DH, MMRegulations

From: DH, MedMarijuana
Sent: Wednesday, April 7, 2021 10:09 AM
To: DH, MMRegulations
Subject: FW: [External] Pennsylvania Cannabis Coalition Comments of Proposed MM Regulations
Attachments: Pennsylvania Cannabis Coalition Comments on Proposed Final Regulation #10-219_ Medical Marijuana.pdf

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From: Meredith Buettner <meredith@pcanna.org>
Sent: Sunday, April 4, 2021 1:09 PM
To: DH, MedMarijuana <RA-DHMEDMARIJUANA@pa.gov>
Subject: [External] Pennsylvania Cannabis Coalition Comments of Proposed MM Regulations

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Director Collins,

I hope this email finds you well. Please find attached the comments from the Pennsylvania Cannabis Coalition regarding the proposed final regulations for Pennsylvania's Medical Marijuana Program.

Please advise if we can be of any further assistance.

Best,

Meredith Buettner
Executive Director, Pennsylvania Cannabis Coalition
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Click here to schedule a meeting with me via Calendly

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Via FedEx and Email

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Re: Pennsylvania Cannabis Coalition Comments on Proposed Final Regulation #10-219

April 2, 2021

Dear Commission Members,

Thank you for the opportunity to provide public comment in response to the proposed permanent regulations for Pennsylvania's Medical Marijuana Program, filed by the Department of Health under 28 Pa. Code §1131 *et. seq*. On behalf of the members of the Pennsylvania Cannabis Coalition ("PCC"), we are providing a series of comments in regard to these proposed regulations for your review and consideration.

The Pennsylvania Cannabis Coalition is the trade association representing the current permit holders in Pennsylvania's Medical Marijuana Program. Our membership represents more than 85% of the medical marijuana operators who hold grower/processor, dispensary, laboratory and clinical research permits in the Commonwealth. The PCC members have proven over the five-year life of the program that they are capable of delivering medicine safely and securely to qualifying patients in a highly regulated environment, and subject to some of the strictest standards of any medical marijuana market in the nation.

As the businesses directly impacted by these regulations, we find it incredibly problematic that the Department did not attempt to conduct any outreach to the industry, build consensus, or even simply solicit informal feedback prior to the submission of these regulations for the Independent Regulatory Review Commission's ("IRRC") consideration. While advanced notice of rulemaking is not required, it is customary for impacted stakeholders to be engaged in the rulemaking process. PCC member perspectives were not considered in the development of the proposed permanent rules now before you – either individually as licensed medical operators, or collectively as the sole advocacy organization representing the Commonwealth's medical marijuana industry. Generally, the Department of Health did not ask for input, feedback, or hold

hearings during their drafting of the proposed final rules. In fact, the last public meeting of the Medical Marijuana Advisory Board scheduled for February 23, 2021 was canceled without any notice to permit holders, patients, or the public. Nonetheless, these rules were not discussed or provided for input at any meetings previous to this meeting. It's important to note that, as many PA permit holders also do business in other states, this type of behavior is not the rule but is the outlier. Other states hold these important input gathering sessions, most often several times before making regulations final.

PCC members have been operating under the temporary regulations for five years. During this time, operators have expressed concerns, asked for clarification, and made suggestions to improve the temporary regulations based on firsthand experience in the Commonwealth, often with valuable perspective from compliant and well-established business practices established in other state jurisdictions. Instead of engaging MMOs as partners in the shared mission to deliver medicine to patients safely and efficiently, the Department has instead refused to garner feedback and perspectives from the very businesses that are implementing the regulations into their daily operations.

During the period in which the existing temporary regulations have been in place, PCC members have been subject to rulemaking via statements of policy, issued by mass email to all Pennsylvania permit holders. DOH's utilization of this arm's length communication strategy has generated significant confusion. To make matters worse, the statements of policy are often issued after the Department's previous approval of permit holders' operational plans and subsequent inspections, and in many instances, contradicted the medical marijuana facility's pre-approved operations and practices. Despite the uncertainty, lack of clear communication, and unorthodox implementation of the temporary regulations on the Department's behalf, Pennsylvania's medical marijuana operators have successfully delivered medicine to over 450,000 patients in the Commonwealth.

The medical marijuana industry has experienced significant innovation over the five-year life of the program. While operators have continued to safely deliver high-quality medicine to patients, the regulations have not kept pace with innovation. The proposed final regulations before the IRRC do not account for new technologies, techniques, and industry best practices. In some cases, the regulations do not even align with standard industry practices.

During the Covid-19 emergency pandemic, the Department made several emergency changes to enhance the overall safety of the program, such as allowing curbside delivery to minimize patient exposure, and permitting practitioners to consult and certify patients via telemedicine conference. Medical marijuana operators were not only able to implement these changes without negatively impacting services to our patients, but were able to do so while sustaining a 2% market growth per week in the program. The Medical Marijuana Advisory Board recommended adopting the Covid-19 emergency protocols into the permanent regulations, citing in part the ability for operators to safely and effectively implement the temporary guidelines. The Department did not accept the Medical Marijuana Advisory Board's

recommendations, and refused to memorialize these changes in the proposed permanent regulations.

Please find our comments regarding the proposed permanent medical marijuana regulations below and attached.

Thank you in advance for your consideration,

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Regulatory Analysis Form - Public Comment and Response

After review of the Regulatory Analysis Form accompanying the Department of Health's (hereafter, "the Department" or "DOH") proposed permanent regulations for Pennsylvania's medical marijuana program, PCC members raise a significant concern over the mischaracterized statement that DOH obtained the input of existing medical marijuana operators in the development of the rules. As will be discussed in turn, PCC members also object to the DOH's sentiment repeated throughout the regulatory analysis that the impact of these rules will improve the medical marijuana industry as a whole. Prior to the proposed permanent regulations being issued, direct input from the currently regulated industry operators should have been sought and considered, and the DOH did not extend this customary courtesy. With the opportunity to now do so before the Commission, the PCC offers the following public comments in response to the DOH's Regulatory Analysis Form.

