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Independent Regulatory Review Commission

MPG Consulting

April 5, 2021

Independent Regulatory Review Commission
Commonwealth of Pennsylvania
via email

Re: Comments – Pennsylvania Regulation 10-219-Medical Marijuana

Dear Madams and Sirs:

This letter contains structured comments and suggestions from MPG Consulting LLC (MPG) to the proposed permanent regulations under the Medical Marijuana Act which would replace the temporary regulations that are set to expire on November 20, 2021.

MPG Consulting provides comments on regulations occasionally when time allows to encourage good public policy and robust regulated medical and adult use cannabis markets. Recently the increase in regulatory changes in the Northeast and Mid-Atlantic States has offered MPG the opportunity to provide comment on proposed laws and regulations and to consult with government and businesses on emerging medical and adult use marijuana and consumable and industrial hemp regulatory systems.

About MPG Consulting

MPG Consulting was formed in late 2013 as a consortium between the University of Colorado's *Business Research Division*, and a major Denver-based consulting firm, *BBC Research and Consulting*. The top analysts from each of these organizations decided that marijuana policy and economics was unique enough to form a single entity that is focused purely upon economic, tax, and business issues within the legal marijuana industry.

MPG staff are renowned economists and strategy consultants, who also have extensive knowledge of the evolution of legalized marijuana markets, as well as substantial experience conducting policy and business strategy consulting specific to this emerging industry. In addition to clients in the cannabis space, MPG principals have a combined 30 years' experience advising businesses in tech, agriculture, retail, resort, real estate, and natural resources industries. Our experience in providing market analyses and policy consulting in Colorado, California, New York, New Jersey, Virginia, Nevada, Florida, and other states has provided us with an unparalleled perspective on regulated cannabis markets.

In 2014, the Colorado Department of Revenue, Marijuana Enforcement Division retained MPG to identify and measure the market size and demand for marijuana, which was subsequently used

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to manage production, and to limit illegal diversion. MPG developed customized marijuana prevalence models with the most accurate federal marijuana usage data available. MPG studies now form the basis for state taxation and production control policy. Alongside MPG adult-use estimates for the state, the research team also identified estimates for how much of the marijuana market is supplied by retail suppliers, medical suppliers, the grey market (caregivers), the illicit market, and by home-growing activity. MPG estimates for 2014 were within 10 percent of the actual outcomes.

Since inception, the MPG has conducted major marijuana market structure and demand studies state-level medical marijuana demand studies in 27 states, completed major national-level reviews of marijuana policies and markets in Canada and Mexico, and developed a landmark study that defines science-based equivalencies between marijuana flower, edibles, and concentrates.

MPG analysis and publications have been recognized by the *Brookings Institution*, the *Wall Street Journal*, *USA Today*, *CNBC Business News*, *60 Minutes*, the *Huffington Post*, and *CNN Money*, in addition to numerous state and local outlets (e.g., the *Denver Post*). MPG principals provide have been solicited to present at national and international policy and industry conferences repeatedly since founding.

Comments to Proposed Permanent Regulations

The following comments are identified by subject and section, and provide a rationale for an alternative to the proposed permanent rule advanced by the Department of Health.

Topic	Section	Comment
Clinical Registrants	§1141a.21 Definitions	**Definition of Medical Marijuana Organization** Excluding clinical registrants from the definition of a "medical marijuana organization" is inappropriate because it facilitates use of the clinical registrant ("CR") license as a commercial vehicle, which is inconsistent with the purpose and intent of the CR license itself. The CR license comprises the foundation of the medical marijuana program and reflects the General Assembly's intent that Pennsylvania prioritize research through the CR program by setting aside a small number of licenses that would pair commercial enterprises with academic research institutions for the *purpose of pursuing clinical study*. These licenses were never intended to be used as unrestricted gateways into a commercial market. If the Department of Health includes CRs in the definition of a "medical marijuana organization," CRs

