DH, MMRegulations

From: Michael Bronstein <michael@atach.org>
Sent: Monday, April 5, 2021 4:45 PM
To: DH, MMRegulations
Subject: [External] Comments on Pennsylvania Department of Health Proposed Rulemaking on Medical Marijuana
Attachments: ATACH PA IRRC Comments_210405 .pdf

Director Collins,

Please find the American Trade Association for Cannabis & Hemp's comments on the proposed regulations.

Thank you for the opportunity to submit.

Michael Bronstein

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Michael Bronstein
President
American Trade Association for Cannabis & Hemp

April 5, 2021

VIA Email to:
RA-DHMMregulations@pa.gov

John J. Collins, Director, Office of Medical Marijuana
Department of Health
Health & Welfare Building, Room 628
625 Forster Street
Harrisburg, PA 17120

Re: Comments on Pennsylvania Department of Health Proposed Rulemaking on Medical Marijuana

Dear Director Collins:

The American Trade Association for Cannabis and Hemp ("ATACH") is a 501(c)6 trade organization that promotes the expansion, protection and preservation of businesses engaged in the legal trade of industrial, medical, and recreational cannabis-based and hemp-based products. ATACH has been named "Trade Association of the Year" and "Corporate Grassroots Organization of the Year" by *Campaigns & Elections* magazine. ATACH's membership includes some of the most influential businesses as well as state, national, federal and international cannabis trade associations and organizations. ATACH has also entered into a historic memorandum of understanding with ASTM International[1] to develop standards for the cannabis industry and has recently launched a pilot Cannabis Certification Program in conjunction with ASTM International and the Policy Center for Public Health and Safety to help standardize best practices in the cannabis industry. ATACH has a long history advocating for Pennsylvania's Act 16 and has been involved from the earliest stages of the program.

[1] ATACH participates in the ASTM process for creating standards for the cannabis committee under D37 and has taken a lead role in the committee. Our organization has assisted in facilitating the following standards applicable to marijuana processing and handling for state regulators to use as a tool when promulgating regulation: D8192-20 Standard Practice for Determination of Water Activity in Cannabis Flower; D8197-21 Standard Specification for Maintaining Acceptable Water Activity Range for Dry Cannabis Flower Intended for Human Use; D8233-19 Standard Guide for Packaging and Labeling of Consumer Resin Cannabis Products for Sale to Adult Consumers, Legally Authorized Medical Users, and Caregivers in a Business-to-Consumer Retail Environment; and D8245-19 Standard Guide for Disposal of Resin-Containing Cannabis Raw Materials and Downstream Products. Links to these standards can be found here: https://www.astm.org/COMMIT/SUBCOMMIT/D3704.htm.

In September 2020, ATACH launched a Task Force to facilitate the harmonization of emerging cannabis-related laws and regulations and provide an industry response to marketplace issues surrounding cannabinoids. The Task Force is led by legal compliance professionals from the country's top hemp and marijuana operators, representatives from financial institutions and testing laboratories, in addition to medical experts and mainstream stakeholders.

We submit these comments on behalf of our members and appreciate Pennsylvania's efforts to advance permanent regulations that increase access to patients while simultaneously keeping patient safety at the forefront of the industry.

§§ 1151a.27 Requirements for growing and processing medical marijuana, 1151.a43 Pesticides, and 1151 Appendix A. Acceptable Pesticide Active Ingredients for Use

The list of approved pesticides has not been updated since the inception of the program. ATACH urges expeditiously approved pesticides containing active ingredients that have been registered with the EPA, have been approved as permissible pesticide active ingredients by other states, and meet the current regulatory requirement of also being labeled for use in greenhouses on food crops.

The Department of Agriculture should have the authority to regulate permissible pesticides that a grower/process may use and to publish a periodic list of approved pesticides, fungicides, and herbicides in the Pennsylvania Bulletin.

The primary issue with the proposed regulations is that there is no mechanism to update the pesticide list or formal review process to be able to petition for expansion. Nor is there a time period for which review is to take place.

In some cases, the pesticide list needs to be updated for clarity and reasonableness of the proposed regulation. For example, in *1151 Appendix A. Acceptable Pesticide Active Ingredients for Use*, Peroxyacetic acid ("PAA") is an accepted active ingredient but hydrogen peroxide is not. This regulation is unclear given that PAA is an organic compound and formulated from the reaction of acetic and hydrogen peroxide.

There are no readily available pesticides approved for greenhouse use that have peroxyacetic acid listed as an active ingredient without including hydrogen peroxide as an additional active ingredient. As such, hydrogen peroxide is a necessary ingredient in peroxyacetic acid products and should logically appear on this list. Indeed, peroxyacetic acid products with hydrogen peroxide as an active ingredient are a standard across a number of states marijuana programs including: Alaska, Colorado, Connecticut, Illinois, Maryland, New Hampshire, Nevada, Ohio, Oregon and Utah.

