



DH, MMRegulations

From: Michael Hutter <mhutter@fgbmp.com>
Sent: Monday, April 5, 2021 1:56 PM
To: DH, MMRegulations
Cc: Frederick Frank; 'Tony Bucci'; 'Johnwpaul'
Subject: [External] PennAlt Organics, Inc. Comment to Proposed Rulemaking
Attachments: Comment to Proposed Rulemaking dated March 6 2021_PennAlt Organics.pdf

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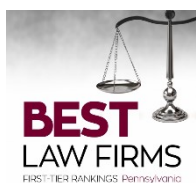
Dear Director Collins:

Attached please find for your consideration a written comment submitted on behalf of PennAlt Organics, Inc., in response to the Pennsylvania Department of Health's proposed regulations for 28 Pa. Code Part IX, dated March 6, 2021.

Best,
 Michael Hutter

Michael J. Hutter, Esquire

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April 5, 2021

Via Email

John J. Collins, Director
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625 Forster Street
Harrisburg, PA 17120
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**Re: Comment to Department of Health's
Proposed Regulations dated March 6, 2021**

Dear Mr. Collins:

I write this letter in my capacity as counsel to PennAlt Organics, Inc., d/b/a Penn Health Group, GP-18-2009 ("PennAlt"). This letter serves as a response to the Commonwealth of Pennsylvania's Department of Health's ("Department") proposed rulemaking dated March 6, 2021 to replace the temporary regulations under Part IX of Title 28 with permanent regulations.

First, there are a number of proposed regulations that PennAlt supports and would recommend the Department adopt as part of its permanent regulations.

PennAlt writes in support of the proposed additions to § 1141.21 that classify "anxiety disorder" and "Tourette's Syndrome" as serious medical conditions. These additions will greatly expand the number of patients who can receive the benefits of medical marijuana.

PennAlt also writes in support of proposed § 1151.29. The change in language from “immediately” to “promptly” will provide PennAlt and other grower/processors a much-needed window of time to report anticipated variations in production to the Department. This is especially important for grower/processors that are still in the initial operational phase as they grow accustomed to market forces and the industry as a whole.

PennAlt further writes in support of the proposed amendments to § 1151.26 that expand both the number of employees a grower/processor may have monitoring its security systems and the times when a grower/processor’s entrances and exits must be locked. PennAlt supports these proposed changes as they will increase the safety and security of grower/processors, their facilities, and their employees.

There are, however, certain proposed amendments which PennAlt either opposes or requests amendment for clarity.

First, as it stands, PennAlt opposes the addition of proposed § 1141.22(f), which permits the Department to “release de-identified data for research purposes, subject to approval and oversight by the Department and an [Institutional Review Board] to ensure that the use of the data is limited to the specified research purpose.” The possibility of potentially confidential or identifying information being released is concerning to PennAlt.

To begin with, the phrase “de-identified data” is not defined. PennAlt proposes the following definition for “de-identified data:”

Data which does not include the telephone numbers of the grower/processor; email addresses of a grower/processor; any personally identifying information regarding shareholders, financial backers or other investors of a grower/processor which is not already subject to disclosure; or any information that is considered confidential under subsection § 1141.22(b).

This proposed definition establishes a standard by which grower/processors will be assured their data will remain confidential and non-identifying even as it is shared with researchers.

Furthermore, with respect to the current construction of proposed § 1141.22(f), the Department is not required to provide notice to or otherwise inform a grower/processor if its data will be or has been disclosed to a research entity. PennAlt

proposes that a grower/processor should be provided at least 30-day notice when the Department intends to release that grower/processor's data to a research entity, so that the grower/processor can object to the release of the information. Along with this 30-day notice, the Department should share the "de-identified data" it intends to disclose.

PennAlt requests clarity on the proposed addition to § 1151.24, regarding the additional 30-day window during which seeds may be purchased and imported from outside the Commonwealth. Specifically, the proposed § 1151.24(a) adds, "...within any 30-day window established by the Department if the Department determines that the importation of additional seeds is necessary." This addition to § 1151.24(a) is unclear. One could interpret the addition to mean that the Department will be setting a blanket 30-day window during which all grower/processors may obtain seeds from outside the Commonwealth. One also could read the addition as providing that grower/processors may submit a request to the Department for a 30-day period, during which the requesting grower/processor may obtain seeds from outside the Commonwealth.

PennAlt submits that the latter interpretation should be adopted by the Department for the proposed addition to § 1151.24(a). Without individualized import periods, the Department is put in the position of anticipating increased demand for the entire medical marijuana industry across the Commonwealth and forcing all grower/processors to work within the Department's determinations. This one-size-fits-all system would hardly provide for the flexibility intended by the proposed addition. Grower/processors are in a better position than the Department to determine variations in the market and would be better able to respond to market forces if the proposed addition allowed grower/processors to have more control over when they are able to import seeds. A system whereby the Department sets blanket windows applicable to all grower/processors, however, would not allow for the flexibility and autonomy grower/processors require in order to fully serve the people of this Commonwealth. PennAlt supports an amending of the proposed § 1151.24(a) to allow for grower/processors to submit requests to the Department for additional 30-day windows to obtain seed from outside the Commonwealth.

Finally, PennAlt opposes the proposed amendment to § 1171.29(c) requiring that the laboratory that tests each process lot before the medical marijuana product is sold be a different laboratory than the one that tested the harvest batch prior to production. The current testing regulations in place have established an appropriate process to test the character of the medical marijuana, as well as its safety. PennAlt has not experienced, nor is concerned with, the need for checks and balances on the laboratory

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testing. This proposed amendment will, if adopted, add unnecessary costs and create operational inefficiencies for all grower/processors.

PennAlt respectfully submits the above comment to the Department's proposed rulemaking dated March 6, 2021, and requests that the Department adopt the proposed regulations incorporating PennAlt's comments above.

Very truly yours,



Frederick N. Frank

CC: Anthony Bucci, Chairman of the Board, PennAlt Organics, Inc. *(via email)*
John Paul, Chief Executive Officer, PennAlt Organics, Inc. *(via email)*