Comments of the Independent Regulatory Review Commission

Department of Health Regulation #10-219 (IRRC #3290)

Medical Marijuana

May 5, 2021

We submit for your consideration the following comments on the proposed rulemaking published in the March 6, 2021 *Pennsylvania Bulletin*. Our comments are based on criteria in Section 5.2 of the Regulatory Review Act (RRA) (71 P.S. § 745.5b). Section 5.1(a) of the RRA (71 P.S. § 745.5a(a)) directs the Department of Health (Department) to respond to all comments received from us or any other source.

1. **Compliance with the provisions of the RRA or the regulations of the Commission in promulgating the regulation; Determining whether the regulation is in the public interest; Fiscal impacts.**

The Medical Marijuana Act (Act) (35 P.S. §§ 10231.101 – 10231.211) allowed the Department to promulgate temporary regulations. The temporary regulations were not subject to three statutes that guide agencies when promulgating regulations. Those statutes are the Commonwealth Documents Law (CDL) (45 P.S. §§ 1201 – 1208), the RRA (71 P.S. §§ 745.1 – 745.15) and the Commonwealth Attorneys Act (CAA) (71 P.S. §§ 732-101 – 732-506). In order to implement the Medical Marijuana Program (Program), the Department periodically published temporary regulations. The temporary regulations are effective for two years from the date of publication. According to the Department, the most recent set of temporary regulations are set to expire on November 20, 2021. The conversion of temporary regulations to permanent regulations requires compliance with the CDL, RRA, and the CAA.

Section 5.2 of the RRA (71 P.S. § 745.5b) directs this Commission to determine whether a regulation is in the public interest. When making this determination, the Commission considers criteria such as economic or fiscal impacts, reasonableness, and need. To make that determination, the Commission must analyze the text of the proposed rulemaking and the reasons for the new or amended language. The Commission also considers the information a promulgating agency is required to provide under Section 745.5(a) in the Regulatory Analysis Form (RAF).

This rulemaking will revise and replace the current temporary regulations found in 28 Pa. Code Chapters 1131 – 1230 with permanent regulations to be found in Chapters 1141a – 1230a. The explanation of the regulations in the Preamble and the information contained on the RAF is not sufficient to allow this Commission to determine if the regulation is in the public interest. It is

our understanding that a complete explanation of the need for each temporary chapter and section was not provided when those regulations were promulgated. This is problematic because commenters have made suggestions to amend various provisions of the proposed regulation which contain specific requirements from the Act. For example, Section 1171a.28 (relating to selection protocol for samples) requires testing of medical marijuana at the time of harvest and before the product is sold to a dispensary. Commenters oppose this as unnecessary and more stringent than other states. However, Section 704 of the Act (relating to laboratory) specifically requires the two tests.

We acknowledge that while the Preamble to this proposed rulemaking explains the changes that are being offered, it does not, in every instance, explain the rationale for those changes. In the Preamble to the final-form rulemaking, we ask the Department to provide an explanation of the basis and rationale for each chapter of this rulemaking and the changes that were made between the temporary regulation and this proposed regulation. If a particular section of the regulation is based on a specific section of the Act, we ask the Department to provide a citation to the section or sections of the Act. This additional information will assist the Commission in determining if the regulation is in the public interest. It will also provide the regulated community with a better understanding of why the Department is regulating the Program in a particular manner.

Furthermore, the RAF fails to quantify the fiscal impacts the changes between the temporary regulations and the permanent regulations will have on the regulated community. Without this information, we cannot determine if this proposed regulation is in the public interest. As the Department prepares the final-form regulation, we suggest that the Department solicit input from the regulated community to gain a better understanding of the fiscal impacts this proposal will have on the industry and the patients they serve. In the RAF submitted with the final-form rulemaking, we ask the Department to provide a more detailed analysis of the fiscal impacts of the rulemaking.

2. Whether a less costly or less intrusive alternative method of achieving the goal of the regulation has been considered for regulations impacting small business; Adverse effects on prices of goods and services, productivity, or competition.

In response to RAF Question #19, regarding the impact the regulation may have on small businesses, the Department explains medical marijuana has not been legalized at the federal level. Therefore, the Department cannot quantify the number of small businesses, as defined in the RRA, and say for certain how many organizations will be impacted by the regulation. The Department further states that it will respond to questions regarding this issue, ". . . assuming that some, if not all, of the medical marijuana organizations may be considered small businesses."

Some of the commenters have described themselves as small businesses and have cited the "small business" criterion in Section 5.2(b)(8) of the RRA (71 P.S. § 745.5b(b)(8)) in their written comments. They have explained that some of the new requirements will impose significant costs and question the need for those requirements. These commenters contend that the additional costs will lead to higher prices for patients. A more detailed discussion of those specific concerns as they relate to growers/processors, dispensaries, and laboratories will be addressed later in these comments. We ask the Department to work with the commenters that

have raised this criterion to determine if the regulation can be amended to provide a less costly alternative while achieving the goal of regulation.

3. Non-regulatory language. – Clarity; Implementation procedures.

A regulation has the full force and effect of law. We have concerns related to the use of non-regulatory language, which does not establish standards that could be predicted by the regulated community, found throughout the proposed regulation. For example:

- Section 1141a.27(b) states, "By submitting an application to the Department, an applicant consents to any investigation, **to the extent deemed appropriate by the Department**, of the applicant's ability to meet the requirements under the act applicable to the application." [Emphasis added.]

- Section 1141a.32(c) states, "The Department will determine whether the stated goals in the diversity plan are **reasonable and represent a good faith effort** to meet the diversity goals…" [Emphasis added.]

- Section 1141a.32(h) states, "The Department will review the diversity plan and provide the medical marijuana organization with **advice** regarding activities that **should be undertaken** by the medical marijuana organization . . . ." [Emphasis added.]

- Section 1141a.47(a)(5)(ii) states, in part, that the Department may issue a cease and desist order . . . "if the agent observes or **suspects** an operational failure or determines that the conditions **will likely create** a diversion or contamination of seeds . . . ." [Emphasis added.]

