PHARMACANN

Plant Based Therapy ORGANIC REMEDIES

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HOLISTIC INDUSTRIES

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April 2, 2021

VIA ELECTRONIC MAIL
Independent Regulatory Review Commission
Commonwealth of Pennsylvania
irrc@irrc.state.pa.us

Re: Medical Marijuana Regulation #10-219 (IRRC #3290); Proposed Permanent Medical Marijuana Regulations by the Pennsylvania Department of Health

To the Honorable Members of the IRRC:

As the Commonwealth's Independent Regulatory Review Commission considers proposed permanent regulations for the medical marijuana program, the undersigned Pennsylvania grower/processor permittees (called "GPs") seek to provide input and guidance on recurring laboratory testing issues experienced by medical cannabis GPs specific to Pennsylvania. The identified regulatory inefficiencies are currently codified in both the existing temporary regulations, and the proposed permanent regulations package drafted by the Department of Health.

The undersigned GPs have reviewed state regulations in other jurisdictions, and received input from scientific and industry experts in the development of recommendations associated with quality assurance testing protocols. Our goal is to optimize laboratory testing regulations, reduce friction in the quantitative analytic process, and improve the validity and reliability of quality assurance testing.

The recommendations relate to three primary areas:

- First, eliminate the unnecessarily redundant "double testing" standard, which mandates scientifically unnecessary contaminant testing in the flower stage. With the requirement to test all final finished products before they are sent to dispensaries, any prior quality assurance testing in the production process is little more than busy work that increases the cost of our products to patients, slows down the production pipeline, and exacerbates the existing flower shortage.

- Second, formalize a workable process to authorize retesting batches that have been remediated, or where the original testing may not be reliable (e.g., for instance, where the testing result falls within the test's margin of error).

- Third, formalize a workable process for safely remediating cannabis that fails certain parts of quality assurance testing. Other states authorize extraction (and retesting) of flower that fails the natural pathogen test because the extraction process necessarily filters out contaminants, leaving only safe and beneficial THC, CBD, and properties within the plant.

I. Removal of Redundant "Double Testing" of Medical Cannabis Products

Current temporary regulations in 28 PA Code §1171.28(c) require cannabis to be double tested -- that is, tested once at the time of harvest, and then again after manufacturing. Simply put, the double testing requirement in PA is an outlier when compared to other state regulations. It places an unnecessary burden on DOH-approved testing laboratories, and an unnecessary cost on cannabis businesses -- which is carried over to the medical patients that they serve. The experiences in other states where a single laboratory quality assurance test at the end of the manufacturing process is required before products can be transported to dispensaries, shows that the streamlined single-test protocol is sufficient to ensure a high quality and safe cannabis product for consumers.

By state-to-state comparison, Michigan's Marijuana Regulatory Agency requires a single passing quality assurance test prior to a batch being "released for immediate processing, packaging, and labeling for transfer or sale."[1] Similarly, the Illinois Department of Agriculture requires a single quality assurance test "immediately prior to manufacturing or natural processing of any cannabis or cannabis-infused product or packaging cannabis for sale to a dispensary."[2] Connecticut's regulatory language matches that of Illinois.[3] Ohio also follows this standard and requires a single quality assurance test from a batch "prior to packaging any plant material intended to be sold to a patient or caregiver through a dispensary."[4] New York's Department of Health also mandates "testing shall only be performed on, the final medical marihuana product equivalent to the sealed medical marihuana product dispensed to the patient," but permissively allows the cultivator or processor to seek testing through state-approved laboratories on components of the product or cannabis extract "at the option of the organization."[5]

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[1] *See Michigan Department of Regulatory Affairs, Marijuana Regulatory Agency* Rule 31(10): Testing; safety compliance facility; available at https://www.michigan.gov/lara/0,4601,7-154-89334_79571_83994-454554--,00.html

[2] *See* 8 Ill. Admin. Code Title 8, Section 1000.510: Laboratory Testing; available at https://www.cyberdriveillinois.com/departments/index/register/volume44/register_volume44_issue_11.pdf

