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Independent Regulatory Review Commission

Standard Farms

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Via Electronic Mail
Independent Regulatory Review Commission
Commonwealth of Pennsylvania
irrc@irrc.state.pa.us

John J. Collins
Office of Medical Marijuana
Department of Health
RA-DHMMregulations@pa.gov

Re: Medical Marijuana Regulation #10-219 (IRRC #3390); Proposed Permanent Medical Marijuana Regulations by the Pennsylvania Department of Health

Members of the Independent Regulatory Review Commission and Department of Health:

As the Commonwealth's Independent Regulatory Review Commission considers the Pennsylvania Department of Health's proposed permanent regulations for the medical marijuana program, Standard Farms, LLC, a subsidiary of TILT Holdings Inc., seeks to offer insight and guidance through the commentary and recommendations listed below.

Proposed Permanent Regulation

§1171a.29. Testing requirements.

(c) At a minimum, testing, as prescribed by the Department, shall be performed as follows:

(1) An approved laboratory shall test samples from a harvest batch or harvest lot prior to using the harvest batch or harvest lot to produce a medical marijuana product.

(2) An approved laboratory other than the one that tested the harvest batch or harvest lot shall test samples from each process lot before the medical marijuana is sold or offered for sale to another medical marijuana organization.

DOH explains this proposed permanent regulation (§1171a.29) as follows:

The current subsection (c) specifies that an approved laboratory must minimally test two samples at harvest and at process stages. This proposed subsection (c) amends the current subsection (c) by providing that one approved laboratory must conduct testing

on the harvest sample and a different approved laboratory must conduct testing on the processed sample. This revision creates checks and balances in the testing process.

Proposed testing requirements violate the Regulatory Review Act as the requirements of §1171a.29:

- are not consistent with Act 16;
- will carry an economic and fiscal burden to operators and patients;
- are unreasonable as the regulatory modification lacks necessity and justification.

DOH is only authorized to promulgate regulations to carry out the provisions of the statue. Act 16 requires grower/processors to "contract with an independent laboratory to test the medical marijuana produced by the grower/processor." Although the Act does not restrict grower/processors to contract with a singular laboratory, newly proposed §1171a.29 would ***mandate*** grower/processors to contract with at least two laboratories which goes beyond the language and intent of the Act. Since a nationwide standard for marijuana testing does not exist, there is no mechanism in place to ensure the proposed "checks and balances" will be effective or accurate. Each laboratory utilizes unique practices and methodologies while adhering to program requirements outlined by the Act, within regulations, and through Departmental oversight and governance. Not every lab provides the same expertise, timeframe for results, or spectrum of cannabinoid or terpene profiles. As a grower/processor, Standard Farms evaluate Department-approved laboratories for methodologies, consistency and accuracy, customer service, and turnaround times of test results in order to establish a relationship with reputable laboratory partners. Standard Farms wishes to remain free to decide which approved laboratories meet our corporate standards and needs as we determine with whom we engage with in business.

Proposed regulations that mandate "checks and balances" through the maintenance of multiple laboratory relationships will disrupt and bottleneck current and future operations. Subsequently, this will result in undue administrative burdens, an increase in costs, and will ultimately affect supply. Increase in production costs will inevitably be passed down to PA Medical Marijuana Patients who already absorb considerable costs due to legislative and regulatory mandates or prohibitions within Pennsylvania that deviate from industry standards (i.e. - surveillance storage requirements, lack of remediation, form/administration restrictions).

Furthermore, the Department's proposed regulations did not include any language outlining the process grower/processors will be required follow when two separate laboratories produce two different results. If two separate laboratories each provide compliant, but substantively different certificate of analyses – one laboratory issuing the harvest batch certificate of analysis and one laboratory issuing a process lot certificate of analysis - which prevails?

Since the inception of the PA Medical Marijuana Program, the Department has never issued any notice informing licensed grower/processors of any circumstance, ongoing investigation, or existing lab testing methodology that would bring into question or compromise the validity of a certificate of analysis issued by a DOH-licensed MMJ Laboratory. Instead, without cause or rationale, the Department is proposing a regulation that implements a disruptive and divisive process change to a system that currently operates with full functionality and continues to yield safe, high-caliber medical marijuana products to PA's patients without incident.

§1151a.24 Start-up Inventory

> *(a) A grower/processor may obtain seeds from outside of this Commonwealth for the purpose of securing its start-up inventory. Seeds 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 established by the Department if the Department determines that the importation of additional seeds is necessary.*

Currently, grower/processors are limited to importing seeds within 30 days after the Department declares them operational. Beyond that 30 day window, grower/processors cannot import seeds. This restriction results in PA patients being excluded from new strains and products they otherwise would have access to if grower/processors were granted a pathway to secure new or improved genetics.

Proposed Regulation Section 1151a.24(a) attempts to address these issues by providing 30-day windows to import seeds "if the Department [of Health] determines that the importation of seeds is necessary." This standard – i.e., if the Department determines that importation is necessary – is ambiguous and too subjective. Grower/Processors are left to guess whether their necessity aligns with the Department's "necessary." Standard Farms proposes that Section 1151a.24(a) provides an importation period each calendar year that coincides with the first 30 days of a grower/processors' annual permit renewal. This proposal would accomplish the same objective of the Proposed Section 1151a.24(a) but resolve the inherent uncertainty of a subjective, undefined standard. Additionally, it would also safeguard the ability to conduct research and development, maintain the consistency of supply, and facilitate the introduction of new products to patients.

Suggested Regulatory Additions

Eliminating Duplicity in Laboratory Testing

Standard Farms suggests the Department utilize historical laboratory data from their approved laboratories to cross-analyze certificate of analyses and verify the identical nature between a

harvest batch sample and finished flower final product sample. If any existing testing requirements should be addressed and revised within final regulations, it should be the elimination of language that mandates costly redundancy in the existing testing process.

Streamlining the Retesting Process

Standard Farms suggests the Department issue regulatory guidance through the retesting process. Currently, §1171a.31 expressly permits a grower/processor to submit a sample for re-testing. However, the regulations do not spell out the standards or rationale the Department could use to decline otherwise approved test results in these circumstances. While the regulations provide for retesting, there has been no standardized process established by the Department for requesting and receiving permission to retest. The challenge is that in order to retest, the Department must authorize the state's seed-to-sale vendor to approve retesting within the seed-to-sale electronic platform. There is routine disconnect between the Department and the state's seed-to-sale vendor that, in practice, roadblocks operators from regulatory remedy.

Establishing a Pathway to Remediate

Along with recommendations for retesting, other states that have recently adopted marijuana regulations recognize an established, usable process for remediation. 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 before retesting. The extract is then submitted to a state-approved laboratory for testing to confirm that the remediation was effective prior to distribution and sale to patients and customers. Standard Farms recommends the addition of regulatory language to allow for remediation.

Standard Farms values the opportunity to provide input and guidance to the proposed final regulations and we remain committed to working with the IRRC and the PA Department of Health to improve the quality of cannabis products for medical patients. We welcome the opportunity to engage in continued dialogue and would appreciate feedback on the recommendations provided.

Respectfully,

Nikki Moyers
TILT Holdings, Inc.
Vice President of Compliance