- Section 1151a.23(a) states, "A grower/processor may only grow, store, harvest or process seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products in an indoor, enclosed, secure facility **as approved by the Department**." [Emphasis added.]

- Section 1151a.26(b)(3) states, "The grower/processor shall retain at the facility, for **at least** 4 years, records of all inspections, servicing, alterations and upgrades performed on the systems . . . ." [Emphasis added.]

- Section 1151a.29(b) states, in part, "The grower/processor shall notify the Department in writing **promptly** . . . ." [Emphasis added.]

- Section 1151a.32(b)(1) states, in part, that a grower/processor shall "**routinely** calibrate, check and inspect the following to ensure accuracy . . . ." [Emphasis added.]

- Section 1171a.23(a) states, "A laboratory . . . shall submit an application for approval to the Department **on a form and in a manner prescribed by the Department**." [Emphasis added.]

- Section 1171a.29(c) states, "**At a minimum**, testing, as prescribed by the Department, shall be performed . . . ." [Emphasis added.]

- Section 1171a.29(e) states, "Sampling and testing under this chapter shall be conducted with a statistically significant number and size of samples and with **methodologies acceptable to the Department** . . . ." [Emphasis added.]

- Section 1171a.29(f) states, "An approved laboratory may not test any samples when there is… **any other factor** sufficient to render the findings of questionable validity." [Emphasis added.]

- Section 1171a.30 states, "An approved laboratory shall follow the methodologies, ranges and parameters **acceptable to the Department** that are contained in the scope of the certificate of accreditation issued to the laboratory." [Emphasis added.]

- Section 1171a.33(b)(3) states that 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 . . . "[p]rotect 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." [Emphasis added.]

- Section 1191a.23(c) states, "The Department may issue an identification card to an individual who is under 21 years of age to serve as a caregiver when a **sufficient showing** is made to the Department that the individual should be permitted to serve as a caregiver, **as determined by the Department**." [Emphasis added.]

- Section 1211a.22(d)(1) states that an approved clinical registrant may not dispense any medical marijuana products until the Department has determined that the registrant is "**ready, willing and able to operate as a grower/processor and a dispensary**." [Emphasis added.]

- Section 1211a.27(c)(11) states that an application for approval of a clinical registrant must include "**[a]ny other information deemed necessary by the Department**." [Emphasis added.]

These emphasized phrases do not set binding norms and lack clarity. For that reason, consistent implementation of these provisions by the Department and compliance by the regulated community could be difficult. We ask the Department to review the entire final-form regulation to ensure the use of regulatory language, setting clear compliance standards for the regulated community to meet.

CHAPTER 1141a. GENERAL PROVISIONS

4. Section 1141a.21. Definitions. – Statutory authority; Protection of the public health, safety, and welfare; Clarity; Implementation.

Clinical registrant

In part, under Subparagraph (iii), this term is defined as an entity that "[i]s approved by the Department **as a clinical registrant**." [Emphasis added.] A term cannot be defined by the term itself. We ask the Department to delete or clarify this subparagraph in the final-form regulation.

Electronic tracking system

The Act requires the Department to establish and maintain an electronic database to include activities and information related to medical marijuana. It is our understanding that the Department utilizes MJ Freeway, a software product to manage the database. Commenters state that there have been problems with the tracking system and have suggested that medical marijuana organizations be allowed to use an application-programing interface (API) of their choice, as long as the API meets the requirements of the regulation and the Act, to connect to MJ Freeway. In the Preamble to the final-form rulemaking, we ask the Department to explain how it administers the electronic tracking system required by the Act, and whether a medical marijuana organization can use an API of its choosing to connect to the database. We also ask the Department to consider the suggestions of commenters as their concerns relate to the use of an API and the potential benefits of safety and efficiency that commenters contend can be realized. Furthermore, we ask the Department to ensure that any changes to the final-form regulation regarding the electronic tracking system also address Sections 1151a.39 (relating to electronic tracking system) and 1161a.39 (relating to electronic tracking system).

Patient consultation

This term is defined as, "A complete in-person examination of a patient and the patient's health care records at the time a patient certification is issued by a practitioner." We note that the definition of "continuing care" in the Act states the following: "Treating a patient, in the course of which the practitioner has completed a full assessment of the patient's medical history and current medical condition, including an in-person consultation with the patient." Commenters have suggested that some of the COVID protocols for the Program currently in place be incorporated into this rulemaking, including the use of telemedicine. Has the Department considered making this particular protocol a permanent provision via this rulemaking? Would the inclusion of COVID protocols for the Program in this regulation be permissible under the Act?

Physician

The Department defines this term as, "The term as defined in section 2 of the Medical Practice Act of 1985 **and** section 2 of the Osteopathic Medical Practice Act." [Emphasis added.] We ask the Department to revise this definition to change "and" to "or." This comment applies to the definition of "physician assistant," as well.

Research protocol

"Research project or study" is a term defined in the proposed regulation. The definition of "research protocol" references a "research program or research study." Should the references to a "research study" within the definition of "research protocol" be revised to "research project or study"?

Serious medical condition

This definition lists the 17 conditions contained in the definition for the same term in Section 103 of the Act. It also includes four conditions listed in the temporary regulations. This proposed definition adds two more conditions and also the following language at Paragraph (xxiv): "Any other condition recommended by the Medical Marijuana Advisory Board [(Board)] and approved by the Secretary [of the Department (Secretary)]." We have several concerns with this definition.

First, Section 1201(j) of the Act specifies the duties of the Board. See 35 P.S. § 10231.1201(j). Under Subsection (j)(4), the Board is to issue a written report two years after the effective date of Section 1201. Id. at § 10231.1201(j)(4). The report is to include recommendations and findings on six topics, including "whether to change, add or reduce the types of medical conditions which qualify as serious medical conditions under this act." Id. at § 10231.1201(j)(5)(ii). Under Section 1202 of the Act, at the discretion of the Secretary, the Department may promulgate regulations to adopt recommendations made by the Board. This section requires the Secretary to issue notice of the recommended changes within 12 months of receiving the report. Id. at § 10231.1202. The Board's final report was issued on April 9, 2018. That report recommended a process be established for a subcommittee of the Board to review and approve additional serious medical conditions on a continuous basis and the Secretary approved that recommendation.

