DH, MMRegulations

From: Debbie A. Schreffler <DASchreffler@hmslegal.com>
Sent: Monday, April 5, 2021 11:08 AM
To: DH, MMRegulations
Cc: Judith Cassel; Steven A. Hoenstine
Subject: [External] IRRC #3290/Regulation #10—219 Medical Marijuana; Comments of Cannabis Law PA
Attachments: Cannabis Law PA Comments to IRRC #3290 (Permanent Regs for MMJ Labs).pdf

Director Collins:

Attached you will find Cannabis Law PA's Comments to the IRRC #3290/Regulation #10 – 219 Medical Marijuana.

Sent on behalf of:

Judith D. Cassel | Cannabis Law PA
100 North 10th Street
Second Floor
Harrisburg, PA 17101
Phone: 717.703.0804
http://cannabislawpa.com

Cannabis Law PA
ATTORNEYS AT LAW

Judith D. Cassel
(717) 703-0804
jdcassel@hmslegal.com

Steven A. Hoenstine
(717) 703-0813
sahoenstine@hmslegal.com

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

April 5, 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: IRRC #3290/Regulation #10—219 Medical Marijuana; Comments of Cannabis Law PA

Dear Director Collins:

Please accept these comments from Cannabis Law PA on behalf of its medical marijuana clients.

Best regards,

Judith D. Cassel
Steven A. Hoenstine

JDC/SAH/das
Enclosure

Comments on IRRC #3290/"Regulation #10—219: Medical Marijuana"
Filed Online with the Pennsylvania Department of Health and the Independent Regulatory Review Commission
April 5, 2021

Introduction

Cannabis Law PA (CLP) represents grower/processors, dispensaries, physician groups, and laboratories approved to test medical marijuana in Pennsylvania. CLP submits these comments to the Department of Health (DOH) and the Independent Regulatory Review Commission (IRRC) to assist in the creation of regulations under the Pennsylvania Medical Marijuana Act (the Act).

In passing the Act, the General Assembly's stated intent was to provide access to medical marijuana through a protocol that balances the need of patients to have access to the latest treatments with the need to promote patient safety, provide a safe and effective method of delivery of medical marijuana to patients, and promote high quality research into the effectiveness and utility of medical marijuana.[1]

Proposed Permanent Regulation

§1171a.29. Testing requirements.

(c) At a minimum, testing, as prescribed by the Department, shall be performed as follows:

(1) An approved laboratory shall test samples from a harvest batch or harvest lot prior to using the harvest batch or harvest lot to produce a medical marijuana product.

(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.

DOH explains this proposed permanent regulation (§1171a.29) as follows:

The current subsection (c) specifies that an approved laboratory must minimally test two samples at harvest and at process stages. This proposed subsection (c) amends the current subsection (c) by providing that one approved laboratory must conduct testing on the harvest sample and a different approved laboratory must conduct testing on the processed sample. This revision creates checks and balances in the testing process.

The proposed regulation at §1171a.29 may violate the Act; Article I, Section 17 of the Pennsylvania Constitution; Article II, Section 1 of the Pennsylvania Constitution; and the Regulatory Review Act (RRA). Additionally, enforcement of §1171a.29 will cause direct and immediate harm to laboratories.

[1] 35 P.S. § 10231.102(3).

Violation of the Act / Lack of Authority

When an agency adopts a legislative rule, it "is valid and binding upon courts as a statute so long as it is (a) adopted within the agency's granted power, (b) issued pursuant to proper procedure, and (c) reasonable."[2] The DOH is authorized to promulgate regulations related to the Commonwealth's medical marijuana protocol only to the extent "necessary to carry out the provisions"[3] of the Act. The Act requires grower/processors to "contract with *an* independent laboratory to test the medical marijuana produced by the grower/processor" (emphasis added).[4] Although the Act does not explicitly restrict grower/processors to contract with a single laboratory, §1171a.29 would *require* grower/processors to contract with at least two laboratories, which is not provided in the plain language of the Act. A proposed regulation that goes beyond its own enabling act cannot be necessary to carry out said act. DOH does not provide the rationale or reasoning that justifies the promulgation of §1171a.29 because such regulation of laboratories goes beyond the Act itself.

