Cannabis Law PA
ATTORNEYS AT LAW

Judith D. Cassel
(717) 236-1300 x232
jdcassel@hmslegal.com

Mariah R. Turner
(717) 236-1300 x225
mrturner@hmslegal.com

100 North Tenth Street, Second Floor, Harrisburg, PA 17101 Phone: 717.703.0804 www.cannabislawpa.com

April 2, 2021

Via Electronic Mail

John J. Collins, Director
Pennsylvania Department of Health
Office of Medical Marijuana
Health and Welfare Building, Room 628
625 Forster Street
Harrisburg, PA 17120
RA-DHMMregulations@pa.gov

In re: Keystone State Testing, LLC's Medical Marijuana Laboratory Regulation Comments

Dear Mr. Collins:

Please accept these comments from Cannabis Law PA on behalf of Keystone Laboratories.

Best regards,

Judith D. Cassel
Mariah R. Turner

JDC/MRT/das
Enclosure

Keystone State Testing, LLC's
Medical Marijuana Laboratory Regulation Comments
Filed with Department of Health, April 2, 2021

Keystone State Testing, LLC ("Keystone"), hereby submits the following Comments in response to the Department of Health ("DOH")'s proposed rulemaking of the permanent regulations to replace the current temporary regulations at 28 Pa. Code Part IX (relating to medical marijuana).

INTRODUCTION

On April 17, 2016, the Pennsylvania Medical Marijuana Act ("Act") was signed into law to create the Commonwealth's Medical Marijuana Program ("Program"). The Act provided DOH with the authority to implement and administer temporary regulations for the Program. DOH promulgated the current temporary regulations at 28 Pa. Code Part IX. On March 6, 2021, the *Pennsylvania Bulletin* posted DOH's proposed rulemaking, inviting written comments, suggestions, or objections within 30 days after its publication.

Keystone is a DOH approved independent laboratory. Keystone is a certified women-owned small business ("WOSB") and woman business enterprise ("WBE"). Keystone provides DOH-licensed growers, processors, and dispensaries with efficient, safe, and accurate testing by using the highest levels of integrity, rigor, and scientific standards. Keystone's Comments are meant to assist DOH in its development of the permanent regulations. Based on the Act's § 102 goal to provide the Commonwealth with a medical marijuana program that balances the needs of its patients to access the latest treatments with the need to promote patient safety, Keystone hereby submits the following:

COMMENTS

Comment No. 1

The proposed regulation is:

§ 1171a.29. Testing requirements.

> **(c) At a minimum, testing, as prescribed by the Department, shall be performed as follows:**
>
> **(2) An approved laboratory other than the one that tested the harvest batch or harvest lot shall test samples from each process lot before the medical marijuana is sold or offered for sale to another medical marijuana organization.**

Keystone opposes the above proposed permanent regulation as it moves from one approved laboratory testing the harvest and process lot samples, as stated in the temporary regulations, to requiring one approved laboratory to test the harvest lot sample and a different approved laboratory to test the process lot sample. DOH justified this change by stating that the "revision creates checks and balances in the testing process."

Keystone opposes this change because it is: (1) contradictory to the unambiguous language of the Act; (2) interferes with the right of private parties to independently contract and is not in the public interest or the private sector; (3) is an unlawful delegation of DOH's duties; and (4) creates an unnecessary and misrepresentation of a mechanism for "checks and balances."

First, DOH is not given the authority to go beyond the unambiguous language of the Act. When reviewing proposed regulations, the Independent Regulatory Review Commission ("IRRC") is required to determine "whether the agency has the statutory authority to promulgate the regulation and whether the regulation conforms to the intention of the General Assembly in

the enactment of the statute upon which the regulation is based." 71 Pa. Stat. § 745.5b(a). The best indication of the General Assembly's intent is the "plain language of the statute." *Matter of Private Sale of Prop. By Millcreek Twp. Sch. Dist.*, 185 A.3d 282, 290-291 (Pa. 2018).

The Act explicitly states that "[a] grower/processor ***shall contract with an independent laboratory*** to test the medical marijuana produced by the grower/processor." 35 P.S. § 10231.704 (emphasis added). The plain meaning of the Act, allows the grower/processors to contract with one independent laboratory to complete the required testing of the harvest lot and process lot samples. The act does not prohibit a grower processor from using multiple testing laboratories, but it does not require the grower/processor to use two separate laboratories for its testing needs. As the Act is unambiguous and the General Assembly clearly did not intend to force the use of two laboratories to complete testing, this proposed regulation goes beyond the Act and as such, DOH does not have the statutory authority to promulgate it.

