April 5, 2021

VIA ELECTRONIC MAIL: irrc@irrc.state.pa.us

Independent Regulatory Review Commission
Commonwealth of Pennsylvania

John J Collins, Director
Pennsylvania Medical Marijuana Program

Dear Members of the IRRC and Director Collins:

I am writing on behalf of Insa to provide guidance and comment on the Pennsylvania Department of Health's (DOH) draft permanent regulations for the medical marijuana program, Regulation #10-219 (IRRC #3290).

Insa is a grower/processer permittee with operations in Shamokin Dam, PA. Through our experience operating in Pennsylvania and Massachusetts we present the following comments and suggestions which we believe will maximize efficiencies creating better and cheaper patient medicine. In addition, we support the attached letter submitted by our industry peers relevant to recurring laboratory testing issues experienced by medical cannabis GPs.

1. Allow dispensary labels to be affixed after shipping from grower processors:

Proposed Regulations for Amendment:

28 PA Code §1151.34(d)(11)- Packaging and labelling of medical marijuana products
28 PA Code §1161.28(c)(9)- Labels and Safety Inserts

Amend 1151.34(d)(11)- Packaging and labelling of medical marijuana products, by deleting the requirement that grower processor's label dispensary information.

Amend 1161.28(c)(9) Labels and Safety Inserts, to make clear that dispensary labels must be affixed by the dispensary rather than by the grower processor.

The requirement for a grower/processor to label the dispensary name and information on our final pack is impacting our packing operations greatly by creating a number of costs and inefficiencies:

- Our product is packaged well before it sold to a particular dispensary. As a result at the time of packaging the dispensary name and address is not available to our packaging team;
- The process of having to go back and label products with the dispensary name and address essentially results in all products having to be processed twice by our packing department; and
- Many dispensaries are already applying a label containing their name and address on the product they sell and are required to do so under 28 PA Code §1161.28(c)(9).

Insa's position is that the most logical process would be for the dispensaries to label the product when they are receiving the transfer from the grower processor.

2. Allow the use of propane in the extraction process:

Proposed Regulation for Amendment:

28 PA Code §1171- Laboratories; OR the Office's Guidance for Quality Testing and Sampling by Approved Laboratories

Amend 28 PA Code §1171 by making clear that propane may be used in the extraction process, or update the Office's Guidance for Quality Testing and Sampling by Approved Laboratories on page 7 to make clear that propane may be used in the extraction process.

Although the testing regulations, 28 PA Code §1171, do not specify which solvents may be used in the extraction process the Office's Guidance for Quality Testing and Sampling by Approved Laboratories creates confusion around this issue by referencing only ethanol and butane for testing on Page 7.

As a result, the testing labs do not test for propane, testing only for butane and ethanol. For reference, the MA regulations allow for the use of propane and butane for extraction, but finished products must have less than 12 ppm of propane and/or butane. The allowable limit of butane in PA is 5,000 ppm.

Based on our experience in MA, propane is much easier to purge from the finished product than butane. Typically, just exposing the finished product to atmosphere is enough to purge propane from it. Therefore, we are confident that the concentrate products in inventory will not exceed 5,000 ppm for propane and are safe for consumption. After speaking with some of the labs in PA, it is our understanding that they could develop a lab test for propane.

3. Allow visitor access to interviewees at the grower processor facility:

Proposed Regulations for Amendment:

28 PA Code §1151.25- Visitor Access

Amend 28 PA Code §1151.25(a) by explicitly stating in the second sentence that job interviewees are individuals requiring access to the facility, at least in areas not containing cannabis.

Amend 28 PA Code §1151.25(g) by stating that local enforcement duties under the act include cooperation and coordination with the licensee in developing and carrying out a security plan.

Insa conducts job interviews off site. This situation is not ideal for Insa or the interviewees prohibiting potential hires from seeing any part of their potential work environment. We believe this creates difficulties in the hiring process as we are seeking to employ the best individuals available. Insa also spends more leadership time travelling off site which could be better used to maintain operations. Insa proposes that interviewees for jobs be permitted to enter the facility for the interview process. This access can be restricted to the areas not containing cannabis. Massachusetts regulations permit on-site interviews with visitor access/credentials and Insa has conducted the same without incident and to the benefit of the company and our employees

Explicitly stating that local law enforcement may enter the facility to coordinate security plans and implementation will make all facilities in Pennsylvania safer. Local law enforcement officers have valuable input from the communities they serve. Officers are expected to respond to grower processor facilities in case of emergency, allowing access to inspect and become familiar with the facility only furthers the safety of those officers and the public at large. Massachusetts regulations permit for this practice which encourages a collaborative approach with local law enforcement that we believe would benefit Pennsylvania.

4. Allow immature plants to be imported in subsequent 30 day periods:

Proposed Regulation for Amendment:

28 PA Code §1151.24-Startup inventory

Amend 28 PA Code §1151.24 (a) to clarify that clones or immature medical marijuana plants may be brought into the Commonwealth and to permit additional 30 day periods upon request by a grower processor.

The temporary regulations allow immature plants and seeds to be imported to Pennsylvania and the new regulations should provide the same, the draft allows only seeds. The language in draft *28 PA Code §1151.24 (a)* allowing the department to grant additional 30 day periods should be expanded to allow the department to grant as necessary and pursuant to a request by the licensee for the same which should include further development of the grower processor's genetics.

By allowing them to make requests, grower processors have more control over their business including the health and genetics of their plants, which in turn benefits patients by provide increased access and variety. The DOH still retains discretion with the ability to grant or deny the request.

Immature plants (or clones) are a great way for our team to utilize our resources for acquiring elite phenotypes which are only available in that form. Insa has the ability to expand on its genetics and broaden its selection to patients through acquiring clones in subsequent approved importing periods by DOH.

Insa requests that the IRRC and DOH implement the above in order to increase efficiencies which will result in better, cheaper medicine for patients in Pennsylvania.

Sincerely,

Stephen M. Reilly, Jr.
Co-Owner/Counsel

PHARMACANN | ORGANIC REMEDIES | cresco yeltrah

HOLISTIC INDUSTRIES | Green Thumb | Jushi

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.

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[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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