**BILL NO.** Senate Bill 3 **PRINTER NO.** 840

AMOUNT

\$1.3 Million FY 2015-16 (BPOA Start-Up)

Professional Licensure Augmentation Account

DATE INTRODUCED PRIME SPONSOR

January 26, 2015 Senator Folmer

## **DESCRIPTION AND PURPOSE OF BILL**

Senate Bill 3 creates the Medical Cannabis Act which provides a mechanism to allow health care providers to recommend the use of marijuana for medical purposes.

Senate Bill 3 defines a "Qualified Medical Condition" to be eligible for medical cannabis as any of the following:

- Cancer.
- Epilepsy and seizures.
- Amyotrophic Lateral Sclerosis.
- · Cachexia/wasting syndrome.
- Parkinson's disease.
- Traumatic brain injury and postconcussion syndrome.
- Multiple Sclerosis.
- Spinocerebellara Ataxia (SCA).
- Posttraumatic stress disorder.
- Severe fibromyalgia.
- HIV/AIDS.
- Glaucoma.
- A condition authorized by the Department of Health

#### State Board of Medical Cannabis Licensing:

SB 3 establishes the State Board of Medical Cannabis Licensing within the Department of State. The board consists of the Secretary of Health, the Commissioner of the Bureau of Professional and Occupational Affairs, the Secretary of Human Services, two public members, one medical doctor who is an expert in the field of pediatrics, the Physician General, two members who are physicians representing specialties that utilize medical marijuana, two members who are registered nurses and a licensed pharmacist. Each public and professional member must be appointed by the Governor with consent of the Senate. The board must meet at least once per month for the first 12 months of the board's existence. After the first year, the board must meet at least six times per year but may meet more frequently.

The board has these powers and duties:

- To license medical cannabis growers, processors, and dispensers.
- To issue occupation permits to medical cannabis (MC) employees.
- To issue certificates to laboratories which test MC.
- To issue, deny, renew, reinstate or refuse to renew, suspend and revoke licenses, certifications of testing laboratories and occupation permits.
- To implement procedures to allow the expansion of qualified medical conditions for which a patient may obtain MC.
- To administer and enforce the provisions of this act.
- To conduct background checks and otherwise investigate applicants for licenses or occupation permits.
- To establish fees for licenses and occupation permits.
- To charge for services related to the enforcement and administration of this act.
- To keep minutes and records of each transaction and proceeding.
- To provide standards for dispensaries of MC so a professional appearance is maintained.
- To require site plans.
- To require the utilization of a prescription monitoring program for use by a health care practitioner to review a patient's pharmaceutical history.
- To develop a system to verify MC access cards and cardholders.
- To develop an inventory tracking system to be used by all licensees.
- To develop regular inspection schedules, unannounced inspections, procedures and other enforcement measures to regulate all MC growers, processors and dispensers.
- To inspect premises occupied for the production, preparation, testing, packaging, processing, storage, sale, distribution and transport of MC.
- To develop standards and requirements for the implementation, use and maintenance of security systems.
- To submit annually to the Department an estimate of financial requirements to operate the board.
- To develop a system for mandatory and voluntary recall of defective products or MC.
- To develop standards for creation and maintenance of qualifying patient records.
- To promulgate regulations, including:
  - Allowing institutions of higher education to conduct studies on the health benefits of MC.
  - o Determination of required quality and safe clinical strength of MC.
  - Advertising and marketing of MC.
  - Containers, tracking and testing.
  - Packaging and labeling.

- To provide the form and content of authority given to a registered patient to obtain MC.
- To adopt requirements relating to the amount of tetrahydrocannabinol authorized for each product.
- To consult information published by the American Herbal Pharmacopeia in the promulgation of regulations.
- To enforce regulations.
- To establish record retention policies.

In addition to promulgating regulations, the board must adopt a schedule of civil penalties for operating without a current license or occupation permit or for other violations of the act. The board has the power to revoke licenses for violations of the act, for refusing to adhere to an order of the board, or for conviction of a criminal offense. The board may also issue cease and desist orders, order restitution, or issue a letter of reprimand or censure.

The board may levy a civil penalty of not more than \$25,000 for a violation of the act, or impose a civil penalty of not more than \$15,000 if a person aids the unlicensed growing, processing, distribution or dispensing of MC. The board may also assess the cost of the investigation against the person.

The board has the ability to set the fees to ensure that all of the fees, fines and civil penalties are sufficient to at least cover projected board and enforcement expenses.