Possible Violation of Article I, Section 17 of the Pennsylvania Constitution

Article I, Section 17 of the Pennsylvania Constitution (the "Contracts Clause") prohibits state regulations from "impairing the obligation of contracts." Contract clause analysis involves three elements: whether there is a contractual relationship, whether a change in law impairs the contractual relationship, and whether the impairment is substantial.[5] If the state regulation constitutes a substantial impairment, the state must justify the impairment by showing that it addresses a significant and legitimate public purpose, such as the remedying of a broad and general social or economic problem.[6] Further, the regulation's adjustment of the rights and responsibilities of contracting parties must be based upon reasonable conditions and be of a character that is appropriate to the public purpose justifying the regulation's adoption.[7]

Grower/processors currently operating pursuant to the Act and DOH's oversight have ongoing contractual obligations—including exclusive supply contracts with laboratories—that §1171a.29 would force the parties to violate. The proposed regulation would cause substantial impairment of existing and proposed contracts between grower/processors and laboratories. These existing contracts are based on real differences in laboratory service levels, prices, and the accuracy of results. DOH has not justified this substantial impairment. DOH merely explains that §1171a.29 "creates checks and balances in the testing process." DOH does not provide any evidence that there is any need for this regulation or how this would benefit patients or improve patient safety.[8]

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[2] *Marcellus Shale Coal. v. Dep't of Envtl. Prot*., 216 A.3d 448, 459 (Pa.Cmwlth. 2019), appeal quashed, 223 A.3d 655 (Pa. 2019), and appeal quashed, 223 A.3d 655 (Pa. 2019) (citing *Tire Jockey Serv., Inc. v. Com., Dep't of Envtl. Prot*., 591 Pa. 73, 108, 915 A.2d 1165, 1186 (2007)).

[3] 35 P.S. § 10231.301(b).

[4] 35 P.S. § 10231.704.

[5] *South Union Tp. v. Com.*, 839 A.2d 1179 (Pa. Cmwlth. 2003), affirmed 854 A.2d 476, (Pa. 2004).

[6] *EmergyCare, Inc. v. Millcreek Tp.,* 68 A.3d 1, (Pa. Cmwlth. 2013).

[7] *Id.*

[8] DOH's assertions in its Regulatory Analysis Form that the entire set of new regulations promulgated as IRRC #3290/"Regulation #10—219: Medical Marijuana" is "necessary for the continued viability of the program" is based on the premise that all of the existing medical marijuana temporary regulations will expire on November 20, 2021. The statewide protocol will, of course, not be viable if those temporary regulations are not renewed or replaced before they expire, but that does not necessitate replacing one specific temporary regulation with a new, *different*

DOH does not explain how mandating two laboratories versus one laboratory achieves its stated goal. The DOH cannot and does not explain why §1171a.29 is an appropriate mechanism to improve patient safety or achieve its purpose.[9]

Given the substantial impairment to existing contracts and the absence of a justification, §1171a.29 likely violates the Contracts Clause.[10]

Violation of Article II, Section 1 of the Pennsylvania Constitution

Article II, Section 1 of the Pennsylvania Constitution (the "Non-Delegation Clause") vests Pennsylvania's legislative power in the General Assembly, which "cannot constitutionally delegate the power to make law to any…other body or authority."[11] The General Assembly may only delegate policymaking authority to an administrative agency if the General Assembly also makes the "basic policy choices and establishes adequate standards which will guide and restrain the exercise of the delegated administrative functions."[12] The General Assembly properly delegated policymaking authority over medical marijuana testing laboratories to the DOH, which is required by the Act to "approve" laboratories before they are allowed to test grower/processors' medical marijuana.[13] It's clear that the General Assembly intended (i) that the Act ensure patient safety and (ii) that the DOH regulate laboratories to ensure the accuracy of their results, which is key to patient safety.[14]

Rather than regulating laboratories to ensure the accuracy of their results as the General Assembly intended, the DOH is delegating its authority to regulate laboratories to *other laboratories* by requiring that laboratories regulated by DOH somehow theoretically double-check each other's results through a completely undefined process. DOH explains that this new requirement "creates checks and balances in the testing process," but the proposed regulation does not achieve any such checks and balance between laboratories. Ceding DOH's gatekeeping function to privately operated laboratories undermines the General Assembly's stated intention that the Commonwealth "carefully [regulate] the program which allows access to medical marijuana" in order to enhance patient safety while continuing research into medical marijuana's

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permanent regulation. The IRRC process, the Pennsylvania Constitution, and fair and equitable commerce concepts require that DOH be more specific; DOH needs to justify what necessitates its decision to change the regulation in question.

[9] Assuming DOH's purpose is to ensure accurate testing, DOH must explain why §1171a.29 is a more appropriate method of achieving its purpose than the proficiency testing it is already empowered to do, and should do, pursuant to its own regulations at 28 Pa. Code 1171.34(a).

