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Independent Regulatory Review Commission

Comments on the Department of Health's Final Rulemaking, Medical Marijuana Regulations
IRRC #3290/"Regulation #10—219: Medical Marijuana"
July 12, 2022

Introduction

Cannabis Law PA (CLP) represents grower/processors, dispensaries, physician groups, and laboratories approved to grow, process, sell, and test medical marijuana in Pennsylvania. CLP submits these comments to the Department of Health (DOH) and the Independent Regulatory Review Commission (IRRC) to request that certain regulations proposed by DOH not be included in the final approved medical marijuana regulations currently being considered by IRRC under the Pennsylvania Medical Marijuana Act (the Act).

Specifically, the proposed permanent regulation in § 1171a.29(c), subsections (1) and (2), that requires grower/processors to use two different approved laboratories to comply with DOH's testing requirements - one laboratory to complete the required harvest tests and a different laboratory to conduct the final process tests - does not achieve the stated goal of providing "checks and balances;" is not supported by any scientific or economic data; runs a foul of DOH's enabling statute; violates the Pennsylvania Constitution and the Regulatory Review Act; and is likely to have dire consequences on patient pricing, laboratory incomes, and program integrity.

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] Section 1171a.29(c), as proposed, will not promote safety or increase effective methods of delivery for medical marijuana. The proposed §1171a.29(c) will increase costs to patients and slow the logistics of getting medicine to market.

DOH included this amendment to §1171a.29(c) in its proposed regulations which resulted in "a plethora of public and legislative comments" and the following three specific requests to DOH:[2]

1. Explain why it believes the language of the Act allows for testing of harvest batches and final product by two different approved laboratories;

2. Provide a more detailed explanation of the specific problems it has encountered with the existing testing protocols and how testing by two different approved laboratories solves those problems; and

3. Quantify the costs for growers/processors associated with entering into a contract with a second approved laboratory.

DOH provided **none** of the requested explanations or calculations.

[1] 35 P.S. § 10231.102(3).

[2] Notice of Final Rulemaking Department of Health Title 28. Health and Safety, at 63 (June 8, 2022).

Without factual, scientific, or economical support, DOH continues to claim that § 1171a.29(c)(1)-(2) creates "checks and balances" when in actuality it creates ambiguity in testing results, likely unnecessary and abundant litigation, increased costs to patients, and sales and profits being taken from superior laboratories in order to provide unearned sales and profits to inferior laboratories. In addition to these real-life impacts, the proposed § 1171a.29(c) violates the Act, the Pennsylvania Constitution, and the Regulatory Review Act (RRA).

Proposed Permanent Regulation

§ 1171a.29. Testing requirements.

(c) Testing 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 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.*

DOH is proposing to create a solution to a problem that does not exist in Pennsylvania. In response to IRRC's May 5, 2021 comments to DOH's proposed final regulations requesting "a more detailed explanation of the specific problems it has encountered with the existing testing protocols and how testing by two different approved laboratories solves those problems",[3] DOH admits that there is no current problem under the existing testing protocols and that the "corruption" it seeks to remedy does not exist here in Pennsylvania.[4] The corruption problem DOH references through citation to a single news article concerns testing laboratories in *other states* inflating THC levels. After more than six years of medical marijuana being legal in Pennsylvania and grower/processors being required to use only one approved laboratory to conduct all required testing, this problem simply does not exist.

Even granting DOH the benefit of the doubt in terms of prospectively protecting against this non-existent problem, DOH has utterly failed to explain how its two-laboratory construct

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[3] *Comments of the IRRC: Department of Health Regulation #10-219 (IRRC #3290) – Medical Marijuana*, at p. 18 (May 5, 2021).

[4] "Pennsylvania's medical marijuana program has not seen widespread corruption in the testing of medical marijuana, other states have experienced these issues." Notice of Final Rulemaking Department of Health Title 28. Health and Safety, June 8, 2022.

would prevent its conjured-up problem. Even a cursory reading of the article DOH cites for support of its proposed two-laboratory requirement makes clear that the article was not advocating for such a system, but instead promotes "random compliance checks" or "proficiency tests" carried out by the agency or an independent laboratory under the supervision of the agency.[5] Most of the suggestions in this article boil down to "the agency must do its own testing, its own checks, and balances on the laboratories"[6] to avoid laboratories misreporting results.

We know of no other state that uses such a two-laboratory process that DOH proposes. For good reason, such a process does not alleviate the "THC inflation" the DOH-referenced article discusses. In fact, § 1171a.29(c) does not address what should occur if the two laboratories come to two different results, THC or otherwise. Additionally, the final processed products test would always (and should) have different THC results than the harvested plant material. Having laboratories somehow police each other is an ineffective and dangerous means of attempting to provide checks and balances in the testing program.