## Licensing of Growers of MC:

Growers of MC are licensed to supply MC for distribution to processors and dispensers. The number of growers is limited to no more than 65 licenses. The cost of a license for a grower of MC is \$50,000. The license must be renewed annually. The cost of renewal is \$5,000. The licensing fees are deposited in the General Fund, and the renewal fees are deposited into the Professional Licensure Augmentation Account.

There is no restriction on the strains of MC that may be grown. However, genetically modified organisms may not be used by growers.

Growers may only grow MC using conventional methods in an indoor, enclosed secure facility. Further, growers must test MC and submit to random tests of the board, must package and label MC in accordance with regulations promulgated by the board, must only sell or deliver MC to a processor, a laboratory, or a dispenser, and must keep accurate records.

## **Licensing of Processors of MC:**

SB 3 provides for the licensure of processors of MC. Licensees process the MC into "oil-based medical cannabis products". The number of processors is limited to no more than 65 licenses. The licensure fee is \$50,000. The cost of renewal of a license is \$5,000. The licensing fees are deposited in the General Fund, and the renewal fees are deposited into the Professional Licensure Augmentation Account.

## A processor of MC must:

- Only use extraction and processing methods approved by the board.
- Submit to inspection by the board.
- Conduct quality testing utilizing a laboratory approved by the board.
- Only sell, transport or deliver MC to either a laboratory or a dispenser.
- Maintain accurate records.

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## **Licensing of Dispensers of MC:**

Under SB 3, the board licenses up to 130 dispensers of MC. The dispensers shall accept MC access cards and dispense MC to patients with qualifying medical conditions in accordance with a health care practitioner's instructions. The fee for a license is \$50,000. The fee for renewal of a license is \$5,000. The licensing fees are deposited in the General Fund, and the renewal fees are deposited into the Professional Licensure Augmentation Account.

### A dispenser of MC must:

- Maintain a system to verify MC access cards.
- Submit to inspection by the board.
- Maintain a record of all MC dispensed.
- Dispense no more than 2.5 ounces of MC in a 14-day period unless a waiver was issued by DOH.
- Comply with recommendation of the health care practitioner.
- Provide patient or their representative with safety information.
- Sell only MC that was approved by a testing laboratory.
- Maintain a security system.
- Provide the supervision of the dispensing of MC at all times.
- Display appropriate signage.
- Provide an inventory and packaging plan and procedures for the oversight of the dispensing facility.
- Appoint a physician to function as a medical director.
- Obtain MC only from a MC processor.
- Maintain accurate records.

### <u>Licensing of Owner or Operator:</u>

SB 3 requires that an "owner or operator" be licensed. The application for a license must have verification of status as an owner or operator from a medical cannabis dispenser, grower or processor. The bill defines the term "owner or operator" as an officer, principal, owner or director of the MC grower, processor or dispenser licensed under section 505; or a person who directly holds a beneficial interest in or has controlling interest in an applicant or licensee; or a person who has the ability to elect a majority of the board of directors of a licensee or to otherwise control a licensee.

## Occupation Permit for Employees and Certain Authorized Providers:

SB 3 requires each MC employee and each authorized provider who is not a parent or guardian of a patient to obtain an occupation permit from the board.

#### Location:

SB 3 specifies that each license for a grower, processor or dispenser is valid only for the specific location for which the license is granted. A person may not distribute MC other than from a licensed facility. Facilities for the manufacturing, preparation and production of MC shall meet the same zoning and land use requirements as other manufacturing, preparation and production facilities. Facilities for the dispensing of MC shall meet the same zoning and land use requirements as other commercial facilities. An owner may petition the board to move the facility.

#### Disposal and donation:

In addition, SB 3 provides that an MC dispenser, grower or processor may donate MC that has been purchased or produced and tested in this Commonwealth in accordance with this act and is in new and unopened condition and can only be donated for research purposes to an accredited research institution, university or college within this Commonwealth and recognized by the Commonwealth.

### **Testing Laboratories:**

The board shall certify laboratories to test MC. A grower and processor of MC must utilize a certified laboratory before they may sell MC.

#### Access Card:

SB 3 provides that a person with a qualified medical condition may apply to the Department of Health (DOH) for an MC access card.

Applications for an MC card shall be developed by DOH. Renewal is required on an annual basis. A patient representative may obtain an MC access card on behalf of a patient. The application must include a certification that the patient has a qualified medical condition. DOH must approve or deny the application within 90 business days. An application fee of no more than \$100 shall be charged along with an annual renewal fee of not more than \$50.

The bill provides that a person must reside within the Commonwealth to obtain a card. However, the bill allows for reciprocity among other states that issue MC access cards. Upon the approval of DOH, a person registered in another state will be issued an MC access card authorizing the person to use MC within the Commonwealth.