A commenter has questioned the Department's statutory authority to amend the list of serious medical conditions outside of the legislative or regulatory process. We agree that further explanation is required on this matter. The statutory language of Sections 1201 and 1202 of the Act appear to limit the scope and timeframe of the Board's authority to make recommendations for changes to one year after the issuance of the required report. What specific section of the Act allows the list of serious medical conditions to be amended by the Board, or a subcommittee of the Board, with approval by the Secretary, on a continual basis?

Second, if the Department has the authority to amend the list of serious medical conditions as provided in Paragraph (xxiv), the process for making these changes should be included in the final-form regulation. Any such process should include the opportunity for public comment on potential changes and an explanation of how changes will be conveyed to the public.

Third, the Pennsylvania Psychiatric Society submitted comments questioning the inclusion of anxiety disorders, autism, opioid use disorder (OUD) (for which conventional therapeutic interventions are contraindicated or ineffective, or for which adjunctive therapy is indicated in combination with primary therapeutic interventions), and post-traumatic stress disorder (PTSD).

We note that autism and PTSD are conditions listed in the Act. OUD was added to this definition and is included in the temporary regulations. Anxiety disorders and Tourette's Syndrome are new conditions being added to this definition through this proposed regulation. For the conditions not listed in the Act, we ask the Department to explain in the Preamble to the final-form regulation, the Board's rationale and authority for adding these conditions to the definition of "serious medical condition."

5. Section 1141a.22. Records subject to disclosure; confidentiality. – Clarity; Implementation.

Section 1141a.29 (relating to initial permit application) states in Paragraph (a)(2), "An applicant shall submit an **initial permit application** using the form posted on the Department's web site together with a **version that is redacted** in accordance with the Right-to-Know Law (65 P.S. §§ 67.101— 67.3104), **as set out in § 1141a.22** . . . ." [Emphasis added.]

In Section 1141a.22, Subsection (d) states, "An applicant's failure to redact confidential proprietary or trade secret information in its **submitted permit application** will result in disclosure to the public of the confidential proprietary or trade secret information in response to a Right-to-Know Law request." We ask the Department to clarify that this provision pertains to a "version" of the initial permit application rather than the initial permit application.

Subsection (f) states, "Nothing in this section shall preclude the Department from releasing de-identified data for research purposes, subject to approval and oversight by the Department and an [institutional review board] to ensure that the use of the data is limited to the specified research purposes." Commenters state that this provision is problematic as the confidential data of a grower/processor may be released. One commenter states that the release of such data is not enumerated in Section 302 of the Act (relating to confidentiality and public disclosure). 35 P.S. § 10231.302. We ask the Department to provide its statutory authority for this provision. If the release of "de-identified data" is retained in the final-form regulation, we ask the Department to define this term, clarifying what type of information and data the Department anticipates releasing for these purposes. Additionally, we ask the Department to clarify how it will implement this provision, including providing notice that the data of a grower/processor will be or has been disclosed.

6. Section 1141a.25. General requirements for permits. – Clarity.

Subsection (a) states that the Department may issue a permit to an applicant only for the specific location identified in the applicant's application, by name and address. Commenters have concerns that, in conjunction with Sections 1141a.28 (relating to fees) and 1141a.40 (relating to application for approval of a change in location of an operational facility), the proposed regulations do not provide a path for preoperational facilities to select a new location within the same region. Commenters assert that circumstances beyond an organization's control, such as zoning prohibitions or environmental risks, may necessitate an organization's relocation after the original application and location have been approved but while still preoperational. We ask the Department to clarify the process for a preoperational facility to select a new location within the same region.

7. Section 1141a.31. Background checks. – Need; Reasonableness.

Subsection (d) states, "A financial backer, principal or employee may not hold a volunteer position, position for remuneration or otherwise be affiliated with a medical marijuana organization or a clinical registrant if the individual has been convicted of a criminal offense relating to the sale or possession of illegal drugs, narcotics or controlled substances." A commenter states that the lifetime ban of individuals with certain criminal histories hinders an organization's ability to hire the best talent. What is the need for and reasonableness of a lifetime ban? We ask the Department to explain the reasonableness of this requirement in the final-form regulation.

8. Section 1141a.36. Permit renewal applications. – Clarity; Implementation.

Under Paragraph (c)(3), a medical marijuana organization must include with a permit renewal application "the medical marijuana organization's history of compliance with the act and this part." How is an organization to demonstrate its compliance? We ask the Department to clarify how this provision is to be implemented.

9. Section 1141a.39. Application for change in ownership of a medical marijuana organization. – Compliance with the provisions of the RRA or the regulations of the Commission in promulgating the regulation; Need.

Subsection (a) states, "In the event of an impending change in ownership involving a change in control of a medical marijuana organization from the ownership listed in the initial permit application or a permit renewal application, the medical marijuana organization shall submit an application for change in ownership, on a form prescribed by the Department . . . ." The RRA requires an agency to submit copies of forms that are required for implementation of the regulation. This requirement applies to submittal of proposed and final-form rulemakings. We ask the Department to provide copies of all forms that are required to comply with this rulemaking, including the form referenced in this subsection, when it is returned in final-form.

Subsection (d) requires "written approval of all individuals affiliating with the medical marijuana organization." A commenter notes that this is a potentially large group and it may not be appropriate for all of them to give this approval. We ask the Department to explain the need for this provision or to delete it.

10. Section 1141a.40. Application for approval of a change in location of an operational facility. – Clarity; Implementation.

Subsection (e) states, "The Department will issue a new permit to the medical marijuana organization for the new location **if the request is approved**." [Emphasis added.] We note that Subsection (g) provides one reason for a disapproval, stating, "The Department will not approve a change of location that is outside the boundaries of the region for which the initial permit was issued." On what basis is the Department evaluating whether to approve or disapprove a request for a new permit? We ask the Department to clarify how this provision will be implemented.