[3] *See* Regulations of Connecticut State Agencies, Sec. 21a-408-58. Laboratory testing; available at https://portal.ct.gov/-/media/DCP/pdf/laws_and_regulations/REGMEDICALMARIJUANAFINAL06Sept2013pdf.pdf?la=en

[4] *See* Oh. Admin. Code 3796:2-2-06: Laboratory Testing

[5] *See* 13 N.Y. Adm. Code 1004.14(c)&(d)

In the development of cannabis testing policies, it is clear that a single test prior to sale or distribution to a dispensary is the model standard that has been adopted and implemented with safety and success in states similarly situated to Pennsylvania. Through discussions with technical experts, the GPs have received consistent feedback that Pennsylvania's double testing requirement adds no enhanced health protections to consumers, but rather places a redundant requirement that unnecessarily hinders production, forces disposal of otherwise good biomass, and inflates costs. As discussed in further detail under Section III of this comment, the double testing requirement further ignores the opportunity for cannabis remediation following harvest to rid a flower lot of microbial contaminants through extraction.

Accordingly, PCC recommends revision of 28 PA Code §1171.28(c) by deleting subsection (1) to more closely align with other state cannabis regulations and established industry standards:

> "§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 at the time of harvest.~~
>
> (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."

II. Streamlining the Retesting Process

Currently, §1171a.31(c) expressly permits a grower/processor to submit a sample for re-testing. A sample that initially fails testing must be resubmitted to the same lab that ran the original test, and then tested again at a different laboratory for confirmation. Even upon approval from the original lab and then again at a second laboratory, the Department maintains the discretion to deny the retest and confirmatory test results that fall within acceptable testing guidelines, and order the batch destroyed. 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 e-platform. There is routinely a disconnect between the Department and the state's vendor that, in practice, renders an express regulatory remedy unavailable to operators.

Again looking to other states for comparison, Michigan's Marijuna Regulatory Agency also explicitly permits retesting, requiring a failed sample to be submitted for retesting by the grower/processor, and to achieve a passing lab result twice thereafter.[6] Michigan's regulations do not require the retest to achieve a passing confirmatory test from a second, different lab.

[6] *See Michigan Department of Regulatory Affairs, Marijuana Regulatory Agency* Rule 30: Retesting

Importantly, the regulations also do not include a catch-all provision allowing the Agency to deny confirmatory test results at its unbridled discretion. Michigan issued guidance on laboratory testing standards very recently, and based its guidelines on the most recent American Herbal Pharmacopeia *Cannabis Inflorescence Monograph*.[7]

Additionally, under the proposed permanent regulation §1171a.31(c)(3), the Department now adds a discretionary process to deny the batch and require its destruction, where the Department simply "does not agree" to accept the confirming re-tests. There is simply no rationale, and no statutory authority, for the Department to add this discretionary standard if the sample passes two successful re-tests. Accordingly, the undersigned GPs propose to render the batch ineligible for production and require its destruction if either of the two re-tests fail.

Based upon Michigan's recent alignment with national industry guidelines, the GPs recommend regulatory changes to Pennsylvania's retesting guidelines consistent with Michignan's standards.

Accordingly, the GPs recommend revision to 28 PA Code §1171a.31(c) by amending subsections (2) and (3) as follows:

(c) If a sample fails any test required under §1171a.29, the following apply to the sample:

(1) The approved laboratory that performed the initial test may re-test the sample upon a request from the grower/processor in accordance with subsection (d).

(2) A failed sample must pass two separate re-tests consecutively in order to be eligible for sale or transfer, which shall be performed by the same laboratory. ~~If the sample passes the re-test, another approved laboratory shall sample the same harvest batch, harvest lot or process lot to confirm the passing test result.~~

~~(3) If the Department does not agree to accept the confirming results from the approved laboratory, the sample shall be disposed of by the approved laboratory under 1151a.40 (relating to management and disposal of medical marijuana waaste).~~

(4) If one or both re-tests fail, the sample shall be disposed of by the approved laboratory under 1151a.40.