I. *Despite its statements to the contrary, the Department of Health did not seek input and feedback from current medical marijuana operators in Pennsylvania in its draft permanent regulations.*

The Department discusses the necessity for permanent regulations "for the continued viability of the [medical] Program … " and, to "keep pace with the evolution of the [medical] Program." (*See* Regulatory Analysis Form, Question 10, p. 3). In fact, due in large part to the failure of DOH to seek the input of current operators in developing the proposed permanent rules, the draft regulations fall short of keeping pace with industry best practices and established standards, and in many instances, have and will serve to stifle the viability of Pennsylvania's medical cannabis program. See the entirety of our comments for detailed examples of how the proposal financially and operationally injures industry operators.

DOH further compares Pennsylvania's proposed permanent regulations to that of the other 35 states with medical marijuana programs. (*See* Regulatory Analysis Form, Question 12, p. 3-4) While there are certainly similarities between the programs, and notable successes specific to the development of the clinical registrant program, in practice, the regulatory experience of medical operators in Pennsylvania is simply not comparable to the working relationships operators have with regulators in other states. Several state operators within Pennsylvania have medical cannabis licenses in multiple states, and have first-hand knowledge of the disparities between the regulatory relationships in Pennsylvania and that of other programs. In many other jurisdictions, medical operators experience a partnership with their regulators, which includes

open communication, regular meetings, data reporting, and a feedback mechanism for regulatory decision-making. Such an open and collaborative dynamic between regulators and industry operators simply does not exist in Pennsylvania.

The Department expressly claims that it has "requested input throughout the temporary regulation drafting process, including regarding changes to the regulations, by surveying different groups of stakeholders, including permittees, approved laboratories, caregivers and patients." (*See* Regulatory Analysis Form, Question 12, p. 4). Frankly, as it pertains to medical marijuana permit holders, this statement is completely untrue. In fact, there was no engagement with the medical marijuana industry prior to the publication of the proposed permanent regulations. When operators asked DOH of the status of final regulations, Director John Collins indicated he did not know what the status was, when drafting might be complete, or when they would be released as a final proposal. Current medical marijuana permittees were made aware of the proposed permanent regulations through outreach by legislative staff, not by the DOH.

The DOH did not conduct any surveys, meetings, or hearings, formally or informally, in order to consider current industry operators' perspectives during the rulemaking process. DOH goes on to state, "Given that stakeholders had input on the temporary regulations, and these proposed regulations are substantially similar, there are no expected public meetings or hearings." (*See* Regulatory Analysis Form, Question 29, p. 21). Here, DOH makes clear its intention to not only draft the proposed regulations without industry insights, but further intends to finalize the regulations without any additional opportunities for public or private discourse with medical marijuana permit holders. Alarmingly, DOH declares that its proposed draft regulations are "the necessary regulatory framework for continued program development and success," without any input from the medical marijuana businesses that are directly tasked with carrying out such developments and program improvements.

II. Despite its statements to the contrary, the DOH does not report de-identified or aggregate data metrics, privately or publicly, that could benefit the industry and public's knowledge about the development of the medical program.

With regard to data transparency and reporting metrics, the DOH now has an established track record of refusing to offer program statistics and data metrics, and these practices are further entrenched within the proposed regulations. In Question 10, the Department demonstrates its own lack of demonstrable figures to assess the impact of its proposed regulations. Since the inception of the program, the DOH has been reticent to provide aggregate and de-identified data on patient numbers, employment statistics, sales, qualifying conditions, or other relevant statistics. Other state regulators provide weekly, monthly, or quarterly program statistics to operators and the general public, in an effort to provide opportunities for trend analysis and help educate the public about the health of the program. Here, the Department specifically acknowledges that they do not keep an updated record of the total cannabis jobs in the state, despite being the state regulator tasked with final approval of all medical marijuana employees.

The Department refers to data that may become available as the result of research into the medical marijuana program and its efficacy by the current clinical registrants in Pennsylvania. (*See* Regulatory Analysis Form, Question 12, p. 4). To date, all of these research summits have been closed, and the Department only coordinates with the clinical registrants themselves, ultimately withholding any beneficial data or information for the benefit of? outside businesses, organizations, or the public at large.

III. Citing medical marijuana's current federally illegal status, the DOH fails to adequately address the regulatory impact on small businesses in Pennsylvania's medical marketplace, either by applicable standards or engagement with independently owned businesses.

In a series of questions related to the regulatory impact on small businesses under the proposed regulations, the Department claims that it is unable to establish a workable criteria or accurately define a "small business" for purposes of the medical marijuana regulations. (*See* Regulatory Analysis Form, Questions 14-16, p. 4-6). It is clear from these questions that the rulemaking process seeks to address the regulatory impact on all businesses, but small businesses specifically, and rightly so. The U.S. Small Business Administration ("SBA") calculates small business designations based upon the average number of employees and average annual receipts of a given industry. (*See U.S. Small Business Administration, Table of Small Business Size Standards Matched to North American Industry Classification Systems Codes,* eff. August 19, 2019). The DOH is the only agency in the state with access to sales figures, transactions, and gross receipts from cultivation to retail sale. As mentioned above, DOH further concedes that despite its oversight over every employee hire and termination in the Pennsylvania medical marijuana program, it "does not maintain information on the numbers of employees each dispensary employs," without explanation as to why it does not keep employment figures on behalf of the state. (*See* Regulatory Analysis Form, Question 15, p. 5). In sum, there is no reason why the DOH could not apply the same SBA standards and guidelines to the medical marijuana program in establishing standards and policies that may be helpful to small businesses.

At a minimum, DOH could have conducted proper outreach to garner feedback from smaller entrepreneurs in the Pennsylvania medical market, such as independently owned and operated dispensaries, and assess how the proposed regulations would impact operations and costs for the businesses who are operating on thinner profit margins and have less access to capital. As a few examples, requiring continuous video surveillance and retention for a minimum of two years, and changing all disclaimer signs from "visitor" to "individual," will cost these dispensaries hundreds of thousands of dollars, and may make the difference between profitability and loss for some Pennsylvania operators.