The Act also expressly prioritizes affordable medicine. In § 10231.1201 of the Act, the legislature authorized the Advisory Board to determine "how to ensure *affordable* patient access to medical marijuana." (Emphasis added.) By forcing growers away from negotiated rates and volume discounts, DOH is adding unnecessary costs to patients' medicine and contradicting the purpose and priorities of the Act.

Second, the proposed regulation interferes with the private sectors right to contract because it substantially impairs the obligations of current and future contracts between laboratories and grower/processors in violation of Article I of the Pennsylvania Constitution. Under the Pennsylvania Constitution, the Contract Clause prohibits state regulations from "impairing the

obligations of contracts." Pa. Const. art. I, § 17. The Contract Clause analysis requires the review of: (1) whether there is a contractual relationship, (2) whether a change in law impairs the contractual relationship, and (3) whether the impairment is substantial. *South Union Tp. v. Com.*, 839 A.2d 1179 (Pa. Cmwlth. 2003), affirmed 854 A.2d 476 (Pa. 2004). If the regulation constitutes a substantial impairment, the state agency must justify it by providing a significant and legitimate public purpose behind the regulation. *EmergyCare, Inc. v. Millcreek Tp.,*68 A.3d 1 (Pa. Cmwlth. 2013). If a legitimate public purpose has been identified, it must be determined whether the adjustment to the contracting parties' obligation is based upon reasonable conditions and whether the regulation is "of a character appropriate to the public purpose justifying adoption." *Id.*

The Department's proposed regulation violates the Contract Clause, because the new regulation would penalize any laboratory that has contracts in place to test both the harvest lot and process lot. DOH claims that the proposed change is necessary "for checks and balances," however, there was no justification of why checks and balances were needed and how such two-laboratory requirement would in fact provide said checks and balances. DOH provided no rationale to usurp the reasoned and calculated choice each grower/processor makes to contract with its chosen laboratory. Therefore, DOH's limitation of the grower/processors' choice of laboratory to perform the required testing unjustifiably impacts their contract obligations and is unconstitutional.

Related to the DOH's violation of the Contract Clause, is IRRC's obligation to consider whether the regulation has any economic or fiscal impacts, such as "adverse effects on prices of goods and services, productivity or competition." 71 Pa. Stat. § 745.5b(b)(1)(ii). The IRRC should find the economic impact of the regulation (i) adversely effects the competition by usurping the grower/processor's choice to contract with whichever laboratory it deems most qualified, and (ii)

impacts a laboratory's profits by removing its ability to perform and charge for the previously guaranteed secondary service. This independent ability to choose a laboratory to provide testing promotes competition because the grower/processors will choose a laboratory that meets their standards of services and quality. This open competition is not only economically important, but it also inherently creates the actual "checks and balances" DOH seeks.

As a result of mandating growers pull business away from laboratories, DOH's proposed regulation may cripple the smaller laboratories as these laboratories rely on providing both services in each contract with a grower/processor.

Third, Keystone submits the proposed regulation is an unlawful delegation of DOH's duties established by the Act. Under Article 2, § 1 of the Pennsylvania Constitution, the Legislature is given the power to delegate its duties in connection with the execution of law. However, in conferring this authority and discretion to an administrative agency, the Legislature's grant of authority "must contain adequate standards to guide and restrain exercise of the delegated administrative function. *Reeves v. Pa. Game Comm'n*, 584 A.2d 1062 (Pa. Cmwlth. 1990). These limits on an administrative agency's power, enjoining it on "certain course of procedure and rules of decision in performance of its function," protect from a pure and unconstitutional delegation of power. *Holgate Bros. Co. v. Bashore*, 200 A. 672 (Pa. 1938).

Under the Act, DOH is specifically given the "regulatory and enforcement authority over the growing, processing, sale and use of medical marijuana in this Commonwealth." 35 P.A. § 10231.301(a)(3). DOH's regulatory oversight, includes requiring a test at harvest and a test at final processing." 35 P.S. § 10231.704. Under the proposed new regulation DOH abdicates its oversight

responsibility and unconstitutionally delegates to a private party (the second independent lab). In lieu of this proposed regulation, the DOH could easily collect samples and have an independent laboratory analyze the samples. In this way, DOH could check laboratory effectiveness, grower/processors' processes, product going to patients, and the entire system that is in place. The DOH could also send known contaminated product to all laboratories (e.g. VGBA-Bacterial Filth) in order to test each laboratory's ability to detect such a contaminant. Such an independent oversight would supply the necessary checks and balances this proposed regulation seeks to create.