11. Section 1141a.42. Failure to be operational. – Clarity; implementation.

Subsection (c) states ". . . Within 30 days of **receiving the Department's notice**, the medical marijuana organization shall submit to the Department for approval a plan . . . ." [Emphasis added.] How will the Department know the date on which notice was received by an organization? We ask the Department to clarify how this provision will be implemented.

12. Section 1141a.47. General penalties and sanction. – Implementation.

This section of the proposed regulation generated significant interest from legislators, the lieutenant governor, representatives of labor unions and hundreds of individuals surrounding the issue of enforcement of permit application commitments. Commenters explain that the Department developed a scoring rubric to use in its review of applications for permits which includes a matrix for scoring an applicant's commitment to community and diverse participation. If an application communicated a plan for community engagement, such as charitable giving, community events, job training, community partnerships, or a labor peace agreement, the applicant would receive additional points.

Commenters express concern that there is nothing in the proposed regulation that would penalize or otherwise sanction a permit holder for failing to implement the community initiatives stated in the application. Nearly all of the commenters focused on the issue of labor peace agreements, stating that applicants have been able to receive additional points on their applications by signing a neutrality and card check agreement with a labor organization, agreeing to stay neutral in the attempt to organize the workforce. Other commenters emphasized other enumerated types of community initiatives. These commenters assert that with a limited number of licenses available, it is critical that a compliance monitoring system exist and that these permit holders be held accountable. We ask the Department to explain in the Preamble to the final-form regulation how it will ensure that a permit holder is implementing the initiatives included in the organization's permit application.

13. Section 1141.48. Training. – Protection of the public health, safety and welfare; Implementation; Clarity.

This section requires principals and employees of a medical marijuana organization to complete a two-hour training course developed by the Department. Principals must complete the course prior to starting initial operation of a facility. Employees must complete the course no later than 90 days after starting employment at the facility. We have several questions. First, does the Department, the medical marijuana organization, or a third-party administer the course? Second, what is the rationale for allowing an employee to start working at a facility *before* the training is complete? Third, if an employee leaves one medical marijuana organization and starts working for a different organization, will that employee need to take the course again? Fourth, Subsection (c) requires the medical marijuana organization to retain the attendance records of its principals and employees. Does the medical marijuana organization have ownership of the records that need to be kept? Finally, must records be kept for individuals that are no longer employed by the organization? We ask the Department to address these questions in the

Preamble to the final-form regulation and clarify how this provision will be implemented in the final-form regulation.

14. Section 1141a.49. Zoning. – Protection of the public health, safety, and welfare; Reasonableness.

Subsection (b) states that a dispensary shall meet the identical municipal zoning and land use requirements as other commercial facilities that are located in the same zoning district. A legislator and two neighborhood associations express concern that in certain areas, local zoning requirements only provide notice to the public and require public hearings if the location requires a variance. These commenters assert the need for community impact statements to be required for all permit applications, and for community impact statements to be considered in determining whether a permit should be granted. Does the Department consider community impact when evaluating the location of a permit application? We ask the Department to explain the reasonableness of zoning requirements included in the final regulation, and how the final regulation protects the public health, safety, and welfare.

15. Section 1141a.50. Advertising by a medical marijuana organization. – Statutory authority; Clarity; Implementation.

Subsection (b) states that promotional, advertising, and marketing materials shall be approved by the Department prior to their use. What is the process for obtaining Departmental approval? We ask the Department to clarify how this provision will be implemented.

Related specifically to promotional materials, commenters assert that the Act does not require the Department to approve this type of materials. What is the Department's statutory authority to require approval of promotional materials?

Subsection (c) states that this part does not apply to information provided by a grower/processor to a dispensary listing various medical marijuana products, instruments, and devices that the grower/processor is offering for sale to the dispensary. If promotional materials are retained in Subsection (b) in the final-form regulation, we ask the Department to clarify whether educational material from growers/processors to be used to educate patients would be considered promotional material.

CHAPTER 1151a. GROWERS/PROCESSORS

16. Use of the term "visitor." – Fiscal impacts; Protection of the public health, safety, and welfare; Need; Reasonableness; Implementation.

Throughout Chapters 1151a (relating to growers/processors) and 1161a (relating to dispensaries), the Department proposes to change the word "visitor" in the temporary regulation to "individual" in the proposed regulation. The Department states in various places throughout the Preamble that the reason for this change is to "emphasize" or "accentuate" that "grower/processor facilities are not open to the public and are not permitted to have non-essential visitors," to "ensure that individuals entering grower/processor facilities are entering for the proper reasons," and to

"emphasize that dispensaries are not open for general visitation." Commenters raise various concerns as noted below.

- There are legitimate reasons for grower/processor facilities and dispensaries to have visitors. The temporary regulations are very protective, and allowing visitors would not impose a danger.
- The proposed regulation is much more stringent that other states.
- This change affects the signage for an entire facility, and one commenter estimates that it will cost $2,000 to become compliant.
- The Department needs to give grower/processor facilities adequate time to order and hang the revised signage.
- Preventing visitors that assist people with disabilities from entering a dispensary may violate 16 PA Code Ch. 44 (relating to Discrimination on the Basis of Handicap or Disability). A commenter asserts that "patients who require the accommodation of a support individual will no longer be able to access the dispensary, unless that support individual becomes a caregiver which is a costly and time-intensive process that not all patients can afford."
- Protocols and controls are in place in the temporary regulation to ensure that anyone entering a facility is properly identified, escorted, and monitored during the visit.
- If the proposed language is retained in the final regulation, it should be amended to address the issue of access for individuals such as prospective principals, financial backers, operators or employees of the organization, local first responders, local law enforcement, lawmakers, and others who may need to enter grower/processor facilities for legitimate purposes such as information gathering, training, or orientation.

If the proposed language is retained in the final regulation, we ask the Department to explain the need for and reasonableness of the change from "visitor" to "individual" in the Preamble, particularly as the change relates to fiscal impacts and protection of the public health, safety, and welfare. Also, we ask the Department to address implementation requirements as related to time for support individuals to become caregivers and for facilities to obtain and change signage. Finally, we ask the Department to amend the relevant RAF questions related to fiscal impacts on the regulated community.