IV. By its own determination, the DOH falsely concludes that the proposed regulations will have no financial impact on Pennsylvania medical operators, and will spur growth rather than create obvious impediments to improve operations.

In a recurring theme, but a sentiment that cannot be understated, the Department of Health concludes on its own accord that "the costs provided in the current temporary regulations would

be unchanged by the proposed permanent regulations." (*See* Regulatory Analysis Form, Question 19, p. 9). This conclusion is drawn without the customary input and feedback from current medical operators, but rather through a cursory analysis of the current fees assessed on the various licenses available in the medical program. Had the Department engaged the industry stakeholders that are operating under the temporary regulations in the development and drafting of its permanent rulemaking, it would have found that the proposed regulations will invoke significant and unnecessary costs in areas such as additional security and surveillance requirements, new signage, increased testing requirements, and labeling and packaging of products, to name a few. Furthermore, the DOH could have added input into its proposed permanent regulations that substantially reduce operating costs and help pass on savings to patients, without sacrificing security or regulatory controls, and truly help to build a better and more effective medical program into the future.

An overshadowing factor that must be considered with all regulatory implementation costs, which will be discussed in further detail throughout this comment, is the inability for medical marijuana businesses to deduct ordinary and necessary business expenses from state and federal corporate income taxes, due to marijuana's continued federally illegal status and the tax penalty provision contained in Internal Revenue Code 280E. (*See* 26 U.S. Code § 280E.) These new proposed regulations in areas such as new signage, new camera and surveillance equipment, and data retention cannot generally be "written off" or deducted to avoid tax implications like other similarly situated manufacturing and retail industries. Unfortunately, these additional costs will in many cases be passed on to the overall healthcare costs for patients that rely on medical cannabis as part of their treatments.

Proposed Final Regulations - Public Comment and Response

I. Visitor Access

- Regulation Sections
  - §1151a.22(a)(2)(ii) - Plans of Operations
  - §1151a.25. - Access to Grower/Processor Facilities
  - §1161a.29(a)(2)(ii) - Plans of Operations
  - §1161a.30. - Access to Dispensary Facilities
- PCC Requested Language Change
  - Strike the proposed changes in §§1151a.25 and 1161a.30, and maintain Temporary Regulations §§1151.25 and 1161.30 (and corresponding provisions) allowing visitor access subject to existing identification, log, and escort protocols.
    - PCC requests that instead of making unnecessary and unwarranted changes to the visitor access regulations in §§1151.25 and 1161.30, that the DOH simply revert to and codify the existing temporary regulatory protocols as written, allowing for secure and documented visitor access into permanent regulation. Further, PCC requests that the DOH actually begin to follow and enforce these rules.
- Rationale
  - Medical marijuana establishments are not public facilities. The premises are strictly regulated and highly secure, with surveillance and access control protocols unrivaled by any other retail or pharmaceutical environment. Medical marijuana facilities are also currently places of significant public interest. Members of the media, government officials, researchers, consultants, investors, and academic institutions are seeking to learn more about the business practices of this nascent frontier in medicine. The ability for relevant third parties to see and appreciate

the sophistication of grow facilities and dispensing floors firsthand is essential to the continued evolution and betterment of medical cannabis operations, which is why every state in the nation, including Pennsylvania, has structured visitor access permissions to facilitate hands-on learning and discussion.

Since the passage of Act 16 and the issuance of temporary regulations for implementation of Pennsylvania's medical cannabis program, specific regulatory protocols have been in effect to allow for safe, secure, and transparent visitor and vendor access at grower/processor facilities and dispensaries. These processes are primarily set forth under §1151.25 "Visitor access to grower/processor facilities" and §1161.30 "Visitor access to dispensing facilities." The current temporary regulations very clearly lay out a reasonable protocol to ensure all visitors to a medical marijuana facility are adults with valid government identification, properly documented by facility security, and escorted by a facility agent at all times. Medical marijuana agents and security personnel are further tasked with preventing the visitor from touching marijuana plants or products while on-site.

There is currently no issue with the regulatory language of the visitor access provisions, which mirrors that of other state jurisdictions. Rather, the issue has been and remains the DOH's unwillingness to abide by the plain language of the regulations. Instead of allowing medical marijuana facilities in Pennsylvania to document and securely escort visitors onto the premises in accordance with the rules, the DOH has granted itself extra-regulatory powers not authorized in statute or regulations, and ostensibly prevented visitor access to operational grower/processor and dispensing facilities throughout the entirety of the Commonwealth's medical program. With a complete disregard for the existing process laid out in temporary regulation, the DOH has instead only permitted visitors to enter the facility after a certificate of occupancy is granted, but prior to medical marijuana plants or products coming on-site, or required legislators (and not other public officials) to make a visitor request on that lawmaker's official letterhead.

The rationale for this constricted interpretation of the rules has not been explained to medical marijuana operators, presumably because there is no legal or regulatory basis to support it. In practice, the outcome has been a mere matter of days in which medical facilities can bring interested and relevant parties into a given facility before it opens. Under the DOH's current practice, the interested parties are not able to see the operations of the facility with employees and

management cultivating and processing live plants or dispensing products on-site, only the hollowed-out structure that will one day house such operations. In many instances, these are not just interested parties, but the local officials that the DOH now proposes to deem "unnecessary" that have facilitated the onboarding and construction of a medical facility within their jurisdiction.

The result is a missed opportunity for the entire Commonwealth of Pennsylvania to educate parties interested in learning more about the cannabis industry -- whether pro or con -- from seeing and attaining such knowledge for themselves, and through consultation with a facility agent. Under DOH's past practices and current proposed visitor access rules, a city's building inspector can gain access to the property for purposes of ensuring compliance with local code and ordinance, but the Mayor and Council members are unable to view the operations while escorted with licensed medical marijuana agents to learn more about the business under their jurisdiction. A state regulator can access the facility at any time, but the very legislators that authorized the medical cannabis industry under Act 16 are precluded from entering an operational facility without a patient card. No interested media outlets, industry researchers, or academic institutions can witness a given facility's operations for the benefit of information gathering and further discovery of the business.