Additional pesticides for approval that have been previously discussed with the Department of Agriculture and the Department of Health should include but not be limited to: Bacillus thuringiensis subsp. Israelensis; Beaveria bassiana Strain GHA; Burkholderia spp. Strain A396; Chromobacterium subtsugae strain PRAA4-1T; Hydrogen peroxide; Isaria

fumosorosea; Potassium bicarbonate; Reynoutria sachalinensis extract; Streptomyces Iydicus WYEC 108; and Sulfur.

Given the above factors and the need for an expansion of the pesticide list, the regulation should be amended to read:

§ 1151a.43. Pesticides.

(a) The use of a pesticide by a grower/processor in the growing or processing of seeds, immature medical marijuana plants, medical marijuana plants or medical marijuana shall be in accordance with the Pennsylvania Pesticide Control Act of 1973 (Pesticide Control Act) (3 P.S. §§ 111.21—112) and this part.

(b) The Department and the Department of Agriculture will periodically review, approve, and update acceptable pesticide and active ingredients and cooperate to inspect for and enforce the requirements of this section.

§ 1141a.21 Definitions and § 1151a.27 (f) Requirements for growing and processing of medical marijuana

The Cannabis Sativa L. plant contains a vast array of chemical compounds. The most relevant to flavor and fragrance are terpenes and terpenoids. Terpenes are not unique or exclusive to cannabis. Flavoring aromatics can be found in other plants, animals or be synthetically derived. The majority of terpenes found in cannabis (both hemp and marijuana) are hydrocarbons and include most commonly myrcene, β-caryophyllene, αhumulene, α-pinene, linalool, limonene, and ocimene. Terpenes occur naturally in the cannabis plant and can be removed and reintroduced later in a subsequent manufacturing process. This should be expressly permitted. Terpenes are volatile and lost during the manufacturing process to arrive at marijuana THC distillate (oil). The resulting THC distillate is flavorless. Terpenes are then added back in as flavoring to mimic the flavor of certain marijuana cultivars.

Terpenes can be sourced from non-marijuana sources. Those non-marijuana sources may be botanically or synthetically derived. Those non-marijuana substances are logically distinguishable from marijuana and hemp terpenes. Unlike marijuana terpenes non-marijuana flavoring can introduce flavoring such as watermelon, grape which are attractive to children and may result in harm to consumers. For example, a commonly used terpene linalool can be sourced from marijuana or lavender. If a patient knows they can safely consume cannabis but has a lavender allergy there is potential for harm. If there is no distinction (and no additional labeling) between whole plant natural marijuana products and those with "added substances" or "non-marijuana additives" there is simply no ability for the consumer to make an informed decision. Therefore, hemp-derived terpenes that are subject to testing should be permitted in medical marijuana for the use by grower/processors if they so choose. So long as hemp-derived terpenes are sourced from lawful licensed sources and undergo further testing requirements as set forth in Pennsylvania's medical marijuana program, these ingredients should not be considered "added substances." The hemp ingredients incorporated into downstream manufactured medical marijuana products will be subject to additional regulatory compliance testing as a final form marijuana product as well.

Instructively, other states permit hemp-derived ingredients for use in regulated medical and adult-use marijuana products. The medical states include but are not limited to Illinois, New York, Colorado, Oregon, Washington, Nevada and Michigan.

§ 1141a.21 Definitions - inclusion of "medical marijuana trim"

The regulations should expressly permit transporting trim[2] between Growers/Processors conflicts with existing statutory authority and is therefore amenable to review by the commission pursuant to 71 P.S. § 745.5b(b)(3)(i) and consistent with the intent of Act 16. As presently drafted, the Department's regulations do not differentiate between parts of the plant, instead creating defined terms for "seeds," "immature medical marijuana plants," or "medical marijuana plants."

Growers/Processors should be permitted to transport trim between other licensed Grower/Processor facilities similar to dry leaf and other plant material and consistent with Act 16. Trim falls into the category of "plant material" which Act 16 permits pursuant to Section 701 of Chapter 7. Critically, trim is a valuable part of the marijuana plant, not waste, that can be processed into medicinal products. Permitting the transport of trim amongst Grower/Processors will facilitate greater product access for all patients across the Commonwealth.

We therefore recommend the following regulatory changes:

§ 1141a.21 Definitions

> *Medical marijuana trim* - the excess snipping of leaves from the flower of medical marijuana plants but prior to any further processing. For purposes of this chapter, "medical marijuana trim" shall be synonymous with "medical marijuana plants."

Electronic Tracking Systems and the Application Program Interface ("API")

Application-programming interface (known as "API") is a commonplace computing process that allows two different applications to communicate with each other and is the standard for business in other state level marijuana programs. This type of software integration is not only in secure applications such as banking software, health care, smartphones and other business software, but also is the standard for every medical marijuana state in the country, with the exception of Utah and Pennsylvania. In fact, when the Pennsylvania program started, API integration was "open" but it has been closed without explanation.

