PCC Supports These Act 16 Amendments

In 2016, the Pennsylvania legislature took a historic and compassionate step forward for medical patients across the Commonwealth and passed the Medical Marijuana Act ("Act 16") into law. Now five years into the program, there have been no significant changes to the law or regulations to improve the safe, efficient access of medical cannabis to medical patients.

With the benefit of highly experienced in-state operators, new research, refined business practices, and effective policies demonstrated by other state medical markets, the Pennsylvania Cannabis Coalition ("PCC") presents a series of Act 16 amendments that will enhance the program through next-generation cultivation techniques, business practices, and product development. The result will create cost savings and higher product quality for our patients. The PCC is grateful for the legislature's consideration of this legislative package.

ADEQUATE SUPPLY FOR PATIENTS

1. Increase Patient Supply by Allowing for Product Remediation

Remediation of agricultural products optimizes manufacturing and quality assurance practices to mitigate against unnecessary product loss, while ensuring safe, lab-tested products ultimately reach consumers. Just like any other harvested agricultural product, medical cannabis is susceptible to unwanted contaminants, which presents operators with the same quality assurance challenges as other industries that produce consumable products using plant-derived ingredients.

A commonly accepted practice in instances where contaminants ultimately make it into a product at unacceptable levels, is to chemically remove -- or "remediate" -- contaminants and allow the product to be retested in a third-party laboratory to ensure it meets safe and acceptable consumer health standards. Not only is remediation a standard practice in the consumer products industry as a whole, but every state with a medical marijuana program, *except Pennsylvania*, allows for the remediation of medical marijuana. While PCC does not interpret Act 16 to require an amendment to allow for remediation, at a Medical Marijuana Advisory Board meeting the Department of Health indicated that for them to allow MMOs to remediate product, Act 16 would need to be amended.

- In allowing for a remediation process, medical marijuana plant material will still be tested for microbial contaminants by independent, state-licensed labs. If a certain threshold of contaminant is met, rather than "failing" that batch of flower and rendering it unusable, the producer is given the option of removing the contaminants through a scientifically sound and safe chemical extraction process. Once extracted, the product is then retested by state-licensed labs to ensure its safety, and that pathogens are not present in the product.

- This extraction process is the exact same safe and established method used to convert the medicinal ingredients in the cannabis flower into an extract for use in manufacturing of topicals, tinctures, edibles, and other medical marijuana products. The process removes microbial contaminants present in the flower, leaving only the usable, extracted oil for final production.

- Every day, thousands of Pennsylvania's patients rely on the ability to access safe cannabis as part of their treatment. Unfortunately, producers have at times been unable to keep up with patient demand for products, in large part, because of unnecessary product losses due to the lack of an approved process for remediation.

- Remediation will allow more plant material to be processed into medicine – increasing supply and also helping to reduce patient cost.

Act 16 should be amended to make clear that remediation is allowed, so that our patients have safe and affordable access to medicine as the Legislature intended.

2. Allow Cannabis Producers to Source and Cultivate New Genetic Strains for Improved Product Quality

Act 16 explicitly allows grower/processors to source plant material. This is an important part of the PA Medical Marijuana Program, and when implemented, will result in the cultivation of more resilient plants for use in the production of medical products and the development of innovative, new medicines for patients. Although Act 16 and the regulations clearly state the General Assembly's intent to allow for the purchase of plant material among in-state operators, now five years into the program, the Department of Health has not put a process into place for MMOs to obtain new genetics and has refused to let many MMOs exchange seeds and post-harvest material.

However, even if the Department ultimately follows the law and regulations and allowed grower/processors to exchange plant material, Act 16 also does not allow for sourcing of genetic plant materials from out-of-state sources. This limitation substantially limits genetics and product development in Pennsylvania's cannabis industry. Asexual propagation, like cloning, also results in "clonal degradation", a phenomenon that results in weaker, lower yielding plants over generations of reproduction from the same genetic material.

Grower/processors who began cultivation in 2019 are using genetics that are three years old, and there is currently no avenue to obtain and develop new genetic strains from inside or outside of the state. Limiting access to genetics ultimately stifles innovation in the types of medicine available to the patients, and also reduces the potential to propagate and cultivate the healthiest, highest quality plants for use in medicine.