17. Section 1151a.24. Start-up inventory. – Fiscal impacts; Clarity; Reasonableness; Implementation.

Section 10231.702(a) of the Act states, in part, that "a grower/processor may do all of the following in accordance with department regulations: (1) obtain seed from outside this Commonwealth to initially grow medical marijuana; (2) obtain seed and plant material from another grower/processor within this Commonwealth to grow medical marijuana."

In implementing the Act, the Department states in Section 1151.24(a) of the temporary regulations that a "grower/processor may obtain seeds **or immature medical marijuana plants** from outside of this Commonwealth for the purpose of securing its start-up inventory."

[Emphasis added.] The Department has removed "or immature medical marijuana plants" from this provision in the proposed regulation, stating in the Preamble that Section 702(a) of the Act (35 P.S. § 10231.702(a)) "only permits the importation of seeds from outside this Commonwealth." In light of this statement, on what basis did the Department include "immature medical marijuana plants" in this provision of the temporary regulations? Commenters note that while Section 702(a) of the Act does not specifically authorize obtaining immature medical plants from outside the Commonwealth, neither does the Act prohibit it. If this provision remains unchanged in the final-form regulation, we ask the Department to explain the reasonableness and address the fiscal impacts of removing immature medical marijuana plants from this provision.

Subsection (a) further states: "Seeds obtained from outside of this Commonwealth shall be obtained within 30 days from the date that the Department determines that the grower/processor is operational or **within any 30-day window established by the Department if the Department determines that the importation of additional seeds is necessary**." [Emphasis added.] Commenters raise several questions regarding implementation of this provision. What precedes the Department determining that importation of seeds in necessary? What criteria will the Department use to determine if it is necessary? May a grower/processor request an importation window, and if so, how much time will the Department have to respond to the request? Commenters request regular, scheduled importation windows for seeds and immature plants in order to refresh and improve genetics and ensure an ample supply. We ask the Department to clarify implementation of this provision in the final-form regulation, and to address in the Preamble the reasonableness and fiscal impacts of this provision.

18. Section 1151a.25. Access to grower/processor facilities. – Clarity; Reasonableness; Implementation.

Subsection (a) states, in part, that ". . . a grower/processor shall require the individual to sign a log . . . ." Under Subparagraph (f)(1), the grower/processor is to "maintain the log for [four] years . . . ." What is the need for maintaining a log for four years? Does the Department require a grower/processor to maintain the original logbook for four years, or could the information be stored electronically? We ask the Department to clarify this provision, and to explain why the timeframe included in the final-form regulation is reasonable.

19. Section 1151a.26. Security and surveillance. – Fiscal impacts; Protection of the public health, safety, and welfare; Clarity; Need; Reasonableness; Implementation.

Commenters raise concerns related to various aspects of security and surveillance provisions. First, under Subparagraph (a)(4), a grower/processor must have security and surveillance systems that include, in part, "[t]he ability to record and store all images captured by each surveillance camera for a minimum of [two] years . . . ." Commenters assert that this requirement for retaining video is very costly, more stringent than other states, and an unjustified economic burden which many other states do not require. One commenter provided an actual cost over two years of $726,000. Commenters provide suggestions to ease the economic impact such as shortening the retention timeframe and/or applying the retention requirement only to video activated by motion, allowing for motion-detection technology, and deleting the

requirement for continuous monitoring. What is the need for retaining video for two years? We ask the Department to explain why the timeframe included in the final-form regulation is reasonable. Also, we ask the Department to address the fiscal impacts of the timeframe for retention of surveillance video. This comment also applies to similar language in Section 1161a.31(a)(4) (relating to security and surveillance).

Second, Paragraph (b)(3) states that "the grower/processor shall retain at the facility, for at least [four] years, records of all inspections, servicing, alterations and upgrades performed on the systems . . . ." Commenters assert that this requirement could be costly, and request the option to retain records electronically. We ask the Department to clarify this provision, and to explain why the timeframe included in the final-form regulation is reasonable. This comment also applies to similar language in Section 1161a.31(b)(3) (relating to security and surveillance).

Third, Paragraph (b)(5) states, "The grower/processor shall designate employees to continuously monitor the security and surveillance systems at the facility." Commenters question the need for an employee to meet this requirement, stating that after three years, there have been zero incidents that haven't been flagged by the offsite monitoring service. We ask the Department to explain the need for employees to continuously monitor the security and surveillance systems. This comment also applies to similar language in Section 1161a.31(b)(5) (relating to security and surveillance).

Fourth, Subsection (d) states, "At all times, all entrances to and exits from a site and a facility must be securely locked." Commenters assert that this requirement to keep all doors locked **at all times** is unreasonable and potentially unsafe. Commenters note that the temporary regulations only require all doors to be locked during nonworking hours. The Department states in the Preamble that it proposes this change to "ensure the safety and security of a grower/processor facility." We ask the Department to explain how implementation of the final-form regulation will protect the public health, safety, and welfare. This comment applies to similar language found in Section 1161a.31(d) (relating to security and surveillance).

20. Section 1151a.27. Requirements for growing and processing medical marijuana. – Fiscal impacts; Clarity; Reasonableness; Implementation.

Subsection (a) states,

> A grower/processor shall use only a pesticide, fungicide or herbicide that is approved by the Department of Agriculture for use on medical marijuana plants and listed in Appendix A (relating to acceptable pesticide active ingredients for use). The Department will periodically publish a notice in the *Pennsylvania Bulletin* updating the list of approved pesticides, fungicides and herbicides.

Commenters note that there is no mechanism to update the pesticide list, nor is there a formal review process to be able to petition for expansion. We ask the Department to clarify how this provision will be implemented, and to address the reasonableness of the provision in the final-form regulation. This comment also pertains to Section 1151a.43 (relating to pesticides).

