INDEPENDENT REGULATORY REVIEW COMMISSION
PUBLIC MEETING MINUTES
10:00 A.M.
Thursday, October 20, 2022
14th Floor Conference Room
333 Market Street

I. CALL OF THE MEETING

The October 20, 2022 public meeting of the Independent Regulatory Review Commission (Commission) was called to order by Chairman Bedwick at 10:00 a.m. in the 14th Floor Conference Room, 333 Market Street, Harrisburg, PA.

Commissioners Present:	George D. Bedwick, Chairman John J. Soroko, Esq. Dennis A. Watson, Esq.
Voting by Proxy:	John F. Mizner, Esq., Vice Chairman Murray Ufberg, Esq.

II. APPROVAL OF THE SEPTEMBER 15, 2022 PUBLIC MEETING MINUTES

Chairman Bedwick asked for a motion for approval of the September 15, 2022 public meeting minutes, as submitted. Commissioner Watson made the motion and Chairman Bedwick seconded, and the motion passed 3-0.

III. NEW BUSINESS

The commissioners reviewed mail submitted to the Commission on the meeting's regulations.

A. ACTION ITEMS

1. No. 3337 State Board of Auctioneer Examiners #16A-6411: Fees

Corinne Brandt, Regulatory Analyst, explained the regulation increases application fees to reflect updated costs of processing applications and increases all the State Board of Auctioneer Examiners' (Board) biennial renewal fees to ensure its revenue meets or exceeds the Board's current and projected costs. She stated the designated standing committees deemed the regulation approved.

Jason McMurry, Board Counsel, State Board of Auctioneer Examiners, and Jacqueline Wolfgang, Senior Regulatory Counsel, Department of State, were present to answer any questions. Mr. McMurry claimed his agency needs to update its fees to cover costs of the

Board's operations.

Chairman Bedwick thanked the panel for requesting a periodic fee increases instead of a large fee increase every several years.

Chairman Bedwick made a motion for approval. Commissioner Watson seconded, and the motion passed 5-0.

2. No. 3354 State Board of Education #6-352: Student Attendance and Students and Student Services (Final-Omit)

Laura Campbell, Regulatory Analyst, explained the regulation conforms existing regulations with amendments to the definition of "compulsory school age" enacted by Act 16 of 2019. She stated the designated standing committees deemed the regulation approved.

Karen Molchanow, Executive Director, State Board of Education, was present to answer any questions. Ms. Molchanow indicated the regulation would amend the age of compulsory school attendance.

Chairman Bedwick inquired why effective dates found in Act 16 are different. Ms. Molchanow replied she is unaware of an answer.

Commissioner Soroko made a motion for approval. Commissioner Watson seconded, and the motion passed 5-0.

3. No. 3263 State Architects Licensure Board #16A-4111: Digital Signature and Seal

Ms. Brandt described how the regulation updates current regulations on seals to be consistent with other design professional boards in the industry and incorporates the National Council of Examiners for Engineering and Surveying's Model Rule on seals on documents. She stated the appropriate standing committees approved the regulation.

C. William Fritz, II, Board Counsel, Office of Chief Counsel, Department of State, and Ms. Wolfgang were present to answer any questions.

Mr. Fritz asserted every one of his agency's architecture drawings utilizes an official seal. He commented the State Architects Licensure Board (Licensure Board) is trying to update its procedures to resemble those found throughout the country. He added the Licensure Board collaborated with the Department of Transportation and other agencies to develop the regulation.

Commissioner Watson made a motion for approval. Commissioner Watson seconded, and the motion passed 5-0.

4. No. 3264 State Board of Professional Engineers, Land Surveyors, and Geologists #16A-4712: Digital Signature and Seal

Michelle Elliott, Regulatory Analyst, noted the regulation updates current regulations on seals to be consistent with other design professional boards and incorporates the National Council of Examiners for Engineering and Surveying's Model Rule on seals on documents. She stated the designated standing committees deemed the regulation approved.

Mr. Fritz and Ms. Wolfgang were present to answer any questions.

Mr. Fritz declared the rationale for the regulation is the same as the previous regulation.

Commissioner Soroko made a motion for approval. Commissioner Watson seconded, and the motion passed 5-0.