Act 16 should be amended to require the Department to establish a process to facilitate the exchange of plant material between grower/processors, and to silence the statute on the

sourcing of out-of-state genetic material, to give operators the ability to increase the variety of their medical offerings and offer patients products manufactured from the highest quality strains.

3. Allow Hemp-derived Ingredients produced by Pennsylvania Licensed Hemp Growers to be Added to Medical Marijuana to Increase the Supply of High-CBD Products

Hemp is a member of the cannabis family but is distinguished from medical marijuana because of its very low-THC content. Whether a product is hemp-derived or marijuana-derived, CBD and THC are both cannabinoids derived from the exact same plant species: *Cannabis sativa L.*

Because both hemp and marijuana plants are botanically the same plant and follow similar cultivation and production processes, hemp can be cultivated and processed to yield an extracted product that can meet the strict testing requirements of Pennsylvania's Medical Marijuana Program. Hemp-extracts that contain CBD can also be added as an excipient to medical marijuana. Combining marijuana-derived THC and hemp-derived CBD into medical cannabis can offer a patient a wider variety of product choices that are more appropriate and effective for the patient's individualized treatment plan, unique symptoms, therapeutic need, and body composition.

- There is a demand for medical marijuana products with a high CBD content because CBD has many medicinal qualities without having the psychoactive effects of THC, but currently the cost for medical patients to purchase high-CBD from a dispensary can be a deterrent for care.
- Allowing medical cannabis grower/processors to partner with and source Pennsylvania hemp will help to support in-state farmers and agricultural producers in both industries.
- Just like any THC and CBD product produced in-house by a grower/processor, the final product that incorporates outsourced hemp-CBD ingredients will be subject to third-party, independent laboratory testing, and held to the same standards and regulations that the Department requires for medical cannabis.
- By comparison, mature and highly regulated medical markets such as Michigan, Delaware, Maryland, and New York allow for licensed operators to source and use hemp-derived ingredients in medical marijuana products.

Act 16 should be amended to allow medical operators to source hemp and hemp extract from entities licensed to grow or process hemp by the Pennsylvania Department of Agriculture or the U.S. Department of Agriculture, subject to the same rigorous testing that medical marijuana products must pass.

4. Allow for the Use of Pesticides as Permitted by the Pennsylvania Department of Agriculture

Act 16 is clear that additional pesticides should be permitted in the program. However, the Department has refused to introduce new pesticides, which is crippling MMO's integrated pest management programs. In the five years since Act 16 was passed, MMOs have made technological gains in growing medicine in the Commonwealth. However, their abilities to manage destructive pests, which have built high levels of resistance to the currently approved pesticides, are hampered by the Department's refusal to honor the legislative intent of Act 16. Giving the Department of Agriculture the sole authority to approve new pesticides for the program would bring medical marijuana in line with other regulated agricultural products in the state.

Act 16 should be amended to allow additional pesticides products to be added to the Program through a rigorous approval process applied to agricultural products by the PA Department of Agriculture.

PATIENT ACCESS

5. Increase Patient Access by Allowing for Relocation of Dispensaries

At the inception of the Pennsylvania cannabis program, medical cannabis businesses selected locations for dispensaries based on the best knowledge available at the time, but without any ability to attain tangible information on the best locations to provide products to patients.

Over time, many dispensaries have found that they are not located in areas with significant patient density, resulting in long commutes and inconvenience for patients and caregivers, and reduced sales. At the same time, host municipalities have come to understand that dispensaries are normal retail operations with the need for ample parking, signage, curb-cuts and other incidentals of a traditional retail location and want dispensaries located in their communities to occupy better premises.

Currently, the Department has full discretion over where dispensaries are located, but seldom allows them to relocate -- even within the same town or community to a more optimal retail location. As the General Assembly is aware, this can be detrimental to any retail business, but is particularly self-perpetuating in the medical cannabis context. If a dispensary is located in an area where there are not enough patients, the dispensary may not be able to afford to operate, and be forced to close their doors, resulting in even greater reduction in dispensary access for patients. What's more, the lack of access could turn some medical patients to untested and unsafe cannabis in the illicit market.