If an authorized provider is no longer employed with a recognized health care facility, the authorized provider's access card is null and void. A health facility shall notify DOH if the authorized provider is no longer employed.

#### Health Care Practitioners:

SB 3 provides the health care practitioner may recommend the use of MC if the health care practitioner:

- has a good faith practitioner-patient relationship with the patient, not limited to the certification of MC use;
- is licensed to practice within PA;
- registers with the Department;
- has the responsibility for ongoing care of a patient;
- has documented an in-person medical assessment of the patient no longer than 90 days prior to certifying the patient to receive MC;
- certifies that the patient is under physician's care for a qualified medical condition and it likely to receive therapeutic or palliative benefit from MC, and the certification must also include the recommended dosage (no more than 2.5 ounces in 14 days without a DOH waiver);
- has adopted a record keeping system for patients recommended to use MC.

## Medical Use Permitted:

SB 3 provides the following with respect to persons who use MC or who are authorized providers of MC:

- Freedom from arrest for use of MC in accordance with the act.
- Possession or application for an MC access card may not alone constitute probable cause to search a person or a person's property.

#### Health Insurance:

SB 1182 provides that nothing in this act shall be construed to require medical assistance or private health insurer to reimburse a person for the costs associated with MC.

### Protection, Prohibitions and Enforcement:

### SB 3 provides:

- For the purposes of medical care, a person's authorized use of MC shall be considered the equivalent of the use of other medicine used under the direction of a health care provider. MC may not be considered an illicit substance or otherwise disqualify a patient from medical care.
- A person may not be denied child custody due to use of MC.
- A person may not be presumed to neglect or endanger a minor child due to use of MC, unless the person's behavior creates an unreasonable danger to the safety of the minor by clear and convincing evidence.
- A landlord may not refuse to lease or otherwise penalize a person because of possession of an MC card or for using MC, unless the landlord would lose a monetary or licensing-related benefit under federal law or regulation.
- A school may not refuse to enroll or penalize a person because of a possession of an MC card or for using MC, unless the school would lose a monetary or licensing-related benefit under federal law or regulation.
- An employer may not discriminate against a person in the hiring or termination of a person due to possession of an MC card. However, the employer can take the possession of an MC card into account if the employer can prove the person is abusing or misusing MC on the premises of the place of employment during ordinary hours of employment or if failure to do so would cause an employer to lose licensing benefit under federal law or regulation. A positive test for marijuana may not be considered by an employer unless the person unlawfully used, possessed or was impaired by the MC while on the premises of the place of employment or during the hours of employment.

### **Prohibitions and Use:**

#### SB 3 provides the following:

- No individual may operate or drive a motor vehicle, an aircraft, a motor boat, or heavy machinery with more than 10 nanograms of THC in their system.
- No individual may undertake any task under the influence when doing so would constitute negligence or professional malpractice.
- MC may not be used by an individual who is not authorized under this act.
- No individual may smoke or utilize a vaporizer to ingest or inhale MC.
- MC may be used in any public place, including public transportation, on school grounds, in a correctional institution or a public park or beach.

#### <u>Unlawful Activities:</u>

SB 3 provides that it is a criminal offense to (1) grow, process, or dispense MC without a license; (2) transport MC from or between an unlicensed grower, processor, or dispenser; (3) grow, process or dispense MC in violation of the act; (4) fail to report or pay a fee under the act; or (5) violate a regulation of the board. The penalties of false swearing apply.

#### Criminal Penalties and Fines:

A grower, processor or dispenser that provides MC to anyone other than a person with an MC card commits a felony of the third degree. A person who falsifies an application or certification commits a misdemeanor of the first degree. Otherwise, a violation of the act is graded as a misdemeanor of the second degree. A second or subsequent offense is graded as a felony of the third degree.

### Daily Log Access:

Establishes proper procedure under court order for law enforcement to access and use a MC dispenser's daily log of MC sold and dispensed.

#### Law Enforcement:

Verification system may only be accessed by department-registered law enforcement agencies in order to confirm MC access card authenticity. Without criminal charges, accessed information shall remain confidential.

#### Surcharge on the purchase price of MC:

SB 3 imposes a six percent surcharge on the purchase price of medical cannabis at the time the medical cannabis is first sold to a medical cannabis dispenser. If the surcharge is not collected by the seller from the medical cannabis dispenser, the surcharge is imposed on the medical cannabis dispenser at the time of purchase. Only one sale shall be surcharged and used in computing the amount of surcharge due.