The highly restrictive visitor access protocols that DOH has enforced also significantly constrain the business operations of current medical marijuana operators. There have been examples where licensed wholesale and sales consultants working as licensed agents for grower/processors are unable to access the dispensaries where the grower/processor seeks to sell medical cannabis products. In some instances, and only where the circumstances permit, wholesale agents have obtained medical patient cards just to step foot into the dispensaries where medical product suppliers are seeking to do business. This is of course not a practical solution, and a regulatory circumstance that no other industry in Pennsylvania would be required to endure, which is why the Temporary Regulations clearly contemplate visitor access permissions with appropriate accountability and oversight.

Astoundingly, under the proposed permanent §§1151a.25 and 1161a.30 and its corresponding provisions, DOH now proposes to amend the regulations and codify its past extra-regulatory practices by expressly excluding "visitors" from third-party access to operational facilities altogether. The amended rules would require "individuals" seeking to gain access to the facility to detail "the need for entry"

under subsection (a), and only grant such permissions to government officials under subsection (g) "if necessary to perform the government officials' functions and duties that pertain to the act or this part." In accordance with DOH's past practices, the rule would now expressly limit all "unnecessary" third parties from access to medical cannabis operations, in spite of the requirements for the visitors to be escorted with a facility agent, under constant video surveillance, and subject to access controls throughout the premises.

The most secure institutions in the United States have some form of access for outside visitors and media members in place. Jails and prisons have permitted third-party visitor access protocols. Nuclear facilities under the highest levels of federal regulatory scrutiny permit secure processes for third-party visitor access. The DOH's current practices, and its proposed permanent rules reflecting these practices, defies reasonable logic and well-established protocols that have existed in this country in highly regulated facilities. Continuing to prevent reasonable study and public knowledge that can only be obtained through firsthand observation only serves to stunt the growth, education, and development of the medical marijuana industry in Pennsylvania.

II. Background Checks

- Regulation Section
    - §1141a.31(d)
- PCC Requested Language Change
    - (d) A financial backer, principal, or employee may not hold a volunteer position, position for remuneration, or otherwise be affiliated with a medical marijuana organization or a clinical registrant if the individual has been convicted of a criminal offense relating to the sale or possession of illegal drugs, narcotics, or controlled substances; provided, however, than an employee may submit an attestation to the Department documenting that he or she has not been convicted of a prohibited criminal offense under this subsection, and begin employment with a medical marijuana organization pending the outcome of a fingerprint submission and criminal history background check pursuant to subsection (a) of this Section. If a prohibited conviction is returned on the applicant's criminal history record, the Department shall notify the applicant and the medical marijuana organization, and the employee shall immediately cease any and all employment duties at the medical marijuana organization.

- Rationale
    - Efforts to prevent diversion and maintain the security of medical marijuana facilities is a paramount priority for the PCC, and is vital to maintain the sustainability of the medical marijuana industry as a whole. PCC members are vigilant in ensuring that careful vetting and background screening are done prior to offering employment to a job candidate, in addition to the State Police and FBI background check requirements required by state law and regulation. However, the current time period between the potential employee's fingerprint submission and the result of a State/FBI criminal history check, which run on average about two months, and can in some instances be delayed up to four months or longer, is e a significant hindrance to staffing operations, and retaining highly qualified and eligible employees through the hiring process. In many instances this issue has caused a facility to not be able to open on time, and left facilities significantly understaffed as operators wait for DOH to approve employees.

      Many times, although a potential employee has been extended an offer, and a medical marijuana operator has conducted and approved an external third-party background check, the employee often moves on to obtain another job, changes their home or location to search for other employment, or simply loses interest in the position due to the very significant lag time between receiving the offer of employment and actually beginning paid work. These circumstances make it difficult to recruit and retain talented employees that are otherwise clearly qualified, and will uphold the security and safety standards intended within the company's operations and required by law. These lost opportunities also run counter to the important job creation goals underlying the authorization of Act 16 at the inception of the Commonwealth's medical marijuana program.

      To maintain security and background check processes, but reduce friction and unnecessary delay in the hiring process, PCC proposes a "provisional" model that has been adopted in other state markets successfully, and that aligns with the criminal history and background check requirements of Act 16.[1] The proposed affidavit process allows employees that have been extended an offer by a medical marijuana organization to submit an attestation to the Department under oath that he or she does not have a prohibited disqualifying conviction for the sale or

[1] *See* State of Illinois, Executive Order 2020-57, eff. Oct 2, 2020; ("Section 1. The requirement that a medical or adult use cannabis cultivation center agent must have a completed background check when applying for an agent identification card pursuant to 410 ILCS 705/20-40(b) and 410 ILCS 130/95(b) is suspended provided that the cultivation center agent's application to the Department demonstrates that the cultivation center agent has submitted a full set of fingerprints to ISP for the purpose of obtaining a State and federal criminal records check.")

possession of illegal drugs, narcotics, or controlled substances, and begin working, provisionally, while the full fingerprint background check is pending.

Of course, if the background check comes back with a disqualifying conviction, the employee will be immediately terminated in accordance with the prohibited convictions requirements of Section 614 of Act 16. This proposal balances the public safety and anti-diversion efforts of PCC members and the Department, with the interests of ensuring a streamlined staffing and hiring process that will promote job growth and retention within Pennsylvania's medical program.

III. Start-up Inventory

- Regulation Section
    - § 1151a.24. Start-up inventory

- PCC Requested Language Change

(a) A grower/processor may obtain seeds or immature medical marijuana plants from outside of this Commonwealth, at least once per year, during a 30-day window upon approval by the Department ~~for the purpose of securing its start-up inventory~~. Seeds or immature medical marijuana plants obtained from outside of this Commonwealth shall be obtained within 30 days from the date that the Department determines that the grower/processor is operational or within any 30-day window following approval ~~established~~ by the Department ~~if the Department determines that the importation of additional seeds is necessary~~.