Currently, there are more than 30 Pennsylvania counties without a single medical marijuana dispensary. Allowing for relocation would give patients in areas of the Commonwealth that are

already disadvantaged by sparsely populated resources access to critical and sometimes life-saving therapeutic alternatives to conventional pharmaceuticals. Furthermore, while larger medical cannabis companies may be able to sustain one dispensary that is not profitable, smaller operators cannot, causing closures and further limiting patient access to important medicine. Further inaction will hurt the medical cannabis industry overall, but particularly the smaller businesses.

Act 16 should be amended to allow dispensaries to relocate within the same region in order to better serve patients.

6. Allow the Use of Application-Programming Interfacing to Increase Transactional Speed, Transparency and Reliability.

Application-programming interface (“API”) is a standard computing interface that creates efficiencies between multiple software intermediaries by allowing two different applications to communicate with the other. By way of example, an API allows your smartphone device to communicate with the Starbucks mobile ordering application, without regard for whether your phone is made by Apple, Samsung, Microsoft, or LG. In Pennsylvania, however, all licensees must use a single, captive seed-to-sale tracking software, while nearly every other state allows licensees to choose their own seed-to-sale software, as long as it accurately and reliably “plugs” into the state’s own seed-to-sale tracking solution via an API.

Allowing for an API to link with the seed-to-sale inventory tracking software mandated by law and regulation (MJ Freeway) and an interfacing software, will lead to faster access to medical marijuana for patients and will help create competition among seed-to-sale vendors, ultimately delivering a better, more reliable patient experience. Simply put, API integration increases overall operational efficiency.

- Currently, *twenty* individual computer functions, or process steps, are required to dispense medication to patients. This unnecessarily cumbersome process is due to the current regulation prohibiting use of an API. For example, employees are spending several hours per day in a redundant software program updating product lists for patients.

- API integration would remove these unnecessary programming steps, create efficiencies in retail and dispensary operations, and give our personnel more time to focus on what’s important -- the safety, security, and positive patient experience within medical cannabis dispensaries across the Commonwealth.

- On average, order fulfillment times are 3-4 times greater for dispensaries without an API integration, resulting in a longer patient wait time.

- On average, patients are spending 2-3 times longer when picking up orders at stores without an API integration, increasing employee and patient interaction times, and thereby

increasing the likelihood of human exposure despite all necessary precautions under the state's Covid-19 emergency guidance.

- By comparison, aside from Utah, every state medical marijuana market in the nation permits API integration for medical marijuana businesses.

Act 16 should be amended to allow for the use of API. The use of API will allow for streamlined and efficient dispensary operations and better patient service, without maintaining the security and accuracy of our seed-to-sale inventory systems.

Program Modernization

7. Holding Privately Held Companies to the Same Disclosure Requirements as Publicly Held Companies

Similar to publicly traded MMOs, privately held companies can have hundreds of investors. Act 16 currently requires privately held companies to obtain fingerprints and conduct extensive background checks for every single financial backer, no matter their ownership percentage, but publicly held companies are only required to provide fingerprints and background checks for individuals who hold an interest of 5% or more. Aligning these requirements for privately and publicly held companies will reduce the financial and operational burden on privately held companies, allowing the MMO's to focus on getting medicine to patients. This particularly benefits smaller businesses with limited capital.

Act 16 should be amended to bring privately held companies in line with publicly held companies, and only require extensive background check requirements on financial backers who own 5% or more of the Company, creating equity amongst business structures in the market.