5. No. 3265 State Board of Landscape Architects #16A-6112: Digital Signature and Seal

Ms. Campbell outlined that the regulation establishes technical standards for digital seals and signatures used by landscape architects on work products.

Mr. Fritz and Ms. Wolfgang were present to answer any questions.

Mr. Fritz declared the rationale for the regulation is the same as the previous two regulations.

Chairman Bedwick made a motion for approval. Commissioner Watson seconded, and the motion passed 5-0.

6. No. 3290 Department of Health #10-219: Medical Marijuana

Scott Schalles, Regulatory Analyst, and Ms. Elliott presented on the Medical Marijuana regulation. Mr. Schalles indicated the regulation establishes permanent regulations under the Medical Marijuana Act which will replace the temporary regulations. He pointed out the commentators raised several issues with the final regulation. He stated the designated standing committees deemed the regulation approved, though a letter of concern was sent to the Commission from Rep. Kathy Rapp and seven other Republican members of the House Health Committee.

Dr. Denise Johnson, MD, Acting Secretary of Health and Physician General, Laura Mentch, Director for the Office of Medical Marijuana, Mariah Turner, Assistant Counsel, and Yvette Kostelac, Chief Counsel, Department of Health (Department), were present to answer any questions.

Dr. Johnson explained the need for transparency led the Department to seek public comment when developing regulations. She added the process worked throughout the COVID-

19 pandemic. She stated the Department incorporated public opinion to balance the needs of patients with maintaining patient safety. She outlined the Department's commitment to effectively treat patients while ensuring they are not exposed to harmful contaminants.

Commissioner Soroko questioned if the Department believes the two required laboratory tests should be conducted by two separate laboratories. Dr. Johnson answered the requirement is due to consideration of patient safety.

Commissioner Soroko contended the law's usage of "one or more" laboratories could confuse the Department's goal of having two laboratories conduct tests. Ms. Turner indicated the Department did not initially have the statutory authority to require two laboratory tests.

Commissioner Soroko asked why the regulation does not say "two or more" laboratories. Ms. Turner explained the regulation attempts to remain within the scope of the Department. She commented the fiscal impact on stakeholders was considered.

Commissioner Soroko inquired if the Department interprets the language to mean one or more than one laboratory. Ms. Turner replied that the Department's interpretation is that at least one laboratory is mandatory, and the Department can require additional laboratories, if it is in the public interest.

Chairman Bedwick wondered if original legislation provided language requiring one independent laboratory before the language was amended to one or more laboratory. Ms. Turner replied in the affirmative.

Chairman Bedwick suggested the regulation contains language that the Department has not received authority to use since it is part of an ongoing court case. Dr. Johnson affirmed the language would not be used unless the Department is authorized by court order.

Chairman Bedwick contended "diverse groups" is broader than "diverse participants." He asked if the definition of diverse participants includes individuals with disabilities and veterans. Dr. Johnson replied in the affirmative.

Chairman Bedwick stated that he is pleased with the regulation but criticized its lack of specificity.

Commissioner Watson requested details on serious medical conditions as outlined in the regulation. Dr. Johnson responded there is an "ongoing process" to get medical conditions covered by the regulation. She illustrated the process to effectuate the regulation's designation of a serious medical condition without having to consult the Commission.

The following members of the public spoke on the regulation:

1. Judith Cassel, Attorney, Cannabis Law PA
2. Shannon Hoffman, Director of Operations, Green Analytics
3. Meredith Buettner, Executive Director, PA Cannabis Coalition
4. Nikki Moyers, Vice President of Products and Brands, TILT Holdings

Ms. Cassel requested the disapproval of the proposed regulation. She argued that the Department is passing the oversight of the testing laboratories to the laboratories themselves. She outlined how medical marijuana products undergo several alterations before they reach testing laboratories. She criticized the regulation for removing accountability over multiple labs with no method of reconciliation.

Ms. Cassel added that the Department is overwhelmed with medical marijuana applications, and the regulation would only lead to further work. She asserted the laboratories chosen for testing are not in the medical marijuana business and the General Assembly could have codified the two laboratory tests requirement before the regulation was proposed.

Ms. Hoffman voiced concerns with the practicability of testing at multiple labs, the lack of specifics about the tests, and the absence of guidance from the Department. She maintained the requirement of two lab tests is too restrictive to the laboratories, medical professionals, and patients. She stated the incident in Arkansas resulted in a dropped lawsuit. She conceded the issues the regulation wants to solve are real, but opined the regulation is not useful.