~~(b) A grower/processor may not obtain medical marijuana plants from outside of this Commonwealth at any time.~~

(b) Within 24 hours of receipt, a grower/processor shall record in the electronic tracking system each seed or immature medical marijuana plant that enters the site during the 30-day period under subsection (a).

(c) Outside any 30-day period permitted under subsection (a), a grower/processor shall only grow medical marijuana plants from seeds or immature medical marijuana plants located physically in its facility, or purchase seeds, immature medical marijuana plants or medical marijuana plants from another grower/processor.

- Rationale

The current and proposed regulations appropriately contemplate sourcing of genetic plants and seeds to begin cultivation at a licensed grower/processor. However, the limited permissions for sourcing plants and seeds fail to recognize that genetics require updating and refreshment over time, and grower/processors in Pennsylvania will remain at a disadvantage in sourcing the best possible strains that can not only maximize plant yields, improve plant resiliency, and pass savings along to patients. Most importantly, establishing an ongoing process for genetic plant sourcing will improve the therapeutic benefits and qualities of higher quality cannabis products for patients within the Commonwealth. Notably, despite these limited permissions already codified in the current temporary regulations, DOH has yet to formally approve a statewide process that allows for sourcing of seeds and plants for all permit holders. As such, PCC proposes a streamlined expansion of the proposed regulatory permissions for sourcing of plant materials on an ongoing basis, following the current protocols that ensure regulatory oversight, security, and accountability in adopting new plant genetics.

The requested change to the regulation will allow MMOs to act within the plain language and intent of Act 16's Section 702(a), and source new genetic plant material both from other in-state MMOs *and* from outside the Commonwealth to initiate new strains and improved genetics to produce the best medical marijuana possible. Denying operators out of state genetics substantially limits opportunities for product development and improvements in Pennsylvania's cannabis industry. From an agronomic perspective, without introducing new genetic plants, continued asexual plant propagation results in a phenomenon known as "clonal degradation," which results in weaker, lower yielding plants over generations of reproduction from the same genetic material.[2]

In addition, the proposed regulation on sourcing of genetic plants fails to establish the standards by which the Department will determine the necessity of importation, which adds a regulatory determination that falls outside of the legislative text of Section 702(a) of Act 16. Operators have the knowledge, resources, and experience to determine the necessity of new genetics, and in accordance with Act 16, regulators must simply establish a secure process that

[2] *See Science News,* August 8, 2011, "Why Plant Clones Aren't Identical." available at https://www.sciencedaily.com/releases/2011/08/110804212931.htm; ("A new study of plants that are reproduced by 'cloning' has shown why cloned plants are not identical. Scientists have known for some time that 'clonal' (regenerant) organisms are not always identical. Now researchers believe they have found out why this is the case in plants: the genomes of regenerant plants carry relatively high frequencies of new DNA sequence mutations that were not present in the genome of the donor plant.")

incorporates plants into the state's inventory tracking system within security and surveillance protocols.

Grower/processors who began cultivation in 2019 are using genetics that are now three years old, and there is currently no avenue to obtain and develop new genetic strains from inside or outside of the state. To date, and only within the past several months, the Department has only authorized a pilot program for the purchase of plant material between in-state operators. While MMOs have been made aware that this pilot took place, the Department has not formally approved a process by which all operators can source plant materials from other in-state grower/processors.

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 medical cannabis. By allowing an annual 30-day window to source out-of-state genetic material, operators will have the ability to increase the variety of their medical offerings and offer patients medical products manufactured from the highest quality strains. Coupled with Pennsylvania's first-in-class clinical research program, this simple change will help generate the best available products for ongoing study of plant biology and agronomic science.

IV. Security and Surveillance

- Regulation Sections
    - §1151a.26
    - §1151a.31
- PCC Requested Language Change

§1151a.26

(a) (2) A professionally-monitored<u>, motion-activated</u> security and surveillance system that is operational 24 hours per day, seven days per week and records all activity in images capable of clearly revealing facial detail. The security and surveillance system must include all of the following:

...

(a) (4) The ability to record and store all images captured by each surveillance camera for a minimum of ~~two years~~90 days in a format that may be easily accessed for investigative purposes. The recordings must be kept:

...

(b) (5) The grower/processor shall designate employees to ~~continuously~~ monitor the security and surveillance systems at the facility.

…

§1161a.31

(a) (2) A professionally-monitored, motion-activated security and surveillance system that is operational 24 hours per day, seven days per week and records all activity in images capable of clearly revealing facial detail. The security and surveillance system must include all of the following:

...

(a) (4) The ability to record and store all images captured by each surveillance camera for a minimum of ~~two years~~90 days in a format that may be easily accessed for investigative purposes. The recordings must be kept:

…

(b) (5) The dispensary shall designate an employee or employees to ~~continuously~~ monitor the security and surveillance systems at the facility.

- Rationale

  - The current temporary and proposed permanent regulations require a minimum two years of data retention for video surveillance systems, which on its own, is an insurmountable economic burden for Pennsylvania medical marijuana operators. The two-year data retention standard runs up facility security costs hundreds of thousands of dollars. It is an outlier requirement that far exceeds the data retention standards established in other state markets, and other similarly regulated industries.

    Pennsylvania MMOs are currently subject to some of the most stringent video retention requirements of any program in the country. Pennsylvania will remain an outlier if the proposed permanent rules go into effect as written. For

comparison, the next highest data retention requirement is at Illinois cultivation sites, requiring a mere 180 days of video retention, and allowing for the use of motion-activated cameras. Maryland, Massachusetts, New York, and Ohio all require 90 days of video retention at dispensary and cultivation sites. A current Pennsylvania grower/processor is required to maintain more data within their video retention systems than the entire written collection of the Library of Congress. Codifying this two-year data retention standard will only perpetuate this unnecessary and insurmountable cost, and place Pennsylvania medical operators at a competitive disadvantage into the future.