The Department of Revenue will collect and administer the medical cannabis surcharge, and collections from the surcharge will be deposited into the General Fund. Senate Bill 3 establishes an administration and enforcement system with regard to surcharge collections, reporting and recordkeeping, filing deadlines, appeals, penalties, etc. A medical cannabis purveyor is required to obtain an annual license from the Department of Revenue and pay a seventy-five dollar licensing fee in order to sell medical cannabis to a dispenser.

## Miscellaneous Provisions:

### SB 3 provides that:

- The board shall promulgate regulations.
- The board shall promulgate temporary regulations, which shall expire within two years of promulgation. The temporary regulations shall not be subject to the Regulatory Review Act, the Commonwealth Documents Law, or the Commonwealth Attorneys Act. The board must begin publishing temporary regulations within six months of the effective date of the act.
- \$1.3 million is appropriated to the Bureau of Professional and Occupational Affairs within the Department of State in order to establish the board and to implement other provisions of the act.

This act shall take effect in 60 days.

## FISCAL IMPACT:

SB 3 will have no adverse impact on the Commonwealth's General Fund. In Fiscal Year 2015-2016, the Commonwealth is estimated to collect from \$13.0 million in license fees under the Department of State and between \$9.8 million and \$19.7 million in MC access card application fees under the Department of Health. In the following Fiscal Years, the Commonwealth is estimated to collect a \$1.30 million in license renewal fees under the Department of State, \$20 million to \$40 million in surcharge collected by Department of Revenue and \$4.9 million to \$9.8 million in MC access card renewal fees under the Department of Health. This revenue will be used to cover all of the cost to implement this act.

### **Department of State License:**

The limited number of licenses for MC growers is 65, processors is 65 and dispensers is 130. Based upon a license fee of \$50,000 each, the Commonwealth will collect \$3.25 million for growers, \$3.25 million for processors and \$6.50 million for dispensers for a total of \$13.0 million. Based upon the annual renewal fee of \$5,000, the Commonwealth will collect \$0.325 million for growers, \$0.325 million for processors and \$0.650 million for dispensers for a total of \$1.3 million annually.

#### Department of Health MC Access Card and Department of Revenue Surcharge:

Department of Health could receive between 98,252 and 196,504 applications. The initial application fee of \$100 will generate from \$9.8 million to \$19.7 million, and the renewal fee of \$50 will generate from \$4.9 million to \$9.8 million, which would accrue to the General Fund. This revenue assumption is based upon a participation rate in Pennsylvania ranging from 0.77% to 1.54%.

The implementation of Senate Bill 3 likely will not take effect in time to have substantial medical cannabis sales subject to a surcharge during fiscal year 2015-16. Therefore, the General Fund fiscal impact for FY 2015-16 is expected to be minimal. For fiscal years 2016-17 and thereafter, the medical cannabis surcharge is expected to generate General Fund revenue in an amount between \$20 million and \$40 million per year. This revenue is anticipated to be significantly greater than administrative costs for the Department of Health to implement its duties under the bill.

The revenue estimate is based upon the number of legal medical marijuana patients in the United States and medical marijuana usage by patients in Colorado, which has the largest state-regulated dispensary program in the nation. Out of 23 states including the District of Columbia with legal medical marijuana as of October 2014, 19 jurisdictions provide information regarding the number of legal medical marijuana patients in each state. As compared to the overall state population, the average percentage of residents who are legal medical marijuana patients in the 19 jurisdictions is 0.77%. Colorado has a high of 2.1% of its population who are legal medical marijuana patients, while states such as New Jersey and Illinois have far less than 1% of their population who are legal medical marijuana patients.

The table below illustrates the revenues that might be realized from medical cannabis by using the national average of 0.77% of the population as legal medical marijuana patients and also by using double the national average (i.e. 1.54%), which is still less than the percentage of Colorado's population who are legal medical marijuana patients.

Estimate % of MC Applicants	0.77%	1.54%
Pennsylvania Population	12,760,000	12,760,000
Estimated MC Recipients	98,252	196,504
Initial MC Card Application Fee	\$100.00	\$100.00
Revenue on Initial Applications	\$9,825,200	\$19,650,400
MC Card Renewal Fee	\$50.00	\$50.00
Revenue on Renewals	\$4,912,600	\$9,825,200
Average Annual Sales per MC Card in Colorado	\$3,382.10	\$3,382.10
Total Sales	\$332,298,089	\$664,596,178
Surcharge on MC	6%	6%
Revenue from Surcharge	\$19,937,885	\$39,875,771