Commissioner Watson asked if Ms. Hoffman recommends disapproving the regulation. Ms. Hoffman replied in the affirmative.

Ms. Buettner stated she wishes the relationship between official regulatory authorities and medical marijuana grower-processors (GPs) was stronger. She claimed the regulation does contain some helpful provisions, but alternate methods would be more suitable. She stated that the Department is provided with too much authority over the medical marijuana industry.

Commissioner Watson asked if Ms. Buettner recommends disapproving the regulation. Ms. Buettner said the PA Cannabis Coalition wishes to move past the regulatory process and asks for approval of the regulation.

Chairman Bedwick questioned how conflict could arise if the product in the first test is different from the product in the second test. Ms. Cassel responded there are changes in the levels of THC between the products, which negates the results of the tests. She stated there is no oversight of the labs to determine why the products are different.

Ms. Hoffman echoed Ms. Cassel's comments. She added the medical marijuana industry could communicate with the Department to identify problems. She states the two labs would keep their information confidential and blame one another if there are issues. She marked contamination of products could also occur.

Ms. Moyers, Vice President of Product and Brands, TILT Holdings, explained marijuana GPs assess their products and foster relationships with labs. She detailed how products could degrade or deteriorate throughout the testing process. She underscored the constant testing of medical marijuana products by GPs instead of the Department.

Chairman Bedwick asked about the need for the two lab testing requirement. Ms. Hoffman related how in New Jersey, GPs were required to contract with only one lab, so other

labs were not used as the industry grew. She argued the intent of the New Jersey legislature was to allow GPs to contract with more than one lab.

Chairman Bedwick asked about the implementation of the two-lab requirement. Ms. Buettner responded that, with the original language, going to another lab requires breaking an existing contract. She pointed out the ability to use multiple labs and Ms. Hoffman added GPs can select which products will go to a certain lab. Ms. Moyers indicated her company cannot wait to send all of their inventory for testing to one lab so it will use multiple. Ms. Hoffman contended GPs choosing where their products go is better for their operations. Ms. Moyers added the Department could investigate labs or GPs they suspect are not following regulations.

Chairman Bedwick requested details about round robin testing. Ms. Hoffman responded GPs are not paid by the Department for round robin testing. She explained that in round robin testing, a single sample is given to multiple entities and the results from all of the entities are compared to determine the accuracy of each lab's testing. Ms. Moyers indicated testing would not be used for every single product.

Chairman Bedwick questioned if GPs like Ms. Hoffman are paid for round robin testing. Ms. Hoffman clarified the government does not pay for testing, though sometimes the GP pays.

Commissioner Watson asked if the regulation should be disapproved. Ms. Moyers replied she would request approval of the regulation so there are defined guidelines that could be amended if needed. Ms. Cassel and Ms. Hoffman indicated they would request that the regulation be disapproved.

Ms. Cassel commented that according to the Department, additives within products must receive federal approval. She contended this is difficult since marijuana is still federally illegal. She stated a preliminary injunction was implemented and the issue is now a court case. She noted that the Department also disapproves products that contain substances that are federally permitted.

Chairman Bedwick suggested the Department should rethink its reasoning for the provision if it could be tried in court. Ms. Moyers argued there is less clarity on additives since the additive could already be approved at the federal level. She noted there are various forms of medical marijuana that undergo testing by GPs, and not all additives are safe for every form of intake.

Ms. Cassel suggested testing for harmful substances and testing for harmful products are different issues. Ms. Moyers argued the "vape crisis" from several years ago was due to black market vape pens being sold to avoid federal regulation. Ms. Hoffman commented tests could be improved by adding vitamin E acetate, the cause of the "vape crisis," to the list of contaminants that are routinely tested for.

Ms. Cassel concluded by professing support for a deemed denied system, which allows the Department 60 days to issue an approval. She repeated that the Department is six months

behind on things like approving applications for employment. She concluded by encouraging the Department to involve itself enough to move on from the temporary guidelines.

Dr. Johnson repeated that the Department seeks public comments and input. She repeated products would not be approved or denied until the ongoing court case ends. She added federal guidelines for products would be utilized.