For comparison into highly regulated industries outside of the medical marijuana markets, Illinois firearm dealers are required to retain video surveillance for a minimum of 90 days.[3] New York State's banks must maintain video surveillance recordings for at least 45 days.[4] Nevada requires casinos to keep video for a minimum of 7 days, unless questioning by security personnel of a subject occurs, in which case the minimum retention period is extended to 30 days.[5] Illinois law enforcement body camera recordings are required to be maintained for a minimum period of 90 days.[6]

To exacerbate this costly data retention requirement, although not required by law or regulation, on November 5, 2020, the DOH recently issued a supra-regulatory mandate on all operators to replace motion-activated cameras with continuous surveillance equipment. Making matters worse, this mandate was issued *after* the Department reviewed operational security plans, conducted inspections that included motion-activated cameras at dispensary and grower/processor facilities throughout the Commonwealth, and approved the installation and use of motion-activated surveillance systems. The Department's about-face caused many operators to have to replace their camera systems entirely.

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[3] *See* 430 ILCS 68/5-80. ("All video surveillance records, along with any sound recordings obtained from them, shall be kept for a period of not less than 90 days.")

[4] *See* N.Y. Laws 2014, Article 2-AA-75-c. ("The recordings made by such cameras shall be preserved by the banking institution for at least forty-five days.")

[5] *See* Nevada Gaming Commission Regulation, Standard 9(1), "Records" ("All video recordings of coverage provided by the dedicated cameras or motion-activated dedicated cameras required by these standards must be retained for a minimum of 7 days, except for recordings of detentions and questioning by security personnel, which must be retained for a minimum of thirty (30) days. All other recordings must be retained a minimum of 3 days.")

[6] *See* 50 ILCS 706/10-20(7). ("Recordings made on body worn camera must be retained by the law enforcement agency or by the camera vendor used by the agency for a period of 90 days.")

The requirement to continuously record on premises without interruption further serves to increase the failure rate of these systems, and in turn, makes the facilities *less* secure. By requiring 24/7 continuous recording without reprieve, the "burn rate" or failure of surveillance hardware and hard drives increases, which could result in missing video retention of relevant activity. The increased failure rate also increases up front and ongoing maintenance costs. The amount of data required to be stored by this new requirement equates to terabytes and would include countless hours of recordings of dark, inactive rooms, providing no value to operators, regulators, or investigators from a compliance or security standpoint.

Together, these requirements place an unjustifiable economic burden on the medical marijuana industry as a whole, ultimately passing security costs onto patients. More importantly, neither of these security requirements provide any additional benefit to the safety or security of dispensary and grower/processor facilities, or provide relevant investigatory or compliance value.

For context, a cost estimate of the data storage and maintenance for continuous surveillance recordings is set forth below:

Dispensary Costs: Two-Year Continuous Surveillance and Data Retention

- 24/7 Data Storage -- 730 days $100,000
- Software System $24,000
- Backup Generator Capacity $10,000
- Total Cost Per Dispensary / 2 yr. **$134,000**

Cultivation Costs: Two-Year Continuous Surveillance and Data Retention (32K sq ft facility with 6K sq ft of Canopy)

- 24/7 Data Storage -- 730 days $500,000
- Software System $72,000
- Backup Generator Capacity $20,000
- Total Cost Per Cultivation Site / 2 yr. **$592,000**

As a reasonable solution, PCC proposes a reduction in the video retention standard, from two years down to the commonly accepted standard of 90 days. A three-month lookback period is well-established in other state medical marijuana markets and other regulated industries, and allows a substantial period of time for regulators or investigators to flag relevant video for further inspection. Once the relevant video is flagged for retention and transferred to regulators and

investigators, it can be retained as evidence, for training, or other relevant compliance purposes, as long as necessary.

Further, the PCC proposes to codify motion-activated cameras, a technology that was previously accepted by the Department, into the security and surveillance standards for medical operators. In accordance with the plain language of Act 16 and the accompanying standards in regulations, this technology will effectively record "all activity" that takes place within a medical marijuana facility, 24 hours per day, seven days per week.

Finally, seeking only additional clarification in the permanent regulations, the requirement for employees to "continuously" monitor security and surveillance of the regulations is open to interpretation, and suggests an employee must watch and monitor cameras 24 hours per day. All facilities are currently required to be monitored 24 hours per day by third-party alarm and security vendors, and facility agents and state regulators have remote access to the facility's cameras in the event an alarm is triggered. Simply put, it is unnecessary and extremely costly for a facility employee to physically monitor surveillance cameras while the facility is not operational, particularly given the current additional protections that are already in place. By removing the word "continuously" from subsection (b)(5) of the Security and Surveillance provisions, clarification is afforded that the remote monitoring of the system by an operator's approved security vendor passes regulatory muster. This change mirrors industry standards across other medical marijuana markets nationwide.

V. Recognizing Food Grade Excipients

- Regulation Section
    - §1151a.27.(f)
- PCC Requested Language Change
    - "A grower/processor may not use any added substance that alters the dosage level, color, appearance, smell, taste, effect, or weight of the medical marijuana unless the grower/processor has first obtained the prior written approval of the Department. Excipients must be pharmaceutical grade <u>or food grade</u>, unless otherwise approved by the Department. In determining whether to approve an added substance, the Department will consider:

- (i) Whether the added substance is permitted by the United States Food and Drug Administration for use in food or is Generally Recognized as Safe (GRAS) under federal guidelines…"

- Rationale

  - Currently, the temporary and proposed permanent regulations recognize that excipients in a cannabis product must be pharmaceutical grade, but do not also expressly accept food grade ingredients as well. In recognition that one of the most popular cannabis products in the Pennsylvania medical marketplace includes orally consumed tinctures, oils, and capsules that may contain food ingredients, and in furtherance of established business practices within Pennsylvania's medical marketplace, PCC proposes to expressly add food grade excipients as an acceptable consideration for the Department when approving medical cannabis edibles or other products intended to be consumed by medical patients.

