates laboratories testing medical marijuana and provides for penalties and enforcement for violations of the Act's provisions.

II. Current Status of Pennsylvania's Medical Marijuana Program

The Commonwealth of Pennsylvania's Medical Marijuana Law was signed into law on April 17, 2016, and it is overseen and managed by the Pennsylvania Department of Health (Department).

On July 25, 2017, the Department began registering physicians for the Medical Marijuana Program. As of April 6, 2018, 511 physicians have registered and have been approved to authorize Medical Marijuana for qualifying patients.

On November 1, 2017, the Department opened the patient and caregiver registry. A person eligible for medical marijuana in Pennsylvania may have up to two caregivers, and each caregiver may have up to five patients. As of April 6, 2018, there were 2,495 caregivers and 28,508 patients registered for the Pennsylvania Medical Marijuana program. A Medical Marijuana Identification Card issued by the Department costs $50.00, and is valid for the amount of time authorized by an approved practitioner, up to a maximum of 1 year. Currently 10,002 Medical Marijuana Identification cards have been issued to patients.

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[2] PennLive. (13 Apr 2016). How medical marijuana came to Pennsylvania: A long arduous path. Pennsylvania Politics. Retrieved from http://www.pennlive.com/politics/index.ssf/2016/04/how_medical_marijuana_came_to.html

[3] Marijuana Policy Project. (2018). Summary of Pennsylvania's Medical Marijuana Act. Retrieved from https://www.mpp.org/states/pennsylvania/summary-sb-3/

The Department has divided Pennsylvania into six regional areas for medical marijuana. The regions are: Region 1 - Southeast; Region 2 - Northeast; Region 3 - Southcentral; Region 4 - Northcentral; Region 5 - Southwest; and Region 6 - Northwest.

Each region has growers/processors and dispensaries. To date, there is a total of 12 grower/processors, 27 primary dispensaries, 15 secondary dispensaries, and 10 tertiary dispensaries that have been awarded permits across Pennsylvania. Currently, there are 14 dispensaries statewide where patients may purchase medical marijuana.

Phase II applications were released on April 5, 2018.

III. Medical Marijuana Advisory Board

Chapter 12 of Act 16 of 2016 identifies the membership, organizational structure and duties of the advisory board. The 15-member board is established within the Department of Health and consists of the following members:

> The Secretary of Health or a designee, who also serves as chairperson of the board;
> The Commissioner of the Pennsylvania State Police or a designee;
> The Chairman of the State Board of Pharmacy or a designee;
> The Commissioner of Professional and Occupational Affairs or a designee;
> The Physician General or a designee;
> The President of the Pennsylvania Chiefs of Police Association or a designee;
> The President of the Pennsylvania District Attorneys Association or a designee;
> One member to be appointed by each of the following:
> The Governor;
> The President pro tempore of the Senate;
> The Majority Leader of the Senate;
> The Minority Leader of the Senate;
> The Speaker of the House of Representatives;
> The Majority Leader of the House of Representatives;
> The Minority Leader of the House of Representatives; and
> One member appointed by the Governor, who shall be a patient, a family or household member of a patient, or a patient advocate.

The advisory board has the following duties:

1) To examine and analyze the statutory and regulatory law relating to medical marijuana within this Commonwealth.
2) To examine and analyze the law and events in other states and the nation with respect to medical marijuana.
3) To accept and review written comments from individuals and organizations about medical marijuana.
4) To issue two years after the effective date of this section a written report to the Governor, the Senate and the House of Representatives.
5) The written report under paragraph (4) shall include recommendations and findings as to the following:

(i) Whether to change the types of medical professionals who can issue certifications to patients;
(ii) Whether to change, add or reduce the types of medical conditions which qualify as serious medical conditions under this act;
(iii) Whether to change the form of medical marijuana permitted under this act;
(iv) Whether to change, add or reduce the number of growers/processors or dispensaries.
(iv) How to ensure affordable patient access to medical marijuana; and
(v) Whether to permit medical marijuana to be dispensed in dry leaf or plant form, for administration by vaporization.

To complete its duties, the Board established four subcommittees: Medical, Patient/Caregiver, Regulatory and Final Report. The first three subcommittees were assigned tasks to investigate, analyze and make recommendations related to these duties. The Final Report Subcommittee was tasked with compiling the information from the other subcommittees to produce the final report.

IV. Analysis & Recommendations

The Advisory Board offers the following analysis and recommendations:

1201(j)(5)(i) Whether to change the types of medical professionals who can issue certifications to patients

Act 16 allows a physician in good standing with a Pennsylvania license to practice medicine to be included on the practitioner registry to issue certifications to patients to use medical marijuana.