[10] DOH also fails to acknowledge the costs associated with the contract disputes to which §1171a.29 will give rise. In Section 19 of its Regulatory Analysis Form, which should include "a specific estimate of the costs…to the regulated community associated with compliance, including any legal…procedures that may be required," DOH notes that laboratories have "contractual arrangements" with grower/processors but does not mention that §1171a.29 will compromise those contracts, leading to legal costs for both grower/processors and laboratories. DOH should be able to estimate this cost with some confidence because it should have a copy of all contracts between laboratories and grower/processors pursuant to its own regulation at 28 Pa. Code 1171.29(a).

[11] *Washington v. DPW*, 71 A.3d 1070, 1087 (Pa. Cmwlth. 2013) (quoting *Blackwell v State Ethics Commission*, 567 A.2d 630, 636 (Pa. 1989)).

[12] *Insurance Federation of Pennsylvania, Inc. v. Com., Dept. of Ins*., 889 A.2d 550, 585 Pa. 630, Sup.2005 (cleaned up).

[13] 35 P.S. § 10231.704.

[14] *See, e.g.* 35 P.S. § 10231.102(3)(ii).

effectiveness.[15] DOH should not use the regulatory process to delegate to the entities it regulates the exact authority that DOH received through legislative delegation. This delegation is not in the best interest of the program or the patients. There are far better means of achieving the oversight of laboratories without abdicating the DOH's oversight role. For example, DOH could secure and test sample product from dispensaries or send product with known contaminants to all laboratories to determine the efficacy of each laboratory's ability to detect such contaminants. To require two different laboratories (who may use very different methodologies) test for two separate and distinct phases of medical marijuana production does not achieve any level of "checks and balances." The likely result is just the opposite.

Violations of the Regulatory Review Act

The RRA requires that IRRC determine whether §1171a.29 is in the public interest.[16] A regulation is not in the public interest if it is promulgated by an agency that does not have the statutory authority to do so, if the regulation does not conform to the intention of the General Assembly as provided for by the enactment of the enabling statute,[17] or if the regulation is unreasonable due to a lack of need for it.[18]

The General Assembly intended that medical marijuana be affordable for patients. It asserts that patients must have "access" to medical marijuana,[19] it requires the Medical Marijuana Advisory Board to report on "how to ensure affordable patient access to medical marijuana,"[20] and it empowers the DOH to institute price controls on medical marijuana if the prices are "unreasonable or excessive."[21] Despite this clear intent by the General Assembly to create a protocol that provides affordable medical marijuana to patients, §1171a.29 will make medical marijuana unnecessarily more expensive for patients by eliminating the volume pricing enjoyed by grower/processors and create process disruption for those who use a single laboratory for all of their testing needs. The proposed regulation will increase the cost of testing to all grower/processors, who will pass along those increased costs to patients. This is another example of §1171a.29's conflict with the General Assembly's clear intent.

There is a real concern as to whether §1171a.29 is reasonable, needed, or appropriately constructed to achieve its proposed goal.

Direct and Immediate Harm

The §1171a.29 will cause the most direct and immediate harm to a laboratory that performs at the highest qualitative levels. The laboratories that currently perform the most precise testing in the most efficient manner likely have the most contracts to perform services. The proposed regulation will mandate that these highly functioning labs give up existing business and constitutes substantial impairment of existing and proposed contracts between grower/processors

[15] 35 P.S. § 10231.102(2).
[16] 71 P.S. § 745.5b(a).
[17] *Id.*
[18] 71 P.S. § 745.5b(b)(3)(iii).
[19] 35 P.S. § 10231.102(3)(i).
[20] 35 P.S. § 10231.1201(j)(5)(v).
[21] 35 P.S. § 10231.705.

and laboratories that are based on real differences in laboratory service levels, prices, and accurate results. Further, by forcing grower/processors to test the same lots using two different labs that may vary widely in their testing practices and accuracy,[22] §1171a.29 would create an industry-wide dynamic that would result in confusing test results and unnecessary litigation. Such a change to the regulations also promotes inefficiencies and discourages laboratory excellence by eliminating the natural competitive structure on which American businesses are founded. Inferior labs will get business because the law requires it, not because they provide compliant and accurate test results. The whole program will be diminished as a result.

[22] ISO17025, the standard DOH requires laboratories to meet under 28 Pa. Code 1171, ensures only that laboratories use certain quality management systems, not that they produce accurate results. Two laboratories holding ISO17025 accreditation could test the same process lot but produce drastically different results. Again, this is why DOH should ensure laboratory quality not by forcing them to regulate each other, but by conducting the proficiency testing it is already empowered to do pursuant to its own regulations at 28 Pa. Code 1171.34(a).