    By its application under well-established FDA standards, codifying the food grade designation will ensure that all products approved by the Department continue to include ingredients that are (1) safe for human consumption, or (2) made with materials suitable to come into direct contact with food products.[7] Moreover, this change creates consistency with subsection (f)(i), which reflects FDA guidelines for inclusion of product ingredients into medical cannabis products that are generally recognized as safe for human consumption.[8]

VI. Labeling and Packaging Clarifications

- Regulation Section

  - §1151a.29.(a)

  - §1151a.34.(b), (c), & (d)

- PCC Requested Language Change

  - § 1151a.29. Limit on medical marijuana processing.

    "(a) In the form intended to be sold to another medical marijuana organization, medical marijuana or a medical marijuana product must have a specific concentration of total THC and total CBD and must have a consistent cannabinoid profile. The concentration of the following cannabinoids, <u>if present in the</u>

[7] *See* 21 CFR §174-179.
[8] *See* 21 CFR §182-186.

cannabinoid profile at greater than 0.1%, at a minimum, shall be reported to the Department by an approved laboratory and included ~~the following~~ on the label:

(1) THC.

(2) THCA.

(3) THCV.

(4) CBD.

(5) D8

(a-5) The concentration of the following cannabinoids, at a minimum, shall be reported to the Department by an approved laboratory, and each label shall include an electronic link to access such cannabinoids contained in the marijuana or marijuana product and its corresponding percentages:

(6) CBDA.

(7) CBDV.

(8) CBN.

(9) CBG.

(10) CBC.

~~(10) D8.~~

(11) Any other cannabinoid or terpene component at › 0.1%.

- §1151a.34. "(b) A grower/processor shall package the medical marijuana products in a package that minimizes exposure to oxygen and that is:
  (1) Child-resistant.
  (2) Tamper-proof or tamper-evident.
  ~~(3) Opaque.~~
  (3) Resealable.

(c) A grower/processor shall identify each process lot of medical marijuana with a unique identifier. Such identifier shall allow for the Department to access a record of the state employee identification number of the employee preparing the package and packaging the medical marijuana product, and the employee identification number of the employee shipping the package.

(d) A grower/processor shall obtain the prior written approval of the Department of the content of any label to be affixed to a medical marijuana product package. Each label must meet the following requirements:

(1) Be easily readable.

(2) Made of weather-resistant and tamper-resistant materials. Labels that are resistant to moisture and contain acrylic adhesive shall satisfy the requirements under this subsection (2).

(3) Be conspicuously placed on the package.

(4) Include the name, address and permit number of the grower/processor.

(5) List the form, quantity and weight of medical marijuana included in the package.

(6) List ~~the number of individual doses contained within the package and~~ the species and percentage of THC and CBD and other cannabinoids enumerated in section 1151a.29 (relating to limits on medical marijuana processing), and the individual terpenes and corresponding percentages. CAS numbers need not be displayed on the label.

(a) For products that are intended to be ingested or swallowed, the label must contain the number of individual doses contained within the package.
(b) This subsection (6) shall be satisfied where the label provides directions to an electronic link to access information regarding cannabinoids in accordance with subsection (a-5) of Section 1151a.29, and the individual terpenes and corresponding percentages.

(7) Contain an identifier that is unique to a particular harvest batch of medical marijuana, including the number assigned to each harvest lot or process lot in the harvest batch.

(8) Include the date the medical marijuana product was packaged.

~~(9) State the employee identification number of the employee preparing the package and packaging the medical marijuana product.~~

~~(10) State the employee identification number of the employee shipping the package, if different than the employee described in paragraph (9).~~

~~(11) Contain the name and address of the dispensary to which the package is to be sold.~~

(9) List the date of expiration of the medical marijuana product.

(10) Include any necessary instructions for proper storage of the medical marijuana product in the package."

- Rationale
    - Within the proposed permanent regulations, the Department seeks to add relevant and comprehensive information to product labels, such as additional cannabinoids and terpenes present in the product. While the PCC strongly supports full product transparency made readily available on labels for the benefit of medical patients, there are many cannabis products that simply do not have enough space on the packaging for more than a dozen categories of information, every cannabinoid and terpene profile, and all requisite disclaimers and warnings.

      To streamline the labeling information, but ensure that full product information and transparency is available to all patients, PCC proposes to add directions to the label for patients, regulators, and law enforcement to access an electronic link that will allow readily available access to such information, without condensing it to a small packaging or container label. CBD, THC, and D8 levels will remain directly on the label, and a full profile of all cannabinoids and terpenes will be accessible electronically.

      To avoid redundant information from the label, PCC proposes to remove the dispensary to which the marijuana or marijuana product is to be sold from the required information on the label. This requirement places a burden on grower/processors to create a unique label for every dispensary. Under §1161a.28, dispensaries are already required to provide patients with a safety insert and exit label that identifies the dispensary location at the point of sale.

      In addition, PCC proposes to provide greater specificity to undefined "weather-resistant" and "tamper-resistant" labeling requirements, ensuring that labels that are resistant to environmental conditions such as rain, snow, or humidity, and have acrylic adhesive, are sufficient to pass regulatory muster. This change gives greater clarity and standardizes the requirements for each label type.

      PCC further proposes to remove the requirement that containers must be opaque. Removing this requirement would reduce packaging costs, and allow for savings that could be passed on to patients. Additionally, patients may prefer greater

transparency in being able to view the product through the container at the point of sale, which increases patient satisfaction at the point of purchase. Allowing for transparent packaging also reduces the potential for product returns, ultimately generating significant cost savings.

Finally, instead of placing the unique processing and shipping employee's identification number on every product label, PCC proposes to allow for the batch identifier to contain such information. This will ensure that the employee who packaged and shipped the product remains easily identifiable for regulators; however, the unique employee identification number is not relevant to medical patients, and therefore should be excluded to allow for the limited label space to only display important product information, warnings, and disclaimers.

VII. Transportation of Medical Marijuana

- Regulation Section
    - §1151a.35(c)
    - §1151a.36(c)
    - §1151a.37
- PCC Requested Language Change
    - § 1151 a.35(c) For deliveries reasonably expected to last longer than five hours in duration, a~~A~~ transport vehicle must be staffed with a delivery team consisting of at least two individuals. For deliveries reasonably expected to last less than five hours in duration, a single driver is sufficient to staff the transport vehicle. All deliveries must also ~~and~~ comply with the following:

        (1) ~~At least one~~ A driver or delivery team member shall remain with the vehicle at all times that the vehicle contains seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products.