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		will be one step closer to transforming into pure commercial vehicles. This will have the effect of marginalizing the critical, groundbreaking research the CR program was intended to facilitate. Perhaps most troubling however, is that companies acquiring CR licenses are doing so based on the presumption Pennsylvania will legalize adult use sales in the near- to mid-term, and that holding a CR license will allow them entry into the market. In some cases, CR licensees are in contractual relationships with some of the Commonwealth's most prestigious academic medical centers. Maintaining a formal relationship with a multi-state adult use cannabis operator, particularly when Pennsylvania authorizes adult use sales, could have material unintended consequences for these important academic institutions. For example, there is currently no federal shield protecting participants in state-legal adult use cannabis programs the way there is for medical cannabis programs, meaning that the relationship could disrupt or even preclude an institution's federal funding. Removing distinctions between Grower/Processor and Dispensary licenses and CR licenses is a policy matter properly addressed legislatively, not in proposed final regulations. For the foregoing reasons the Department should not make the proposed change.
Definition of THC	§1141a.21 Definitions	**Definition of THC** The definition of THC should not be revised to exclude all variations other than delta-9 tetrahydrocannabinol. There are 136 or more cannabinoids in the cannabis plant, and the public is familiar with only two: THC

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		and CBD. THC as used in ordinary discourse is associated with an intoxicating effect when consumed. It is an important to public health, safety, and welfare that the THC definition is not narrowed. For example, an entire cottage industry of hemp-derived delta-8 THC products emerged over the past 8-12 months that could be confused with regulated products. These products are effectively outside any regulatory framework – which means there is no consumer safety or other protections associated with these products. The Department needs to address this emerging issue and narrowing the definition to ignore it will bear adverse consequences. By carving out delta-9-thc the Department could lead the public to believe it is deemed safe and has no psychotropic effect. Further, it ignores an emerging regulatory issue in delta-8-THC.
Background checks	1141a.31 Background checks	**Background Check Lag Time** The additional requirements for employment in the medical cannabis industry are frequently an issue in emerging markets. The lag time between applicant fingerprint submission and receiving the results of a State/FBI criminal history check, generally takes months and is a significant hindrance to onboarding and retaining highly qualified potential employees through the hiring process. The industry risks competitiveness with other industries when qualified applicants must wait for background check results before beginning work duties and receiving compensation. During the lag, applicants may obtain jobs in other industries, move to other locations in search of employment, or simply lose interest in medical cannabis industry positions. These circumstances make it difficult to recruit and retain talented applicants and runs contrary to stated job creation and diversity and inclusion policy goals. Several states, such as Illinois, incorporate a "provisional" model that aligns with the criminal history and background check requirements, but

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		allows for a more competitive hiring process. A provisional process allows applicants with a live employment offer to submit an attestation to the Commonwealth under oath that he or she does not have a prohibited disqualifying conviction and begin a probationary work period, while the full background check is pending. If the background check reveals a disqualifying conviction, the new hire is terminated.
Genetic Import	1151a.24 Start-up Inventory	The proposed regulations contemplate adding an additional period in which a grower processor can obtain seeds while at the same time eliminating the ability to import immature medical marijuana plants altogether. We agree that there should be a reoccurring window to import new genetics to ensure the health and viability of plant material and the continuity of the supply chain. We disagree that the authorizing statute should prohibit the importation of immature medical cannabis. In the first matter, the proposed language in §1151a.24 is vague and provides no avenue for grower/processors to seek a window for importation should there be a need. There is no standard that would alert the Department that there is a need and no metric that would trigger the importation window. The department would better support the genetic foundation of the medical cannabis program by designating a regular, annual importation window for seeds and immature plants. Additionally, the proposed regulations removes the term "immature medical marijuana plants" as being disallowed by statute. This is inaccurate, as the statute states: **2016 Act 16 §702. Grower Processors.** **(a) Authorization.--Subject to subsection (b), a grower/processor may do all of the following in accordance with department regulations:** **(1) Obtain seed from outside this Commonwealth to initially grow medical marijuana.**