Recommendation #1: The Medical Subcommittee and the Regulatory Subcommittee recommend that the program not expand the types of medical professionals who can issue certifications to patients. The Medical Subcommittee and the Regulatory Subcommittee further recommend that the program continue to accept input from the patient and provider community and consider adding additional medical professionals in the future.

Vote #1		
Yes	**No**	**Abstain**
10	**1**	**1**

1202(j)(5)(ii) Whether to change, add or reduce the types of medical conditions which qualify as serious medical conditions under this act

Act 16 defines a serious medical condition as any of the following:
1. Cancer;
2. Positive status for human immunodeficiency virus or acquired immune deficiency syndrome;
3. Amyotrophic lateral sclerosis;
4. Parkinson's disease;
5. Multiple sclerosis;

6. Damage to the nervous tissue of the spinal cord with objective neurological indication of intractable spasticity;
7. Epilepsy;
8. Inflammatory bowel disease;
9. Neuropathies;
10. Huntington's disease;
11. Crohn's disease;
12. Post-traumatic stress disorder;
13. Intractable seizures;
14. Glaucoma;
15. Sickle cell anemia;
16. Severe chronic or intractable pain of neuropathic origin or severe chronic or intractable pain in which conventional therapeutic intervention and opiate therapy is contraindicated or ineffective; and/or
17. Autism.

Recommendation #2: The Medical Subcommittee recommends that no medical conditions be removed from the list of serious medical conditions.

Vote #2		
Yes	**No**	**Abstain**
11	**0**	**1**

Recommendation #3: The Medical Subcommittee and the Patient/Caregiver Subcommittee recommend that "Severe chronic or intractable pain in which conventional therapeutic intervention and opiate therapy is contraindicated or ineffective" be changed to "Severe chronic or intractable pain".

Vote #3		
Yes	**No**	**Abstain**
11	**0**	**1**

Recommendation #4: The Medical Subcommittee recommends a process be established for a subcommittee of the Board to review and approve additional serious medical conditions on a continuous basis.

Vote #4		
Yes	**No**	**Abstain**
12	**0**	**1**

Recommendation #5: The Medical Subcommittee recommends that patients under the age of 18 be certified by a practitioner who is Board Eligible/Certified in Pediatrics or Pediatric Specialties, Neurology with Special Qualifications in Child Neurology, Child and Adolescent Psychiatry, or Adolescent Medicine (whether through Pediatrics, Internal Medicine, or Family Practice).

Vote #5		
Yes	**No**	**Abstain**
10	**2**	**1**

Findings/comments: The developing brain is especially vulnerable to the effects of a wide range of medications and other treatments. These effects are not limited to the immediate use of the medication or treatment, and agents that affect the brain may have long term consequences even after the drug has been stopped. Of course, this is true of any medication being used in clinical medicine; however, most medications in clinical uses have gone through years of investigation before reaching widespread clinical use. In the case of cannabis, we do not have the benefit of years of investigation. Furthermore, dosing of medications in children is different than in adults. Therefore, great caution will be needed when treating children with cannabis products.

The Medical Subcommittee recommends that physicians with expertise and training in the care of patients under 18 years is necessary to certify the use of cannabis in patients under 18 years of age. Furthermore, the practitioner issuing the certification should have expertise in the condition for which the cannabis is being certified. And, finally, a practitioner knowledgeable in the condition as well as the cannabis dosing recommendations for that condition needs to be involved in the care of the patient.

More broadly, the Medical Subcommittee recommends that specific guidelines and possibly restrictions be placed on the use of cannabis in patients under 18 years of age. Specifically, wording that cannabis products could have untoward and unknown effects on the developing brain needs to be included in the certification process.

Recommendation #6: The Medical Subcommittee recommends that more research be done on the use of medical marijuana for addiction treatment.

Vote #6		
Yes	**No**	**Abstain**
12	**0**	**1**

Recommendation #7: The Patient/Caregiver Subcommittee recommends that the medical condition of "Cancer" be revised to "Cancer; including remission therapy."

Vote #7		
Yes	**No**	**Abstain**
10	**1**	**1**

Findings/comments: Patients have reported for years that they have used cannabis, alone or with other interventions and treatments, to cause their cancer to go into remission. Those who continued to use small "maintenance doses" of cannabis reported a lower recurrence of cancer than those who didn't. The change is recommended to allow patients to continue with cannabis therapy to reduce the recurrence of cancer.

Recommendation #8: The Patient/Caregiver Subcommittee recommends that the medical condition of "Neurodegenerative Diseases" be added to the list of serious medical conditions.

Vote #8		
Yes	**No**	**Abstain**
11	**0**	**1**

Findings/comments: This condition would be more inclusive in that it would combine ALS, Parkinson's and MS as well as other Neurodegenerative diseases, such as Alzheimer's and Dementia.