        (2) ~~Each~~ A driver or delivery team member shall have access to a secure form of communication with the grower/processor, such as a cellular telephone, at all times that the vehicle contains seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and

medical marijuana products.

(3) ~~Each~~ A driver or delivery team member shall carry an identification badge or card at all times and shall, upon demand, produce it to the Department or its authorized agents, law enforcement, or other Federal. State or local government officials if necessary to perform the government officials' functions and duties.

(4) ~~Each~~ A driver or delivery team member shall have a valid driver's license.

(5) While on duty, a driver or delivery team member may not wear any clothing or symbols that may indicate ownership or possession of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products.

- §1151a.36 (c) Transport manifest.

  (c) All seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products being transported shall be packaged for shipment ~~in shipping containers~~ and labeled in accordance with § 1151 a.34 (relating to packaging and labeling of medical marijuana products).

- §1151 a.37 Transportation of seeds, immature medical marijuana plants, medical marijuana plants, and medical marijuana products.

- Rationale

  - PCC members recognize the importance of product inventory control and driver safety during vehicle transport from a secured grower/processor facility to a medical dispensary. To this end, vehicle deliveries are tightly controlled, and constantly monitored as part of each respective medical operators' inventory tracking and security controls.

    Grower/processors have learned, however, that two agents are not necessary to maintain these high standards of security and monitoring for every delivery, particularly for shorter day trips. The ability to monitor deliveries remotely from a grower/processor site is sufficient to ensure that the transport vehicle is

consistently tracked. On the back end, dispensary management and security also strictly adhere to delivery times and are able to communicate with the vehicle transport driver. With modern technology available for constant oversight of the driver's travel, and both sites holding the delivery drivers accountable, proper authorities can be contacted in an instant along the route of travel if any issues during vehicle transport arise.

As a reasonable solution within the proposed permanent regulations, PCC members propose to require two delivery drivers for trips longer than five hours, where driver fatigue may be an issue. Notably, this is merely half of the 10-hour driving limit for passenger-carrying vehicles required under the current Federal Motor Carrier Safety Administration standards.[9] For trips less than five hours in duration, PCC proposes to permit one driver to carry out the delivery. This reasonable change will help reduce delivery costs significantly and increase efficiencies, in the form of reduced product costs that can be passed onto medical patients, and create greater efficiencies in supply chain management for the medical industry.

Additionally, PCC proposes to provide simple clarifying language on applicable container standards for deliveries. Removing the words "shipping container" and replacing it with "for shipment" eliminates vagueness, and allows medical marijuana suppliers to continue to transport products in appropriate duffle bags, boxes, or other storage materials given the quantity and type of products.

Finally, by adding "medical marijuana products" to the title of §1151a.37, the regulation will make clear that grower/processors can sell medical marijuana products, such as processed or extracted THC, to other grower/processors for the purposes of processing them into finished products. This simple change will codify a practice that is already currently in place across many state medical markets, and in line with the legislative and regulatory intent of Pennsylvania's medical program.

[9] *See* 49 CFR §395.5 "Maximum driving time for passenger-carrying vehicles. (a) No motor carrier shall permit or require any driver used by it to drive a passenger-carrying commercial motor vehicle, nor shall any such driver drive a passenger-carrying commercial motor vehicle: (1) More than 10 hours following 8 consecutive hours off duty;"

VIII. Waste

- Regulation Section
    - § 1151a.40(b)
- PCC Requested Language Change
    - (b) The following types of medical marijuana waste shall be rendered unusable and unrecognizable prior to being transported from a grower/processor or an approved laboratory:
    - (1) ~~Unused,~~ Opened, surplus, ~~returned,~~ recalled, contaminated or expired medical marijuana.
- Rationale
    - The current and proposed regulations require grower/processors to destroy sealed and unopened products that are returned by patients. A simple regulatory change will allow grower/processors to safely sanitize the packaging and reinsert unopened medical products back into inventory that have been returned by patients, but of course destroy any products that have had the seal or container opened in accordance with standard product destruction protocols. The ability to resell unopened and sealed products that are returned will increase patient access to limited medical products, and reduce overall costs that can be passed on to patients.

      Currently, products that are returned to grower/processors must be destroyed, even where the products remain sealed and unopened, are lab-tested and compliance approved, and still fall clearly within the expiration date for resale. For example, if a dispensary simply accepts an incorrect order and then returns it to the grower/processor, it must be destroyed, because under the plain language of the current and proposed regulations, it has been "returned" or "unused." By allowing unopened and sealed products to be redistributed, substantial savings and efficiencies can be achieved within the medical program.

IX. Stability Testing and Retention of Samples

- Regulation Section
    - §1171a.26
- PCC Requested Language Change

    Repeal §1171a.26:

    ~~(a) A grower/processor shall request that a sample be identified and collected by an approved laboratory from each harvest batch sufficient to perform stability testing at six-month intervals for a one-year period.~~

    ~~(b) The stability test shall be performed to ensure product potency and purity and provide support for expiration dating.~~

    ~~(c) An approved laboratory shall retain a sample from each harvest batch sufficient to provide for stability testing and properly store the sample for 1 year.~~

- Rationale
    - Six and twelve-month stability testing creates redundancies in the testing process, unnecessarily increases product costs for patients, and should be eliminated entirely. The current industry standard applies a one-year expiration date on all products. With current demand for product continuing to rise, the shelf-life of products typically falls well below six months. A redundant stability testing requirement serves no benefit to patient consumer safety standards, which is already covered with the applicable expiration date.

      PCC grower/processors hold themselves to the highest internal quality assurance standards, and are already held to some of the most stringent laboratory testing standards in the nation. The elimination of six and twelve-month stability testing would make a very significant difference in accomplishing laboratory testing efficiencies, and more importantly, will ultimately make medical marijuana products more affordable for patients.