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		2) Obtain seed and *plant material* from another grower/processor within this Commonwealth to grow medical marijuana. Clearly the intent was to allow for the importation of plant material – in particular, immature medical cannabis plants. Such material allows for a more consistent and predictable product from inception and reduces inefficiencies associated with growing from seed. In practice, prohibiting immature medical cannabis does not offer any additional product security, it does, however contribute to increased production (and patient) costs.
Non-cannabis merchandise sales	1161a.27 Sales of unrelated items at dispensaries	The proposed change to §1161a.27 to prohibit the sale at dispensaries of items unrelated to the use of medical marijuana represents an unnecessary change from a status quo that has presented no issues. The proposed new regulation creates the increased possibility that patients will have to make additional visits to other stores to pick up convenience and ancillary items currently offered for sale at dispensaries currently without issue. We propose that the propose §1161a.17 (e)(4) be deleted and the current regulatory scheme be maintained.
Labeling	1161a.28 Labeling	The proposed §1161a.28 (c)(15) requires that all label information be included on both the exterior packaging and any interior packaging. We propose the words "to the extent practicable" is included. In some cases, the interior packaging may simply be too small to accommodate this requirement and is not practical. Additional information through QR code and a web link is another alternative. The new §1161a.28 (c)(15) would read: Is firmly affixed to the container directly holding medical marijuana **to the extent practicable** and is firmly affixed to outer packaging if used.

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Physical Security	1161a.31 Security and surveillance	The proposed §1161a.31(d) states that "At all times, all entrances to and exits from the facility must be securely locked." This change presents a number of concerns while failing to offer any enhanced safety or security. To begin with, all facilities have security personnel on site at all times when open. Having the doors locked during business hours will not enhance security. But locking the doors, especially the exits as required by the regulation as written, poses serious safety concerns in the event of an emergency. Dispensaries have been operating with on-site security and doors unlocked during business hours successfully for years – adding this regulation is not solving a problem but does have the potential to create new ones. We recommend that regulation be modified as follows: §1161.31(d) "At all times when not open for business, all entrances to and exits from the facility must be securely locked."
Testing	1171a.28 Selection protocols for samples	**Redundant Testing** Pennsylvania has implemented a strong medical cannabis program that insures both patient safety and product security. However, there are elements of the regulations that add costs that are passed on to the patient which in do not improve the safety or security of the marketplace. One area that does this is the redundant testing program. The current temporary regulations in 28 PA Code §1171.28(c) require cannabis to be tested twice - once at the time of harvest, and then again after manufacturing. The new regulations add testing to a process that is already an industry outlier – Pennsylvania is the only state that requires this. The additional testing requirement adds significant costs to the final product while in no way adding any patient safety. In both cases the finished product in its final form is tested to ensure that patients are only

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		receiving tested and safe medication. Testing prior to processing does not enhance this, but it does lead to a higher final cost to patients already unable to access insurance coverage for their medication. MPG recommends revision of 28 PA Code §1171.28(c) by deleting subsection (1) to match established industry standards and to match other state systems: "§1171a.28(c): While at a grower/processor facility, an employee of an approved laboratory shall identify and collect the following for testing: (1) Samples of medical marijuana product before being sold or provided to a dispensary. (2) Test samples at other times when requested by the Department."
Re-testing and remediation	1171a.31 Test results and reporting	**Standardize retesting and remediation processes** The lack of a standardized retesting process for failed batches; and the absence of a remediation pathway for failed product to re-enter the stream of commerce stand out in our analysis of comparable programs in mature markets. Many states, including Maryland, Ohio, Michigan, and Colorado, include detailed and transparent processes for retesting and remediation to ensure a minimum amount of commercially safe product is destroyed. The current retesting process envisioned in 1171a.31 has an unusual amount of department discretion, even after multiple tests are completed. In question is whether the products are safe to enter the stream of commerce, and a scientific testing lab is the most transparent judge of that question. We suggest that failed samples that subsequently pass two consecutive retests be automatically allowed into the stream of commerce. This policy change would appropriately take the department out of what is a scientific decision. This would place Pennsylvania in