Recommendation #9: The Patient/Caregiver Subcommittee recommends that the medical condition of "Damage to the nervous tissue of the spinal cord with objective neurological indication of intractable spasticity" be changed to "Damage to the nervous tissue of the CNS (brain-spinal cord) with objective neurological indication of intractable spasticity, and other associated neuropathies."

Vote #9		
Yes	**No**	**Abstain**
11	**0**	**1**

Findings/Comments: This condition has been modified to include the complete central nervous system and associated neuropathies.

Recommendation #10: The Patient/Caregiver Subcommittee recommends adding the medical condition of "terminally ill", meaning a medical prognosis of life expectancy of approximately one year or less if the illness runs its normal course.

Vote #10		
Yes	**No**	**Abstain**
11	**1**	**1**

Findings/comments:

This definition is currently found in Act 16 but is otherwise not addressed. It is believed that the legislative intent was to allow for terminal illness to be included as a serious medical condition.

Recommendation #11: The Patient/Caregiver Subcommittee recommends adding the medical condition of "Dyskinetic and Spastic Movement Disorders".

Vote #11		
Yes	**No**	**Abstain**
10	**1**	**1**

Findings/Comments:
This condition was suggested by a medical marijuana clinician to cover certain neurological conditions and other disorders that respond well to cannabis therapy. The state of Maine adopted this condition and that is working well for them.

This medical condition would cover symptoms such as tics, tremors and similar involuntary movements and include diseases and conditions such as Tourette's Syndrome and dystonia. Anecdotal evidence suggests that cannabis therapy may be an effective option for compassionate use in severe neurologic diseases such as these.

Recommendation #12: The Patient/Caregiver Subcommittee recommends that the Department of Health encourage Clinical Registrants under Chapter 20 to study the medical benefits of cannabis for individuals with autoimmune diseases.

Vote #12		
Yes	**No**	**Abstain**
12	**0**	**1**

Recommendation #13: The Patient/Caregiver Subcommittee recommends adding the serious medical condition of "Addiction substitute therapy – opioid reduction".

Vote #13		
Yes	**No**	**Abstain**
6	**4**	**2**

Findings/Comments:
Cannabis can offer pain relief and has been reported by patients to ease the symptoms and process of opioid withdrawal. It has been used by patients as an "exit drug" to get off of heroin and other opiates.

Given the current state of the opioid epidemic, the Patient/Caregiver Subcommittee recommends allowing cannabis to be used for opioid addiction therapy and opioid reduction.

1201(j)(5)(iii) Whether to change the form of medical marijuana permitted under this act

Act 16 allows medical marijuana to only be dispensed to a patient or caregiver in the following forms:

a. pill;
b. oil;

c. topical forms, including gels, creams or ointments;
d. a form medically appropriate for administration by vaporization or nebulization, excluding dry leaf or plant form until dry leaf or plant forms become acceptable under regulations adopted under section 1202;
e. tincture; and/or
f. liquid.

Recommendation #14: The Medical Subcommittee, Patient/Caregiver Subcommittee and Regulatory Subcommittee recommend that the program expand the form of medical marijuana permitted under Act 16 to include dry leaf or plant form for administration by vaporization.

Vote #14		
Yes	**No**	**Abstain**
11	**0**	**1**

Findings/Comments: Information supporting this recommendation is included in section 1201(j)(5)(vi) below.

The Patient/Caregiver Subcommittee reports that there has been minor interest in commercially produced cannabis-infused food products, known as edibles, by the patient community. Some patients and caregivers are interested in making their own products and seem satisfied in this approach, which would be less expensive than commercially produced products. However, edibles are an effective and well-managed way to administer medical cannabis for some patients, and this option should be considered in the future as the program matures.

1201(j)(5)(iv) Whether to change, add or reduce the number of growers/processors or dispensaries

Act 16 allows permits to be issued to 25 grower/processors and also to 50 dispensaries, each of which may have up to three locations. In the first round of granting permits, 12 permits were issued for grower/processors and 27 permits were issued for dispensaries. Additionally, up to eight clinical registrants may be issued a permit to operate a grower/processor facility and a dispensary, which may have up to six locations.

Recommendation #15: The Regulatory Subcommittee recommends that the program make no changes to the Act concerning the number of growers/processors and dispensaries at present. The program should assess the numbers as the program expands.

Vote #15		
Yes	**No**	**Abstain**
12	**0**	**1**

Findings/Comments: The Regulatory Subcommittee believes with the program in the beginning stages of growth, the current numbers are adequate. The program should assess the numbers as the program expands.

1201(j)(5)(v) How to ensure affordable patient access to medical marijuana

Affordable patient access to the medical marijuana program and products is of primary concern to the patient and caregiver communities. Patients and families with members who have serious medical conditions are frequently burdened with considerable medical expenses, coupled with limited earning capacity. Efforts to control costs for patients at all levels of the program should be considered and implemented.