Allowing for an API to link with the electronic seed-to-sale inventory tracking software mandated by law and regulation (MJ Freeway) and an interfacing software, will prevent human error from uploading the incorrect test results, prevent duplicate record keeping, and allowing

[2] The scientific (plant science) and regulatory communities commonly define "trim" as the excess snipping of leaves from buds of marijuana plants but prior to any further processing..

laboratory systems to communicate results using their business software that would link to the MJ Freeway system seamlessly. API integration will increase overall operational efficiency.

To determine whether a regulation is in the public interest, 71 P.S. § 745.5b(b)(3)(v) permits the commission to consider whether a regulation is based on acceptable data. As explained above, the prohibition of API is based on flawed data and we therefore recommend the following changes to § 1141a.21; § 1151a.30; 1151a.39; § 1171a.27; and § 1171a.31:

§ 1141a.21. Definitions.

Electronic tracking system — An electronic seed-to-sale system with open application-programing interface between each medical marijuana organization's inventory, accounting, and point-of-sale software with the software of the Department or its vendor with regard to that operator and excluding patient data, approved by the Department that is utilized by:

§ 1151a.30. Inventory data.

(a) A grower/processor shall maintain the following inventory data in its electronic tracking system with open application-programing interface between each medical marijuana organization's inventory, accounting, and point-of-sale software with the software of the Department or its vendor with regard to that operatortor, which must include an accounting of and an identifying tracking number for:

§ 1151a.39. Electronic tracking system.

A grower/processor shall use the electronic tracking system, which shall have an open application-programing interface between each medical marijuana organization's inventory, accounting, and point-of-sale software with the software of the Department or its vendor with regard to that operatortor, prescribed by the Department containing the requirements in section 701 of the act (35 P.S. § 10231.701).

§ 1171a.27 Sampling procedures for testing

(9) Entering all required information into the electronic tracking system via open application-programing interface between each medical marijuana organization's inventory, accounting, and point-of-sale software with the software of the Department or its vendor with regard to that operatortor.

§ 1171a.31 Test results and reporting

(b) The test results for each sample collected pursuant to § 1171a.28(c) (relating to selection protocols for samples) shall be entered into the electronic tracking system via open application programing interface and shall only be accessible to the grower/processor submitting the sample and to the Department.

§ 1151a.28. Forms of medical marijuana

Consistent with 71 P.S. § 745.5b(b)(3)(i) and (ii), ATACH recommends two clarifications in § 1151a.28 by expressly permitting the use of medical marijuana edible products and medical marijuana beverage products.

I. Medical marijuana ingestible products

The legislative intent underlying Article 16 is patient-focused and enables patients to use medical marijuana forms to best aid ingestion. §304 of Article 16 embodies this intent by permitting the incorporation of "medical marijuana into edible form by a patient or caregiver in order to aid ingestion of the medical marijuana by the patient." Indeed, patients with severe forms of cancer or chronic pain may find it easier and more tolerable to ingest a medical marijuana product via chewing or other oral administrations.

If the Department permitted additional form factors consistent with the intent of Article 16, the Commonwealth's patient community will benefit greatly by increasing the options patients have for administering medical marijuana products[3].

II. Medical marijuana beverages[4]

In addition to Article 16's legislative intent described above, medical marijuana beverages are expressly permitted under the Act. Accordingly we ask that the Department formalize the legislature's intent and expressly permit medical marijuana beverages in §1151a.28.

That section sets forth permissible forms of medical marijuana that a grower/processor may process for dispensing to a patient or caregiver. Permitted form factors include (1) pill, (2), oil, (3) topical forms, including gel, creams or ointments, (4) A form medically appropriate for administration by vaporization or nebulization, including dry leaf or plant form for administration by vaporization.; (5) tincture; (6) liquid.

By the section's plain language, liquids are permissible. Since liquids cannot be interpreted to mean tincture (if so, it would create an unnecessary redundancy in both Article 16 and §1151a.28), beverages is the only other permissible form factor that falls into the liquid category.

Moreover, beverages have been an approved form factor in many other states medical marijuana programs. For example, California, Colorado, Oklahoma, and Arizona all permit beverages as an approved form factor for patients. As more jurisdictions permit cannabis beverages, technology has advanced at a rapid pace to create beverage products that are more palatable for patients. This category of "liquid" is contemplated by Act 16 and should be expressly permitted by regulation.

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[3] As many commenting physicians have pointed out, edibles are an essential form factor for cancer patients who can't smoke or vaporize products. *See e.g.,* Comments from Rene Rothstein Rubin, MD; Comments from Dr. Brian Schwab, DO;

[4] In January, 2021 ATACH launched the Cannabis Beverage Council, bringing together the most established cannabis and beverage leaders in adult-use and medical markets in the US and Canada. ATACH would welcome an opportunity to discuss beverage regulation with the Department.

Conclusion

ATACH thanks the Department for this opportunity to submit comments and looks forward to further discussion on these important issues facing the Commonwealth's medical marijuana program.

Sincerely,

Michael Bronstein
President and Co-Founder
American Trade Association
For Cannabis and Hemp