Chairman Bedwick asked if any new product would be approved. Ms. Turner stated vaporized products with additive substances would not be approved until the case is ended. Ms. Mentch stated certain substances within the products would need to be studied further due to potential health risks.

Chairman Bedwick wondered how many vaporized products are approved by the Department. Ms. Turner replied she is unaware of a number because not all vape products have additives.

Dr. Johnson reiterated that the Department does not have complete statutory authority to oversee laboratories. She reaffirmed the Department's focus is on keeping patients safe and ensuring contaminated products are not sold.

Commissioner Soroko questioned if the Department does not have full statutory authority to oversee laboratories, how it could mandate two laboratory tests. Dr. Johnson explained the Department first determines whether a product or laboratory is contaminated.

Commissioner Soroko asked if the checks and balances on product would be completed by GPs during the harvest lot testing and process lot testing. Ms. Mentch claimed there could be a prior relationship between GPs and laboratories. She argued the regulation increases competition and assures products are safe.

Commissioner Soroko inquired if a round robin system has merit. Ms. Mentch repeated her claim GPs and labs could coordinate with each other. She outlined her belief GPs could round robin evaluate their products, but the Department aims to implement accountability in the process.

Chairman Bedwick and Commissioner Soroko requested the definition of round robin testing from the Department. Dr. Johnson responded round robin testing is when products are sent to multiple labs for testing. She explained priority is placed on the safety of the products and opined the two lab requirement is not overly burdensome.

Commissioner Soroko wondered about the current testing procedure. Dr. Johnson affirmed the two tests are still completed during the testing process, but are done at a single laboratory. Commissioner Soroko again raised issue with the law's language of "one or more" laboratories. Ms. Turner answered that the Department is authorized to treat labs like GPs, except for in how they grow their products.

Chairman Bedwick argued the regulation's language could be taken literally and there could be only one lab within the Commonwealth. Ms. Turner replied in the negative and detailed the Department's flexibility towards labs in contract with a GP.

Commissioner Soroko questioned if a statue exists providing the Department the authority to mandate the two lab testing. Ms. Kostelac explained the legislature authorized the Department to ensure medical marijuana products are safe. She stated that the Commission received a letter of concern from some members of the House designated standing committee.

Chairman Bedwick asked if due process is in place for GPs, so they are not erroneously non-compliant and sanctioned. Dr. Johnson answered a due process system is in place. Ms. Turner added that any of the Department's actions may be appealed.

Commissioner Watson pondered why the two lab requirement was developed. Dr. Johnson replied permittees would need to contract with an approved lab, making fraud more difficult. She highlighted the issue needs to be addressed by the Department.

Commissioner Watson wondered if the two lab requirement was to direct business to non-approved labs. Ms. Turner responded she has not heard of any fraudulent behavior like Commissioner Watson suggested.

Chairman Bedwick clarified the previous panel was not accusing anyone of wrongdoing.

Chairman Bedwick announced he would motion to approve the regulation, but he commented he is still confused over the regulation's language. He expressed his hope that the Department would work with GPs to address both of their concerns.

Commissioner Watson claimed the regulation is within the public interest. He added that two commentators promoted moving past temporary regulations, the Department has the authority for the two-lab requirement, patients want safety, and permanent regulations are now needed.

Commissioner Soroko reiterated his difficulty with the regulation's language. Despite his concern, he indicated he finds the regulation in the public interest and would vote in approval.

Chairman Bedwick again urged the regulated community and the Department to cooperate with one another on the issue.

Chairman Bedwick made a motion for approval. Commissioner Watson seconded, and the motion passed 4-0, Vice Chairman Mizner abstained.

IV. OTHER BUSINESS

Approval of Vouchers

Commissioner Watson made motions to approve vouchers and expenses for the period July 22, 2022 through September 15, 2022. Chairman Bedwick seconded, and the motions passed 3-0.

V. DATE AND PLACE OF SUBSEQUENT MEETING

Chairman Bedwick announced the next public meeting is scheduled for Friday, October 28, 2022, at 10:00 a.m. in the 14th Floor Conference Room, 333 Market Street, Harrisburg.

VI. EXECUTIVE SESSION ANNOUNCEMENTS

Chairman Bedwick announced that no executive session would be held.

VII. ADJOURNMENT

Chairman Bedwick adjourned the meeting at 12:36 pm.