Recommendation #16: The Patient/Caregiver Subcommittee recommends allowing dispensaries to purchase vaporizing devices and other ancillary products from sources other than grower/processor permittees.

Vote #16		
Yes	**No**	**Abstain**
9	**3**	**1**

Findings/Comments: Currently, regulations mandate that dispensaries purchase these items only from permitted growers/processors. This could cause an unnecessary markup in costs for these necessary patient products. Dispensaries should be permitted to source these products where they wish to ensure competitive pricing for patients.

Recommendation #17: The Patient/Caregiver Subcommittee recommends that the certification to use medical marijuana be modified to limit the practitioner's ability to specify medical marijuana form and dosing.

Vote #17		
Yes	**No**	**Abstain**
3	**8**	**1**

Findings/Comments: Patients have reportedly been prohibited from purchasing at a dispensary that did not stock the specified items on a certification. Costs will rise for patients if the certification does not allow flexibility with the purchasing process, as they may need to revisit the practitioner for modifications to the certification.

Dispensaries are best equipped to determine the appropriate dose and form for each patient. The certification issue was raised by a Board member early on in the process upon reviewing the Act 16 regulations. It was also a concern noted by most stakeholders we engaged as a subcommittee. Additionally, if a practitioner recommends a form and dose of medical cannabis, it strongly mirrors a prescription for any other medication, making this a concerning issue for federal law.

Therefore, the Patient/Caregiver Subcommittee strongly believes that medical marijuana form and dosing be left to the medical professionals at dispensaries. While doctors may provide guidance, it should not restrict a patient's or caregiver's ability to work with dispensary experts to obtain the form and dose that is the most effective.

Recommendation #18: The Patient/Caregiver Subcommittee recommends establishing a default time period of one year on a patient's certification.

Vote #18		
Yes	**No**	**Abstain**
6	**5**	**1**

Findings/Comments: Currently, practitioners are able to issue a certification for less than 12 months. There have been patients with chronic illnesses certified for only a short duration, making their card invalid when that time period expires. The patient is then required to complete the process again and pay an additional $50 for a new card to continue to access their medication.

Recommendation #19: The Medical Subcommittee and Patient/Caregiver Subcommittee recommend that practitioners have the option to opt-out of the public registry.

Vote #19		
Yes	**No**	**Abstain**
12	**0**	**1**

Findings/Comments: The Patient/Caregiver Subcommittee has received feedback that some doctors have removed themselves from the program due to the influx of calls from prospective patients or have decided not to participate because they do not wish to be on a publicly listed registry. It is anticipated that allowing doctors the option to opt-out of the public registry will result in greater doctor participation in the program and ultimately drive down costs for patients.

Recommendation #20: The Medical Subcommittee, Patient/Caregiver Subcommittee and Regulatory Subcommittee recommend permitting medical marijuana to be dispensed in dry leaf or plant form, for administration by vaporization.

Vote #20		
Yes	**No**	**Abstain**
11	**0**	**1**

Findings/Comments: The patient community fully supports the addition of dry leaf or plant form marijuana due to its lower cost and ease of use. Because plant form marijuana requires minimal processing, it will always be the least expensive product offered, making it an affordable option for patients. When vaporized, the medical benefits can be felt within minutes, allowing the patient to accurately titrate their dose without using too much.

Plant form will be the most affordable form of medical cannabis for patients to purchase. The costs for many forms are prohibitively high. Failing to include dry leaf will undoubtedly force patients to obtain medical cannabis through the black market and jeopardize the program's long-term success and patient safety.

This issue is overwhelmingly the largest concern of the patient and caregiver community.

1201j5(vi) Whether to permit medical marijuana to be dispensed in dry leaf or plant form, for administration by vaporization

Recommendation #21: The Medical Subcommittee, Patient/Caregiver Subcommittee and Regulatory Subcommittee recommend permitting medical marijuana to be dispensed in dry leaf or plant form, for administration by vaporization.

Vote #21		
Yes	**No**	**Abstain**
11	**0**	**1**

Findings/Comments: The patient community fully supports the addition of dry leaf or plant form medical marijuana due to its lower cost and ease of use. Because plant form medical marijuana requires minimal processing, it will always be the least expensive product offered, making it an affordable option for patients. When vaporized, the medical benefits can be felt within minutes, allowing the patient to accurately titrate their dose without using too much.

Plant form will be the most affordable form of medical cannabis for patients to purchase. The costs for many forms are prohibitively high. Failing to include dry leaf will undoubtedly force patients to obtain medical cannabis through the black market and jeopardize the program's long-term success and patient safety.

This issue is overwhelmingly the largest concern of the patient and caregiver community.

Adoption of the final report captured the following vote count:

Vote #22		
Yes	**No**	**Abstain**
13	**0**	**0**