8. Allow Motion Activated Recording for Video Surveillance to Increase Security While Reducing Costs

In November 2020 the Department of Health issued guidance via email directing operators that they must record surveillance twenty-four hours a day seven days a week AND retain that footage for two years. While this appears to provide the ability to discover security related issues it actual creates more gaps in coverage as the storage burden stresses security systems causing disruptions. This new interpretation of the regulation is particularly burdensome to smaller MMOs who do not have the capital to absorb the cost of adding hundreds of thousands of dollars of equipment and labor costs related to implementation. Allowing MMOs to use motion activated recording maintains a stringent level of security while allowing for storage of footage that contains motion – dead space and time is not stored. Pennsylvania's security and surveillance requirements are some of the strictest of across the country's medical marijuana

programs. By way of example, the Department of Homeland Security Privacy Impact Assessment for the DHS CCTV Systems (July 18, 2012) stated that data is stored for a maximum of six months and then automatically deleted. Records retrieved pursuant to a suspected crime would be retained until an investigation or enforcement action is completed. The lengthy storage requirements create privacy concerns for individuals being recorded.

PCC authored a detailed memo regarding this suggested amendment that serves as an addendum to this memo.

Act 16 should be amended to allow motion activated recording for video surveillance at MMO facilities.

9. Elimination of Redundant Testing While Continuing to Provide Patients Medicine Safely and Securely

Act 16 requires redundant testing of medicine, creating delays in getting medicine to patients while providing no increase in safety. Medical marijuana products undergo extensive testing for microbials and heavy metals before the products are made available to patients. Products that fail final testing are not sold to patients. Final product testing is the safe and efficient standard practice used by the majority of medical marijuana programs. Multiple testing at all different phases of medicine production is redundant and costly. The savings experienced by elimination of redundant testing can be passed on as cost savings to patients.

Similarly Act 16 requires "stability" testing for medical marijuana. This is a standard and worthwhile practice, as it assists MMOs in assuring that their medicinal products are safe to use through the expiration date on products that are available to patients. The current regulations require MMOs and laboratories to stability test medicine that is no longer in stock and past its expiration date. Allowing for stability testing at three-month intervals would reduce the likelihood of out-of-stock medicine being subject to testing again creating cost savings that can be passed on to patients.

Act 16 should be streamlined to eliminate redundant and unnecessary testing requirements.

10. Removing Marketing and Advertising Approvals from DOH Authority

Act 16 does not require the Department to approve MMO marketing and advertising. However, the Department's emergency and proposed final regulations require MMO's to have all marketing and advertising approved by the Department. The has created confusion and frustration among operators, as the standard for what will and will not be approved is unclear; further, Act 16 already states the advertising and marketing standard that MMOs must follow. Pennsylvania MMO operators have consistently and responsibly followed the Act 16 requirements governing advertising and marketing. By removing the process of pre-approval MMO's can focus on communicating available medicine to patients in a timely manner.

Act 16 should be amended to clarify that the Department should not pre-approve advertising and marketing materials; instead, they should regulate these activities as they do all other MMO activities – through inspections and investigative activities.

SOCIAL EQUITY

11. Allow Individuals with Prior Misdemeanor Drug-related Convictions to Obtain Medical Cannabis Employment, and a Path to Rehabilitation

Act 16 prohibits *any* individual convicted of *any* charge related to "the sale or possession of illegal drugs, narcotics, or controlled substances" from obtaining employment in the industry – even someone with a several decade old misdemeanor conviction. This prohibition defies logic in securing a path of rehabilitation for those individuals who commit even the most minor offenses in our criminal justice system. It goes without saying, this prohibition blocks employment opportunities within communities of color most acutely, where the focus of law enforcement activity and enforcement for nonviolent drug possession has persisted for decades, despite longitudinal research showing that all Americans use drugs at similar rates regardless of race or demographics.

As an example, Act 16 keeps individuals arrested for simple possession of drug paraphernalia or personal use amounts of a controlled substance from obtaining employment. Additionally, there is no time-limit to this exclusion, indefinitely prohibiting someone who has sought treatment and successfully stopped using drugs from obtaining a living-wage job that will only serve to support a sustained recovery from drug use and addiction. The Pennsylvania medical cannabis industry has already created nearly sixteen thousand family-sustaining jobs for the Commonwealth, but the current law prohibits access to employment for the very communities that need economic opportunity the most. As the industry continues to grow and thousands of good jobs remain available, this simple policy change can support the goal of remedying the harms created by the War on Drugs by opening up employment to those convicted for misdemeanor drug offenses.

Act 16 should be amended to provide a path to allow individuals with a past misdemeanor drug-related charge to work in the industry.