Subsection (h)(3) states that a grower/processor may not process a medical marijuana plant that has mold, rot, or other fungus or bacterial diseases "higher than the minimum levels acceptable

to the Department." We have two concerns. First, what are the acceptable minimum levels and what criteria will be used to determine the minimal levels? We ask the Department to clarify how this standard will be implemented in the final form regulation. Second, commenters note that mold and mildew are not anomalies, and remediation can safely process out mold and mildew. We ask the Department to explain the reasonableness of not permitting the option for remediation in order for growers/processors to achieve acceptable levels as this could have fiscal impacts on the regulated community.

21. Section 1151a.29. Limit on medical marijuana processing. – Fiscal impacts; Protection of the public health, safety, and welfare; Clarity; Reasonableness; Implementation.

In part, Subsection (a) provides a label requirement for medical marijuana or a medical marijuana product which is to be sold to another medical marijuana organization. Subsection (a) requires the concentration of 11 listed cannabinoids, at a minimum, to be included on the label. Commenters assert that this information does not readily fit on a label, and would require the print to be very small, possibly unreadable. Commenters suggest that if the profile for cannabinoids listed in Sections (a)(5-11) is 0.00, then it should be excluded from the label. These commenters assert that including this information detracts from other information that needs to be on the packaging to better inform the patient. We ask the Department to explain the reasonableness of this requirement, and how the final-form regulation protects the public health, safety, and welfare. Additionally, commenters state that changes to labeling requirements are costly and suggest a phase-in period to use up existing product. We ask the Department to address the fiscal impacts of this provision, as well as the reasonableness of the timeframe for implementation.

As noted earlier, Subsection (b) contains non-regulatory language: "The grower/processor shall notify the Department in writing **promptly** upon becoming aware of a potential increase or decrease in the forecasted amount occurring within any subsequent [six]-month period." [Emphasis added.] We ask the Department to clarify the timeframe within which a grower/processor must notify the Department of a potential increase or decrease.

22. Section 1151a.34. Packaging and labeling of medical marijuana products. – Clarity; Reasonableness; Implementation.

Subsection (d) states, "A grower/processor shall obtain the prior written approval of the Department of all packaging and the content of any label to be affixed to a medical marijuana product package. Each label must meet the following requirements: . . . .

> (6) List the number of individual doses contained within the package, the species and percentage of THC and CBD and other cannabinoids enumerated in § 1151a.29 (relating to limit on medical marijuana processing), and the individual terpenes and corresponding percentages. CAS numbers need not be displayed on the label. . . .
>
> (9) State the employee identification number of the employee preparing the package and packaging the medical marijuana product.

(10) State the employee identification number of the employee shipping the package, if different than the employee described in paragraph (9).

(11) Contain the name and address of the dispensary to which the package is to be sold. . . .

(18) List THC as the first number when THC and CBD are listed on a label as a ratio.

Commenters express several concerns related to implementation of the requirement to obtain prior written approval of all packaging and the content of any label to be affixed to a medical marijuana product package. We ask the Department to clarify how a grower/processor obtains approval, including how a request is made, the timeframe for the Department to respond, and the criteria that the Department will use to approve or disapprove packaging and labels.

Related to Paragraph (d)(6), some commenters ask the Department to define "species" while others believe that the species may be irrelevant in some circumstances. We ask the Department to clarify the term "species" and to explain the reasonableness of requiring the species to be included on packaging and labels. This comment pertains to Section 1161a.28 (relating to labels and safety inserts), as well.

Commenters raise additional concerns. For example, commenters assert that Paragraph (d)(11), which requires the label to include the name and address of the dispensary to which the package is to be sold, includes too much information, is too burdensome, poses significant operational challenges, and provides no benefit to patients. Commenters offer alternatives such as replacing the detailed packaging data from (d)(9-11) with a batch identifier. Other commenters raise the issue that containers holding concentrates are very small, making it difficult to label the outer packaging and the container itself. Another commenter cites the need to list as many as 30 terpenes on a label. Did the Department consider alternative labeling options for smaller products? We ask the Department to explain the reasonableness of labeling requirements in the final-form regulation.

Similar to Section 1151a.29 (relating to limit on medical marijuana processing), commenters suggest a phase-in period to use up existing product. We agree and ask the Department to address the reasonableness of the timeframe for implementation of this provision in the final-form regulation. This comment also pertains to Section 1161a.28 (relating to labels and safety inserts).

23. Section 1151a.35. Transportation of medical marijuana. – Fiscal impacts; Need; Reasonableness.

Commenters raise concerns related to several requirements under this section. For example, Paragraph (b)(1) requires transportation vehicles to be "equipped with a secure lockbox or locking cargo area." Subsection (c) states that a transport vehicle must be staffed with a delivery team consisting of at least two individuals. Commenters assert that these are additional fiscal burdens. What is the need for these requirements? Commenters note that requiring a delivery team of two individuals is a costly requirement which other states do not have. We ask the Department to explain the need for and reasonableness of these requirements, as well as the

fiscal impacts. Also, we ask the Department to address these concerns as they relate to Sections 1161a.35 (relating to transportation of medical marijuana products) and Section 1171a.33 (relating to transporting samples).

Commenters also raise concerns regarding Subsection (f) which states,

> A grower/processor shall immediately report to the Department, either through a designated phone line established by the Department or by electronic communication with the Department in a manner prescribed by the Department, vehicle accidents, diversions, losses or other reportable events that occur during transport of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products.

Commenters request that the Department provide a protocol that should be followed if product is delivered to wrong dispensary as an incident can be very costly. We ask the Department to clarify how this provision is to be implemented in the final-form regulation, taking fiscal impacts into consideration.

24. Section 1151a.36. Transport manifest. – Clarity.

Subsection (c) states that all seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products being transported "shall be packaged in **shipping containers** . . ." [Emphasis added.] Commenters request that the Department make clear that the intent of the phrase "shipping container" is appropriate-sized packaging, not a large metal shipping apparatus. We ask the Department to clarify the intent of this provision in the final-form regulation.

25. Section 1151a.37. Transportation of seeds, immature medical marijuana plants and medical marijuana plants. – Clarity.

Commenters raise the question of whether the transportation of medical marijuana products should be addressed in this section. Is a grower/processor permitted to sell medical marijuana products to another grower/processor for purposes of turning them into finished products? We ask the Department to clarify this provision as it relates to the transportation of medical marijuana products in the final-form regulation.