Moreover, abandoning the existing one approved laboratory system as DOH proposes is simply bad governance. There are many other good and valid reasons why the legislature may have expressly provided for growers/processors to contract with a single approved laboratory as initially enacted. First, choosing the laboratory with the most state-of-the-art technology can increase testing accuracies which benefits patients. Choosing a single laboratory, that uses the same techniques, equipment, personnel, and storage facilities for all phases of testing increases consistency in results which translates to consistency for patients. Selecting a single approved laboratory can generate cost savings in volume discounts, transportation costs, and retesting costs all of which translate to cost savings for patients. Growers/processors currently do and should continue to enter into contracts with the best laboratory for their needs and cost benefits. If the proposed § 1171a.29(c) goes into effect, contracts that are currently in place providing for multi-phase testing with a single laboratory over future months or years could be voided. This would not only spawn unnecessary litigation, but it would also increase costs to patients.

Not only does §1171a.29(c) not provide any checks and balances, but it also likely violates the Act, Article I, §17 and Article II, §1 of the Pennsylvania Constitution and the RRA. Additionally, enforcement of § 1171a.29 will cause direct, substantial, immediate, and irreparable harm to certain laboratories.

Violation of the Plain Language of the Act

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." The DOH is authorized to promulgate regulations related to the

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5 https://fivethirtyeight.com/features/Americas-pot-labs-have-a-thc-problem.

6 *Id*. Pot labs face regular proficiency tests and the state requires labs to collect two samples for every test and then hold a reserve sample, which is used to investigate complaints. The second sample is also used as a calibration tool, with the state randomly retesting reserve samples.

Commonwealth's medical marijuana protocol only to the extent "necessary to carry out the provisions" of the Act.

DOH first published it proposed permanent regulations in March of 2021. Notably in June 2021, the legislature specifically reviewed and made changes to the Act relative to the regulation at issue here.[7] The specific changes the legislature made are highlighted in bold below:

> Section 704. Laboratory. (a) General testing.--A grower/processor shall contract with **one or more independent laboratories** to test the medical marijuana produced by the grower/processor. The department shall approve **a** laboratory under this subsection and require that the laboratory report testing results in a manner as the department shall determine, including requiring a test at harvest and a test at final processing.

In June of 2021, when the legislature was presented with an opportunity to codify what it knew was DOH's proposed 2-laboratory regulation, the legislature not only rejected the opportunity to approve DOH's 2-laboratory setup, it expressly amended the Act[8] to grant grower/processors the flexibility to contract with *one or more* laboratories. By its express language, Section 704(a) provides grower/processors the right to use a single approved laboratory for its testing requirements. The necessary implication of the plain language in Section 704(a) is that the Department cannot require that a grower/processor use more than one approved laboratory to conduct testing. To interpret otherwise makes the legislature's amendment superfluous and nonsensical. If the legislature wanted to mandate that grower/processors must have two different labs, they would not have provided grower/processors the "one" laboratory option. This is further supported by the second sentence of Section 704(a) which grants DOH the authority to mandate the manner laboratories would be required to "report testing results." The legislature granted to the grower/processors the authority, or choice, to contract with one or more labs and granted to DOH the authority to determine how testing results would be reported. This distinction was purposeful and rooted in sound judgment.

The second sentence of Section 704(a) further demonstrates the legislature's intent to allow for grower/processors to contract with a single laboratory for both the harvest and final processing phases. This second sentence describes the mandatory testing in terms of a single laboratory: "[t]he department shall approve **a** laboratory…" – the singular "a" was another amendment to Section 704 the legislature added in June 2021. The contemplation of "**a** laboratory" was added in the context of both the harvest testing and the process testing. The only coherent reading of the amended Section 704(a) is that grower/processors are required to contract with at least one Department-approved laboratory to conduct testing at harvest and final processing and the Department cannot prohibit a grower/processor from contracting with only one approved laboratory.

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7 Act 44 June 30, 2021.P.L. 210, No. 44 (June 30, 2021).

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

Despite the legislature providing grower/processors with the authority to contract with "one or more" laboratories for their testing needs, § 1171a.29(c) attempts not only to wrestle this grant of discretion entrusted with the grower/processors but also seeks to negate the flexibility provided by Section 704(a) by mandating that grower/processors contract with two separate laboratories. A proposed regulation that travels beyond, or even contradicts, its own enabling act cannot be necessary to carry out the said act. DOH does not provide the rationale or reasoning that justifies the promulgation of § 1171a.29(c) regulation, because such regulation would go beyond, and in fact contradict, the Act itself.