Fourth, DOH would not need a mechanism for "checks and balances" if it required specific methodologies and enforced them through its own independent review and testing process. Until then, forcing any grower/processor to utilize multiple testing facilities with varying methodologies does not create checks and balances; it creates unnecessary inconsistencies. The ISO17025 does not ensure approved laboratories are accurately performing testing, only that they adhere to a quality management system prescribed by ISO17025. Proficiency tests are not sufficient to ensure approved laboratories can correctly do testing, particularly within similar ranges of certainty. The acceptance ranges of proficiency tests can be as wide as 30%, which would imply one laboratory could provide a systematically low value and a second laboratory a systematically high value that could lead to the change in results being as high as 60% with both laboratories passing proficiency tests. Under § 1171a.34(a), DOH could and should provide multiple laboratories samples from the same grower's batch in order to test and ensure that all laboratory results are in agreement within an acceptable deviation. This option would cause less quality assurance issues from grower/processors and would also provide "checks and balances."

Comment No. 2

The proposed regulation is:

§ 1141a.27. General requirements for application.

(a) The types of applications to be submitted to the Department under this part include:

(1) An initial permit application.

(2) A permit renewal application.

(3) An application for change in ownership of a medical marijuana organization.

(4) An application for approval of a change of location of an operational facility.

(5) An application for approval of alteration of a facility.

(6) An application for additional dispensary locations

(7) An application for approval of a laboratory.

Keystone suggests that § 1141.27(a) be revised to include "(8) An application for renewal of a laboratory" because § 1171a.25 of the laboratory regulations requires laboratories to submit a renewal application and the addition of such would properly reflect this requirement.

Comment No. 3

The proposed regulation is:

§ 1151a.25. Access to grower/processor facilities.

(e) A grower/processor shall do the following when admitting an individual to a site or facility:

(5) Ensure that the individual does not touch any seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products located in a limited access area.

Keystone suggests that subsection (e)(5) explicitly exclude laboratory sampling agents. A laboratory sampling agent is required to physically handle samples to ensure representative samples are collected. This guarantees that laboratories are not simply testing preferred samples handled and provided by a grower/processor.

Comment No. 4

The proposed regulation is:

§ 1171a.26. Stability testing and retention of samples.

(a) A grower/processor shall request that a sample be identified and collected by an approved laboratory from each harvest batch sufficient to perform stability testing at 6-month intervals for a 1-year period.

The Guidance for Quality Testing and Sampling by Approved Laboratories (the "Guidance") issued by DOH's Office of Medical Marijuana in August 2018, required finished flower products to be tested at 1 and 3-month intervals. DOH's proposed regulation should include the Guidance issued after the adoption of the current temporary regulations, in order to eliminate uncertainty.

Comment No. 5

The proposed regulation is:

§ 1171a.31. Test results and reporting.

(a) Only the results of the following tests are in compliance with the testing requirements of this chapter:

(2) Tests conducted on process lot samples requested by a grower/processor under § 1171a.29 and identified collected by either an employee of a grower/processor or an employee of an approved laboratory.

Keystone opposes the adoption of subsection (a)(2) as currently proposed. Keystone suggests the removal of "an employee of a grower/processor" as a permitted party to collect process lot samples for testing. This clearly contradicts § 1171a.28(c)'s requirement where only laboratory employees are permitted to collect samples.

Comment No. 6

The proposed regulation is:

> **(b) The test results from each sample collected under § 1171a.28(c) (relating to selection protocols for samples) shall be entered into the electronic tracking system and shall only be accessible to the grower/processor submitting the sample and to the Department.**

Keystone notes that this is not currently the practice. Currently, if a laboratory tests the same harvest lot or harvest batch as another laboratory, both results are visible to both laboratories.

Comment No. 7

The proposed regulation is:

> **(e) An approved laboratory shall issue to a grower/processor a certificate of analysis, including the supporting data, for each harvest batch, harvest lot or process lot sample that was tested at the request of the grower/processor. The certificate of analysis must include the following:**
>
> **(2) That the presence of the following contaminants within the harvest batch, harvest lot or process lot does not exceed the levels as determined by the Department for the following:**
>
> **(iii) Any microbiological impurity, including:**
>
> **(C)** ***P. aeruginosa.***
>
> **(D)** ***Aspergillus spp.***
>
> **(E)** ***S. aureus.***

Keystone requests additional information or clarification on the testing of microbiological impurities of *P. aeruginosa, Aspergillus spp*, and *S. aureus* found under subsection (e) paragraph (iii). Specifically, DOH's regulations require the COA to list these microbiological impurities, whereas the Guidance does not list such microbiological impurities under the chart for "Required Contaminant Analyses and Acceptance Criteria." Further, DOH's ELIMS do not include these microbiological impurities as entries for data. Laboratories need clarification on what microbial impurities are required and DOH's ELIMS should have areas to enter all required data.