26. Section 1151a.40. Management and disposal of medical marijuana waste. – Fiscal impacts; Need.

Subsection (b)(1) states that "returned" medical marijuana shall be rendered unusable and unrecognizable prior to being transported from a grower/processor or an approved laboratory. Commenters assert that unopened, returned merchandise should be returned to inventory instead of destroyed. We ask the Department to explain the need to destroy unopened, returned medical marijuana, and to address the fiscal impacts of this provision if it is retained in the final-form regulation.

27. Section 1151a.42. Complaints about or recall of medical marijuana products. – Clarity.

Several provisions within this section address a "condition" as relating to mandatory recalls. For example, Paragraph (c)(1) provides a requirement for a mandatory recall if a grower/processor discovers that a **condition** relating to the seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana, or medical marijuana products grown or processed at its facility poses a risk to public health and safety. [Emphasis added.] Likewise, Subsection (h) states that the Department may initiate a mandatory recall upon receipt of information that a **condition** relating to the seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana, or medical marijuana products grown, processed, or dispensed by a medical marijuana organization poses a risk to public health and safety. What does the term "condition" mean? We ask the Department to define or clarify this term.

Additionally, commenters suggest the Department address other types of complaints that may not cause an adverse event, such as mold or contaminated product. We ask the Department to clarify in the final-form regulation how other types of complaints are to be handled. This comment pertains to Section 1161a.38 (relating to complaints about or recall of medical marijuana), as well.

CHAPTER 1161a. DISPENSARIES

28. Section 1161a.30. Access to dispensary facilities. – Protection of the public health, safety, and welfare; Need.

Subsection (a) permits a patient who is under the age of 18 to enter if the patient is accompanied by a parent, guardian or caregiver. A commenter asserts that prohibiting minors from accompanying parents/guardians who are patients into dispensaries creates a hardship for patients. We ask the Department to explain the need to prohibit children from accompanying parents or guardians who are patients into dispensaries, and how the final-form regulation protects the public health, safety, and welfare.

CHAPTER 1171a. LABORATORIES

29. Section 1171a.26. Stability testing and retention of samples. – Need; Reasonableness.

This section requires samples of harvest batches to be collected by an approved laboratory in a sufficient amount to perform stability testing at six-month intervals for a one-year period. Commenters have questioned the need for this provision and note that the average shelf life of medical marijuana is less than six months. A commenter has suggested that testing be performed at one year, and only if the product remains in inventory. We ask the Department to explain the rationale for and reasonableness of testing requirement at six- and twelve-month intervals. In addition, we question the need to perform stability testing under Subsection (c) if a product is no longer in inventory.

30. Section 1171a.29. Testing requirements. – Statutory authority; Conforms to the intention of the General Assembly; Fiscal impacts; Need; Reasonableness.

Subsection (c) has generated significant interest from the regulated community. This subsection is different from the temporary regulation. The proposed regulation requires a different approved laboratory to test finished product than the approved laboratory that tested the harvest batch product. The Department states in the Preamble that testing by a second laboratory is needed to provide additional "checks and balances." Issues raised by commenters include the following:

- Section 704 of the Act requires testing of product at harvest and at final processing. It requires a grower/processor to ". . . contract with **an** independent lab." [Emphasis added.] This statutory language indicates that the intent of the General Assembly was for one approved laboratory to perform the required testing.
- The regulated community is not aware of any issues related to one approved laboratory performing both tests and questions the reasonableness and need for this requirement.
- Standardized methods have not been widely accepted for potency and purity, so each testing lab develops and validates their own analytical methods for each required test. Will the test results in the electronic tracking system be meaningful?
- The accreditation process for approved laboratories provides the necessary "checks and balances" related to product quality and integrity.
- If two different approved laboratories testing a particular harvest batch at different times are required to interact, it could be a risk to laboratory independence, data integrity, data impartiality and client confidentiality. This could compromise sections of a laboratory's accreditation.
- There are additional costs associated with entering contracts with two different approved laboratories.

We ask the Department to explain why it believes the language of Section 704 of the Act allows for testing of harvest batches and final product by two different approved laboratories. In addition, we ask the Department to 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. Finally, we ask the Department to quantify the costs for growers/processors associated with entering into a contract with a second approved laboratory.

31. Section 1171a.31. Test results and reporting. – Clarity; Need; Implementation.

Subsection (c) of this rulemaking differs from the temporary regulation and the changes have generated interest from commenters. This subsection will allow a grower/processor to request a retest if a sample failed initial testing by an approved laboratory. If the retest passes, a second approved laboratory must confirm the passing test result. Finally, if the Department does not agree to accept the confirming test results, the re-tested sample and the lot must be disposed of.

Commenters point to the fact that this subsection provides the Department a great deal of discretion to reject results, but does not provide criteria for determining why results would be deemed unsatisfactory. We agree and ask the Department to include language in the final-form regulation that clarifies and specifies what criteria will be used to implement this provision and determine if a result is unsatisfactory.

We also ask the Department to explain the overall need for changes being made to this subsection, including the requirement that a second approved laboratory confirm the test results of the first approved laboratory when retesting occurs.

32. Section 1171a.35. Laboratory reporting. – Clarity; Implementation.

Paragraph (b)(1) states, "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." Commenters assert that this requirement is unnecessary and burdensome. How is a laboratory to comply with this requirement, and what is meant by "immediately"? We ask the Department to explain the need for this requirement, and to clarify in the final-form regulation how the provision is to be implemented.

CHAPTER 1181a. PHYSICIANS AND PRACTITIONERS

33. Use of the term "practitioner" and "physician." – Clarity.

The term "practitioner" is defined in Section 103 of the Act and Section 1141a.21 of this regulation, while the term "physician" is defined only in Section 1141a.21 of this regulation. A commenter has stated that terms appear to be used interchangeably by the Department throughout the regulation. We ask the Department to review the use of both terms as they are used throughout the rulemaking to ensure usage is clear and appropriate.