Obviously, it was the intent of the legislature to allow growers/processors to contract with a single laboratory for all testing needs. The legislature also determined that grower/processors could contract with multiple laboratories for their testing needs. In doing so, the legislature intended to preserve the sanctity of businesses to contract with the best-approved laboratory or laboratories in order to obtain cost savings, accuracy, and testing integrity. DOH's disregard for the legislature's specific changes to the Act by mandating two laboratories be used for the two different phases of testing seeks to substitute its judgment for that of the legislature and in so doing violates its enabling act.

Violation of the Contract Clause of Pennsylvania's Constitution (Art. I, §17)

Section 1171a.29(c) will violate the Contracts Clause of the Pennsylvania Constitution, Article I, §17, by imposing upon existing contracts conditions that are not expressed and impairs obligations stated therein. 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.[9] 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.[10] 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.[11]

Grower/processors currently operating pursuant to the Act and DOH's oversight have ongoing contractual obligations—including exclusive, long-term supply contracts with approved laboratories—that §1171a.29 would force the parties to void or violate. The proposed regulation would cause substantial impairment of existing and proposed contracts between grower/processors and approved laboratories. These existing contracts are based on real differences in laboratory locations, 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."

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

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

11 *Id*.

DOH does not explain how mandating two different laboratories with different processes testing at two very different phases of the production process provides a check and balance of the laboratories nor does DOH explain how this regulation improves patient safety or achieves its purpose.[12] Exactly what this two-laboratory process is intended to "check" or "balance" is not explained.

Given the substantial impairment to existing contracts and the absence of an explanation of how this contract impairment achieves DOH's stated goal, §1171a.29(c)(1)-(2) likely violates the Contracts Clause.[13]

Violation of Article II, Section 1 of the Pennsylvania Constitution (Art. II, §1)

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."[14] 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."[15] 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.[16] 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.[17]

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 approved 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 this proposed regulation does

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[12] 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).

[13] 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 have been 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).

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

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

[16] 35 P.S. § 10231.704.

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

not achieve any such checks and balances 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 effectiveness.[18] DOH should not delegate to the entities it regulates the exact regulatory authority vested in the DOH by the legislature. 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. DOH could secure and test sample product from dispensaries. DOH could send product with known contaminants to all laboratories to determine the efficacy of each laboratory's ability to detect such contaminants. But to just have two different laboratories (who may use very different methodologies) test at two separate and distinctly different phases of medical marijuana production does not achieve any level of "checks and balances". The likely result is just the opposite – confusion over varying test results and no way to reconcile such variances.

Violations of the Regulatory Review Act

The RRA requires that IRRC determine whether § 1171A.29 is in the public interest.[19] 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,[20] or if the regulation is unreasonable due a lack of need for it.[21]

The General Assembly intended that medical marijuana be affordable for patients. It asserts that patients must have "access" to medical marijuana,[22] it requires the Medical Marijuana Advisory Board to report on "how to ensure affordable patient access to medical marijuana,"[23] and it empowers the DOH to institute price controls on medical marijuana if the prices are "unreasonable or excessive."[24] Despite this clear intent by the General Assembly to create a protocol that provides affordable medical marijuana to patients, DOH's § 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 currently use a single laboratory for all of their testing needs. The § 1171a.29 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.

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18 35 P.S. § 10231.102(2).

19 71 P.S. § 745.5b(a).

20 *Id.*

21 71 P.S. § 745.5b(b)(3)(iii).

22 35 P.S. § 10231.102(3)(i).

23 35 P.S. § 10231.1201(j)(5)(v).

24 35 P.S. § 10231.705.

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

Section 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. Section 1171a.29 will mandate that these highly functioning labs "give up" existing business. Section 1171a.29(c) constitutes substantial impairment of existing and proposed contracts between growers 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,[25] § 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.

The most accurate and regulatory-compliant laboratories stand to incur millions of dollars in lost revenue and potential litigation.

Conclusion

DOH does not state where in the Act, it is authorized to mandate a two-lab testing requirement, to abdicate its regulatory responsibilities, or to delegate oversite of the medical marijuana laboratories to the laboratories themselves. DOH does not state how § 1171a.29(c) is intended to provide checks and balances on laboratories or even what those "checks and balances" are. Neither does DOH respond to IRRC's request to analyze the very real financial impact this regulation could have on patients, growers/processors, and of course laboratories. Finally, DOH admits that this regulation is intended to cure a problem that does not exist in Pennsylvania.

The true impact of this proposed § 1171a.29(c) will be to financially penalize laboratories that are currently outperforming their peers, increase prices to patients, provoke unnecessary litigation, and create confusion over different results coming from different laboratories. As described in the article DOH cites, other states implement true oversight over laboratories by creating or employing a separate, independent laboratory to spot check and audit results from their program laboratories.

[25] 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).