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		closer parity to the states noted above in retesting policy. Further, we recommend establishing a safe remediation process, whereby cannabis that fails microbial, pesticide residue, or residual solvents testing be diverted into a separate, tracked process where toxins are removed from cannabis. A safe and well-established process for remediation of cannabis flower is to extract it into concentrate and remove any harmful contaminants in the process. The extract is then submitted to a state-approved laboratory for retesting to document safety to enter the stream of commerce. As mentioned above, many states have implemented effective remediation processes to retain value in the supply chain, while maintaining stringent safety standards. These retesting and remediation comments and suggestions are provided to allow Pennsylvania to implement more predictable supply chain regulations while still maintaining the highest degree of patient protection.
Official Orders	1230a.43 Service of process	The proposed §1230a.43 (b) states that: "Service of the Order to Show Cause, order or other petition filed by the Office shall be by personal service or by United States first class mail, postage prepaid. The date of service shall be the date specified on the certificate of service." The concern with this regulation is born out of the experiences of the past year – where mail service was delayed by circumstances not foreseen or addressed by this regulation. The concern is that a mailed order could take several days to arrive all while the clock to respond has begun. The consequence of this change to the Department is effectively meaningless, perhaps unnoticeable. However, if such an important document is materially delayed in the mail, the consequence to a permitholder could be enormous.

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		The solution is a simple change to the regulation to require certified mail for service and setting the date of physical receipt as the date of service. The new §1230a.43(b) would read: Service of the Order to Show Cause, order or other petition filed by the Office shall be by personal service or by United States certified mail – return receipt requested, postage prepaid. The date of service shall be the date of physical service or the date on the receipt for the certified letter.
Communications – Regulation via email	General	On several occasions, licensees have received guidance – regulations – via email. For example, In March of 2019, an email from the department made a number of policy and regulatory announcements, including the following: **Electronic Tracking System** • **MJ Freeway is the required system of record. Entry into MJ Freeway must occur at the point of sale.** • **No sales of medical marijuana products or devices can be made outside the MJ Freeway system.** The concern is that this method of communication of a policy makes commenting on it problematic. The regulation cited above, for example, requires participants to use a specific vendor. This was promulgated by email and absent a comment period. Similar regulatory action and policy has been set by email raising this concern – that absent industry objections, this precedent becomes policy and regulations are promulgated by email and absent public scrutiny. Part of this concern is that these emails are not published as part of a regulatory filing making their existence obscured from the public and industry. Because of the potential for confusion and inconsistency in the standards applied under these circumstances clarification would be beneficial to

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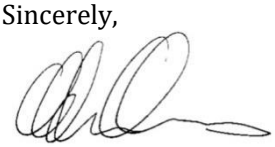
		market participants, specifically as it pertains to the section below which purportedly prohibits such method of policy and regulatory pronouncement: (c) Publication.--The department shall begin publishing temporary regulations in the **Pennsylvania Bulletin** no later than six months after the effective date of this section. As the language appears to make clear, the legislative intent was for regulations and policy pronouncements to be promulgated and published in the Pennsylvania Bulletin to ensure their visibility. It is inconsistent that subsequent regulations could be promulgated by email and avoid the public notice the statute clearly requires. Given the new nature of the industry and the need to be flexible in establishing standards and protocols, we understand that there will be areas that need to be revised. A clear and consistent standard allows all the opportunity to comment on proposed regulations in the future.

Thank you very much for the opportunity to provide comment to these regulations. Feel free to contact us at adam@mpg.consulting to discuss further.

Sincerely,



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