34. Section 1181a.26. Denial, revocation or suspension of a practitioner registration. – Clarity.

Subsection (d)(3) includes the phrase ". . . except in accordance with applicable law." We ask the Department to clarify what the applicable law or laws are so that the regulated community can comply with those laws.

35. Section 1181a.27. Issuing patient certifications. – Conforms to the intention of the General Assembly; Protection of the public health, safety, and welfare; Clarity; Implementation.

A commenter has raised several concerns with this section that relate to consistency with the Act, implementation procedures, need, and clarity. The comments question how this section will be implemented as it relates to the interaction between practitioners, medical professionals, caregivers, and patients that are homebound or physically unable to visit a dispensary. The commenter asks how the Department will implement the requirements of this section of the regulation and Section 801 of the Act (relating to dispensing to patients and caregivers). We ask

the Department to review all of the concerns, clarify how the final-form regulation will be implemented, ensure that the requirements of the regulation are consistent with the Act, and ensure that the health, safety, and welfare of the patients are protected.

36. Section 1181a.28. Modifying a patient certification. – Clarity; Need; Reasonableness; Implementation.

Subsection (a) states that a practitioner may not modify the form of medical marijuana products on a patient certification for 30 days from the date the receipt is entered into the electronic tracking system by the dispensary unless the practitioner notifies the Department. A commenter has questioned the need for this prohibition and whether the prohibition exists in the Act. Commenters also question how a modification can be made. We ask the Department to explain in the Preamble to the final-form regulation the need for and reasonableness of this provision. If this prohibition remains in the final-form regulation, we ask the Department to clarify how this provision will be implemented, particularly as relates to the procedures or forms needed to modify the certification.

37. Section 1181a.31. Practitioner prohibitions. – Clarity; Implementation.

Subsection (g) provides that a "practitioner may not excessively charge a patient for any expense related to the certification and follow-up process." A commenter has stated that this requirement is vague. We agree and ask the Department to either define "excessive" as it relates to this requirement or clarify in the final-form regulation how this provision will be implemented, indicating how the Department and the practitioner will make this determination.

38. Section 1181a.32. Training. – Protection of the public health, safety, and welfare; Clarity; Implementation.

This section requires a physician that wants to be included in the practitioner registry and a medical professional that wants to work at a dispensary to complete a four-hour training course approved by the Department. We have two concerns. First, as noted by a commenter, Subsection (d) requires individuals who are required to take the training to submit documentation of completion of the course to the Department, but does not explain how or when this should be done. We ask the Department to clarify in the final-form regulation how this requirement is to be implemented.

Second, Subsection (e) states, "The Department will maintain on its publicly-accessible web site a list of approved training providers that offer the 4-hour training course." What process and criteria does the Department use to approve training providers? We ask the Department to clarify how this provision will be implemented, including the processes and criteria for approving training providers, in order to demonstrate that training providers are meeting the requirements of this regulation and protecting the public health, safety, and welfare of patients.

CHAPTER 1191a. PATIENTS AND CAREGIVERS

39. Section 1191a.25. Application for, and issuance or denial of, identification cards. – Clarity; Implementation.

While we addressed the issue of non-regulatory language in a previous comment, we note that this section includes a significant number of vague and non-binding phrases.

- Subsection (a) states, "An applicant shall submit an identification card application **on a form prescribed by the Department**. The application will be made available on the Department's publicly-accessible web site and in hard copy upon request." [Emphasis added.]
- Subsection (b) states, "An identification card application submitted by or on behalf of a patient must include, **at a minimum**, the following information . . . ." [Emphasis added.]
- Paragraph (b)(9) states that an identification card application submitted by or on behalf of a patient must include . . . . "**[a]ny other information deemed necessary** by the Department." [Emphasis added.]
- Subsection (d) states, "An identification card application submitted by a caregiver must include, **at a minimum**, the following information . . . . " [Emphasis added.].
- Paragraph (d)(10) states that an identification card application submitted by a caregiver must include . . . "**[a]ny other information deemed necessary** by the Department." [Emphasis added.]
- Subsection (f) states, "The Department will **promptly** notify an applicant in writing if an identification card application is incomplete . . . ." [Emphasis added.]

As in the comment above, we ask the Department to ensure that these provisions use regulatory language, setting clear compliance standards for the regulated community.

Similarly, Subsection (g) states, "An applicant shall have 60 days **from receipt of a notification** under subsection (f) to submit to the Department the documents or information requested." How will the Department know the date on which notice was received by an applicant? We ask the Department to clarify how this provision will be implemented.

40. Section 1191a.26. Application fees. – Need; Implementation.

This section establishes the amount of application fees for an identification card, renewal of an identification card and the replacement of an identification card. Subsection (c) states that the Department may establish higher fees for the issuance of a second and subsequent replacement identification card by publishing notice of those fees in the *Pennsylvania Bulletin.* Subsection (d) allows the Department to waive or reduce the fees for applicants that demonstrate financial hardship. The qualifications for financial hardship will be published by the Department in the *Pennsylvania Bulletin.* We have two questions. First, we note that Section 501 of the Act permits the Department to establish higher fees for replacement cards and to waive or reduce fees. Why did the Department decide to administer these provisions by publishing notices in the *Pennsylvania Bulletin* instead of including them in this rulemaking?

Second, Subsection (d) begins with the phrase, "Subject to § 1191a.32 (relating to medical marijuana patient authorization letters) . . . ." What is the need for this opening phrase? We ask the Department to address these questions in the Preamble to the final-form regulation.

CHAPTER 1211a. CLINICAL REGISTRANTS AND ACADEMIC RESEARCH CENTERS

41. Section 1211a.25. Certifying ACRCs. – Need.

Subsection (b) states that the Department will publish notice in the *Pennsylvania Bulletin* announcing the availability of ACRC applications and the time period during which applications will be accepted. Is the Department still accepting applications? If not, is this subsection needed? We have a similar concern with Section 1211a.27(a) (relating to application for approval of a clinical registrant).

42. Section 1211a.29. Practices and procedures of research programs, projects or studies. – Clarity.

Under Subsection (b), the word "medical" should be added to the beginning of the first sentence.