III. Establishing a Process for Remediation

In line with the recommendation for retesting, other states that have recently adopted cannabis 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

[7] *See Michigan Licensing and Regulatory Affairs, "*Safety Compliance Facility Information," (August 15, 2018); available at https://www.michigan.gov/documents/lara/FINAL.TESTING.GUIDE_630223_7.pdf

submitted to a state-approved laboratory for testing to confirm that the remediation was effective prior to distribution and sale to consumers.

In its state regulations, the Illinois Department of Agriculture recognizes such an extraction process in its current medical cannabis rules,[8] and in its proposed adult use cannabis rules.[9] With regard to remediation by extraction, the Illinois medical cannabis regulations state as follows:

> "If a sample of cannabis does not pass the microbiological, mycotoxin, pesticide chemical residues or solvent residues test, based on the standards set forth in this Section, the following shall apply:
>
> (1) If the sample failed the pesticide chemical residue test, the entire batch from which the sample was taken shall, if applicable, be recalled as provided for in Section 1400.410(c)(1) and disposed of in accordance with Section 1000.460.
>
> **(2) If the sample failed any other test, the batch may be used to make a CO2 or solvent based extract. After processing, the CO2 or solvent based extract must still pass all required tests."** [emphasis added]

The remediation process uses scientifically sound justification and methodologies to remove contaminants such as microbials and heavy metals, and after following additional testing to ensure the remediation was successful, results in a safe product for the consumer. The remediation process further mitigates against considerable waste for grower/processors, allowing for them to refine a harvest that falls outside of testing guidelines in order to conform it to safe and acceptable standards. The practice has become mainstream among Illinois cannabis cultivators, with successful results throughout the duration of the state's medical and adult-use programs.

By comparison to Pennsylvania's border states, the Maryland Medical Cannabis Commission permits remediation of products that fail laboratory testing, broadly allowing growers to "rework or reprocess the batch according to their standard operating procedure," and resubmit a sample for testing and product approval.[10] The State of Ohio's Medical Cannabis Control Program also permits remediation by extraction through its regulations, and in lieu of destroying a product that fails laboratory testing, allows a cultivator to designate a batch for "extraction by hydrocarbon-based or carbon dioxide-based methods."[11] A similar remediation by extraction

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[8] *See* 8 Ill. Admin. Code Title 8, Section 1000.510: Laboratory Testing; available at https://www.cyberdriveillinois.com/departments/index/register/volume44/register_volume44_issue_11.pdf

[9] *See Illinois Register,* Title 44, Issue 11, Section 1300.700(g); available at https://www.cyberdriveillinois.com/departments/index/register/volume44/register_volume44_issue_11.pdf

[10] *See* COMAR 10.62.15.06(B), Grower Determination That a Batch May be Released; available at http://www.dsd.state.md.us/comar/comarhtml/10/10.62.15.06.htm

[11] *See* OAC 3796:4-2-04(F), Testing laboratory analysis requirements; available at http://codes.ohio.gov/oac/3796%3A4-2

process is also followed in other industries, used for refinement in consumable products such as fish oil and cannabidiol.

Building off of the proposal in Section II above to further reflect remediation, the GPs propose adding a section in 28 PA Code §1171a.31 similar to the provision in Illinois' current medical regulations, as follows:

(c) If a sample fails any test required under §1171a.29, the following apply to the sample:

…

(4) If one or both re-tests fail, the sample shall either (i) be disposed of by the approved laboratory under §1151a.40, or (ii) the batch may be used by the grower/processor to make a CO2 or solvent-based extract. If the grower/processor elects to make a CO2 or solvent-based extract under item (ii):

(a) A sample of the CO2 or solvent-based extract must be submitted to an approved laboratory and pass all required testing under §1171a.29 following remediation in order to be eligible for sale or transfer.

(b) If the CO2 or solvent-based extract fails testing, the sample shall be disposed of by the approved laboratory under §1151a.40.

As always, the undersigned GPs remain committed to working with the IRRC and state regulators within the Commonwealth of Pennsylvania to improve the quality of cannabis products for medical patients, and are open for continued discussion and feedback on the recommendations provided.

Respectfully submitted by,

/s/ Jeremy S. Unruh

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