Comment No. 8

The proposed regulation is:

> **(e) An approved laboratory shall issue to a grower/processor a certificate of analysis, including the supporting data, for each harvest batch, harvest lot or process lot sample that was tested at the request of the grower/processor. The certificate of analysis must include the following:**
>
> **(2) That the presence of the following contaminants within the harvest batch, harvest lot or process lot does not exceed the levels as determined by the Department for the following:**
>
> **(iv) Whether the harvest batch, harvest lot or process lot is within the specifications for the strain for the characteristics of:**
>
> **(D) Moisture content.**

Keystone requests clarification on the COA's requirement of the moisture content for process lots. Except for finished flower, process lots are not tested for moisture content. The regulation, as written and proposed, does not provide any distinction.

Comment No. 9

The proposed regulation is:

§ 1171a.33. Transporting samples.

(b) An employee of an approved laboratory, grower/processor or third-party contractor who transports process lot samples from a grower/processor to an approved laboratory shall:

(1) Protect the physical integrity of the sample.

(2) Keep the composition of the sample intact.

(3) Protect the sample against factors that interfere with the validity of testing results, including the factors of time, temperature and other environmental factors that may work to jeopardize the integrity of the sample.

Keystone suggests that subsection (b) include harvest batch and harvest lot samples. As the regulations are currently proposed, only samples from process lots require safe transportation standards.

Comment No. 10

The proposed regulation is:

§ 1171a.35. Laboratory reporting.

(a) An approved laboratory shall enter into the electronic tracking system the following information for each sample collected under § 1171a.28(c) (relating to selection protocols for samples) and each test conducted:

(3) The employee identification number of the employee of the approved laboratory who identified and collected the sample at the request of the grower/processor.

(4) The date and time the sample was collected from the grower/processor.

(5) The date and time the sample was received by the approved laboratory.

Keystone requests clarification on the requirement to include the subsection (a) information listed above in the electronic tracking system. Currently, laboratories are unable to include this information as DOH's ELIMS does not provide a way or section to insert this information.

Comment No. 11

The proposed regulation is:

> **(b) An approved laboratory shall keep for 4 years a paper or electronic copy of the certificate of analysis performed on samples submitted by a grower/processor or test samples submitted by the Department including test results not required to be entered into the electronic tracking system under § 1171a.29 (relating to testing requirements).**
>
> **(1) Regarding tests results not entered into the electronic tracking system, the approved laboratory shall immediately provide to the Department an electronic copy of the certificate of analysis.**

Keystone requests clarification or additional information as to the proposed requirement to immediately provide DOH with an electronic copy of COAs that are not required to be entered into the electronic tracking system. As written, laboratories would be required to always provide these COAs to DOH, and not only upon request. Keystone submits that supplying DOH with every test not entered into DOH's ELIMS is a large burden for laboratories but, more importantly, will result in DOH receiving a large quantity of useless data daily.

Comment No. 12

The proposed regulation is:

§ 1141a.21. Definitions.

Keystone comments on the following definitions:

(8) Certificate of analysis ("COA"), which is defined as "a document that confirms that the test performed by an approved laboratory on a harvest batch, harvest lot or process lot meets the testing requirements set for by the Department"; and

(9) Chain of custody ("COC"), which is defined as "the written procedures used by employees of an approved laboratory to record the possession and transfer of samples and test samples from the time the samples and test samples are collected until the test of the sample or test sample is completed."

Limiting the COA to the results of the harvest batch, harvest lot, or process lot is not accurate because it does not include stability testing. Additionally, if the Department, or a grower/processor requests only the number of analytes, such as total cannabinoids, the limited definition of COA does not include reporting such information. The definition should provide for a broader range of testing, results, and timing.

The definition of COC, should be bifurcated into "COC manual/procedure" as the standard operating procedure to follow for the chain of custody of samples and "COC record" to mean the logging of the chain of custody.

CONCLUSION

Keystone State Testing, LLC respectfully requests that the Department of Health consider and adopt the foregoing Comments.

Dated: April 2, 2021