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Background

Per the Pennsylvania Medical Marijuana Act (35 P.S. § 10231.101 - 102131.2110), which became effective on May 17th, 2016, the Department of Health periodically published temporary regulations relating to various sections of the Act. These regulations are effective for two years from the date of publication and are to be followed by the promulgation of formal permanent regulations. The most recent set of temporary regulations are set to expire November 20, 2021, and the Department now seeks to promulgate the permanent regulations to replace the current temporary regulations. As part of this planned rulemaking period, the following comment is offered for consideration.

Proposal

This proposal opens up the sale of hemp-derived raw material produced under the PA Hemp Program to the PA Medical Marijuana (MMJ) wholesale market in support of rounding out MMJ patient medicinal regimes with high CBD/low THC options. This solution improves the quality and access for patients, reduces the alternative medicine cost of healthcare and boosts the local PA agriculture industry.

This proposal has been developed through collaborative discussions with the **PA Hemp Steering Committee** (representing over 600 PA Hemp Farmer and Processor permittees in 2020), the **PA Department of Agriculture** and the **PA Cannabis Coalition**.

Research

Multiple avenues of research were completed to validate the recommendation. These include gathering:

- MMJ Patient satisfaction and demand for high CBD/low THC options
- the voice of the Hemp Farmers and Processors
- projected financial savings to be passed onto patients
- other State regulatory benchmarks (such as Illinois, New York, Kentucky, Maryland, Oregon).

MMJ Program Findings

A recent survey of 160+ PA MMJ Patients revealed:

- Sixty-three percent (63%) of the MMJ Patients incorporate low THC (or THC free) high CBD products into their health regime. Thirty-seven percent (37%) use CBD products daily and a majority, 51%, occasionally use CBD products to supplement their wellness program.
 - Clearly there is a high demand for quality CBD products as an integrated wellness offering.
- Fifty-two percent (52%) of MMJ patients are most likely to purchase products that contain CBD at their MMJ dispensary with 96% of the respondents reporting the price of MMJ CBD products as high. Fifty-three (53%) responded that there is not a broad selection of high CBD/low THC products even offered in their dispensary and 48% alternatively purchase these products online or in retail stores not known to the MMJ program.

- An alarming rate of consumers are forced to purchase from unknown suppliers with varying degrees of unproven quality standards.
- Thirty-nine percent (39%) of the patients are currently compounding (mixing THC with retail purchased CBD sources) at home to address the challenge.
 - These practices, an outcome of regulatory constraint, raise patient safety concerns.

In summary, a majority of the Patients, 61%, did not know the PA MMJ program blocks local PA Hemp Farmers/Processors from selling their materials to Growers/Processors in the MMJ program and 95% would be in favor of this initiative.

Relative to cost considerations, MMJ growers have limited canopy space, capacity, and high costs to consider when cultivating cannabis. Their greenhouse and production facilities are dedicated to their primary market demand and the cost can be as high as 10 times a Hemp grower's per gram cost due to regulatory requirements of growing indoor and associated overhead. This initiative would alleviate constraints on the MMJ supply chain.

PA Agriculture Findings

Most Pennsylvania farmers are struggling to make ends meet and as the profitability of farming declines, farmers are unable to sustain farming operations (continue leases, purchase new land, or even retain ownership of their land). As a result, there are fewer upcoming generations willing to take on the family farm business and many farmers have or are considering closing down. As of 2017, the USDA's Census of Agriculture shows more than 400,000 acres were lost from production in PA since 2012, about 5 percent of all farmland in the commonwealth.

Farmers are desperate to introduce new crops to keep Pennsylvania farming alive. This was evidenced when the farming community embraced the opportunity to cultivate hemp following Sec 7606 of the 2014 Farm Bill (7 U.S.C. 5940). Since 2017 the PA Department of Agriculture recognized significant increases in new permit requests, even after the cannabinoid biomass market crash of 2019.

With regard to the Hemp Farmer and Processor Permit holders in Pennsylvania:

- There have been 885 grow permits over a four-year period of which 90% have grown for cannabinoids;
- The majority have expressed (including constituents from the Plain Community) that lawmakers have not embraced the hemp opportunity nor opened avenues to find markets for sale of their products;
- In 2020 the PA Department of Agriculture launched processing permits of which it authorized 71 permits in the first year;
- The majority of both Farmers and Processors would be interested in meeting the demand of the MMJ market even if it required additional tracking and testing around the quality of their harvest and/or processed material.

Recommendation and Suggested Language

Pennsylvania has a unique opportunity to accomplish a regulatory and economic win/win scenario by opening up the MMJ wholesale market to Hemp growers and processors.

Several other States have adopted these types of regulations, such as Illinois, New York, Kentucky, Maryland and Oregon and can be evaluated on their merits. With the right balance of regulation, quality control and education, this proposal can lead to a better MMJ patient program while offering a lifeline to the farmers of PA struggling to survive.

Success would be determined by:

- Improving MMJ Patient access to high quality CBD products;
- Improving Patient safety;
- Reducing production costs for MMJ processors through lower cost of ingredients;
- Reducing the cost to Patients of alternative medicines;
- Increasing revenues for struggling Hemp farmers in Pennsylvania;
- Demonstrating a strong relationship between the Department of Health and the Department of Agriculture in support of Pennsylvanians.

Suggested Language for CHAPTER 1151 (Reserved) §§ 1151.21—1151.45 (Reserved) (see attached)

Thank you for considering our research and comments. Should you have any questions, please contact:

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CHAPTER 1151a. GROWERS/PROCESSORS

§ 1151a.27. Requirements for growing and processing medical marijuana.

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(f) A grower/processor may not use any added substance that alters the dosage level, color, appearance, smell, taste, effect or weight of the medical marijuana unless the grower/processor has first obtained the prior written approval of the Department.

Excipients must be pharmaceutical grade, unless otherwise approved by the Department.

In determining whether to approve an added substance, the Department will consider:

- (i) Whether the added substance is permitted by the United States Food and Drug Administration for use in food or is Generally Recognized as Safe (GRAS) under federal guidelines.
- (ii) Whether the added substance constitutes a known hazard such as, but not limited to, diacetyl, CAS number 431-03-8, and pentanedione, CAS number 600-14-6.

A. Notwithstanding subsection (f) a grower/processor may obtain hemp and hemp-derived extract from an authorized hemp producer with a permit to grow hemp from either the Pennsylvania Department of Agriculture, or the U.S. Department of Agriculture, to process and add to medical marijuana products, provided the hemp and hemp-derived extracts comply with § 1171a.29(d) (relating to Testing Requirements).